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Welsh Health Survey: Cognitive testing of data linkage consent forms and supporting documents

**Summary of Key Findings from Round 1
and Round 2 of cognitive testing**

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PART ONE

1 Study Introduction

In 2011 the Welsh Government commissioned the Questionnaire Development and Testing (QDT) Hub at NatCen Social Research (NatCen) to test a new Welsh Health Survey (WHS) procedure. This procedure seeks consent from individuals who take part in the WHS to link their individual survey answers with other information held on them elsewhere (permission for data linkage) using a consent form and supporting material. This study explored how the proposed consent form and supporting materials worked with the types of respondents who would be asked for their permission using cognitive interviewing methods.

The Welsh Health Survey (WHS) is an annual survey conducted with households across Wales. The information collected is used to help plan health services in Wales and track changes in the nation's health over time. The purpose of data linkage is to allow researchers to use data from the WHS with other sources, to answer their research questions. For example, using answers to survey questions about people's health as well as actual health records held about them. Data linkage makes it possible for additional analysis to be conducted on the data; it allows researchers to investigate research questions that were not the focus of the original survey or would not be possible to ask in a survey context. It also allows researchers to carry out limited longitudinal analysis, for examples looking at health outcomes over time in relation to data about health related behaviours from the survey. As well as enriching the 'picture' researchers have about a population, data linkage also reduces the need to ask extra questions in surveys and therefore reduces burden on respondents. This allows greater value to be extracted from the data collected. Data linkage also offers the potential for cost savings. Data linkage does not compromise the anonymity of respondents who have taken part in their research.

Two rounds of cognitive interviewing were carried out. An initial round of cognitive interviews was carried out in Spring 2011, which informed recommendations on the administration and proposed wording changes to the consent form and supporting documents. Revised documents were subject to further testing, again using cognitive interviews with another group of respondents. The findings and recommendations from both these rounds of testing are presented in this report. Part one of this report provides background information on the study and the methods used. Part two presents findings from the first round of testing and the recommendations made and part three presents findings and recommendations from the second round of testing. More details on the content can be found in section 2.4.

2 Background

2.1 The SAIL database

At some point in the future it is hoped that WHS data will be added to the Secure Anonymised Information Linkage (SAIL) database held by at the Health Information and Research Unit (HIRU) at the University of Swansea. The SAIL database currently holds information from GP practices, hospitals, births and deaths and many other sources of administration data. It also holds survey datasets collected by publicly funded organisations.

The SAIL database is not limited to holding data on health, but also contains information from other settings including housing, transport and education. For example, the SAIL database contains information from the National Pupil Database on educational attainment. The SAIL database is still expanding and in the future may contain information from an even broader range of sources.

All data held in the SAIL database is anonymous i.e. it contains no names, addresses, or other potential identifiers. Instead, all cases stored in the SAIL database have a unique identifier. This unique identifier is generated by the NHS Wales Informatics Service using NHS numbers. The fact unique identifiers are generated by a third party means that HIRU do not have access to any personal data such as name, date of birth or address that could identify respondents¹.

2.1.1 Practicalities of linkage

If a WHS respondent gives their consent to the data-linkage the following steps will occur:

- The respondent's WHS serial number, name, address, and date of birth will be sent to the NHS Wales Informatics Service.
- NHS Wales Informatics Service will use these details to identify the NHS number of the individual. The NHS number is used to generate a unique identifier for each respondent.
- Once NHS Wales Informatics Service has generated a unique identifier the respondent's name, address and date of birth are deleted from their records².
- The WHS serial number and the new unique identifier are then sent to HIRU.
- Using this unique identifier, HIRU can then link respondents' WHS survey answers to other sources of information held by them in the SAIL database.

¹ It should be noted that combinations of data e.g. the lowest geographical data combined with rare ethnicity and or illness could be potential identifiers. This indicates that decisions on what data is released will need to be considered and passed through a data release committee.

² The unique identifier and NHS number are retained to allow future linkages.

2.2 Aims of testing

The aim of both rounds of cognitive testing were to explore the procedures used to ask respondents for their consent to link their WHS survey answers to the SAIL database. Following the first round of testing revisions were made and retested in the second round. In particular we examined how respondents reacted to three different documents. These were:

- 1) the data linkage consent form,
- 2) a flow-chart explaining the linkage process, and
- 3) the details on how data is used contained in the WHS information leaflet.

The cognitive interviews aimed to establish whether respondents understood the key messages and the terminology used in all the above documents. Critically, the testing aimed to establish whether respondents understood the nature of the request sufficiently well to give *informed consent*. The testing also aimed to establish whether respondents felt there was any information missing from the documents provided. Finally, the testing aimed to explore the processes by which respondents made their decision on whether or not to give consent, and what could be done to allay any concerns or sensitivities around this decision.

2.3 Methods

2.3.1 Cognitive testing

Cognitive interviewing methods are derived from cognitive psychology and allow researchers to examine the mental processes people go through when processing information and making decisions. Traditionally, cognitive interviewing methods have been used to test survey questionnaires to ensure that questions work as intended and that respondents are willing and able to answer them. Cognitive testing methods have also been adapted to test other survey materials such as advanced letters and information leaflets. For this project respondents were asked to think aloud as they read and used the documents. Once they had finished reading the documents, interviewers asked specific retrospective probes about their understanding of and views of the documents and data linkage in general. Additionally, interviewers were asked to make observations about the use of documents and reactions throughout the interview. Interviewers made detailed notes on each interview which were analysed using a qualitative approach. For more details about the cognitive methods used in this project please refer to Appendix A.

2.3.2 Sampling and recruitment

Cognitive interviews are qualitative in nature and rely on small, purposively selected samples. A sample plan was designed to ensure that a range of respondents were

interviewed in both rounds. It was felt important to test the consent procedures on respondents who varied in terms of age, sex and educational attainment.

Respondents for both rounds were recruited from a pool of people who had taken part in the Welsh Health Survey in 2009 and who had given their permission to be contacted about future studies. All potential respondents in the pool were sent an advance letter, informing them that they may be contacted about a new study and giving them the opportunity to 'opt-out'. After the two week opt-out period, NatCen's telephone unit made contact with respondents and gained their consent to take part. It should be noted that at the recruitment stage respondents were not explicitly informed that we were testing data linkage consent forms.

In total 17 interviews were conducted in round one and 18 interviews in round two. Breakdowns of respondent characteristics in both rounds are provided in the tables 1.1 to 1.4.

Table 1.2.1 Respondent age and sex in round one

Age	Male	Female	Total
16-30	2	2	4
31-64	4	3	7
65+	3	3	6
Total	9	8	<u>17</u>

Table 1.2.2 Respondent highest qualification in round one

Highest Qualification	Number of respondents
Degree level or above	5
Other Qualifications (A-levels, GSCEs, City and Guilds) etc.	9
No Qualifications	3
Total	17

Table 1.3 Respondent Age and Sex in round two

Age	Male	Female	Total
16-30	1	4	5
31-64	2	3	5
65+	5	3	8
Total	8	10	<u>18</u>

Table 1.4 Respondents Highest Qualification in round two

Highest Qualification	Number of respondents
Degree level or above	4
Other Qualifications (A-levels, GCSEs, City and Guilds) etc.	9
No Qualifications	5
Total	18

One advantage of recruiting former WHS respondents was that they were already familiar with the WHS and what taking part involves. However, it should be noted that the only WHS respondents who could take part in the cognitive testing were people who:

- A) Gave their permission for future contact; and
- B) Agreed to take part in an hour-long cognitive interview.

The respondents who took part may be more 'willing' than most to engage and participate with research (and thus more likely to agree to data-linkage). And the concerns raised by respondents in both rounds could be even more pronounced in the general population.

2.3.3 Documents tested in round one

Two different versions of the data linkage consent form were tested in round one. The first version (V1) required respondents to sign *once* for their WHS survey answers to be linked to all the information held in the SAIL database. The second version (V2) asked respondents to give permission to link their WHS survey answers to *health data* held in the SAIL database, and secondly for their permission to link their WHS survey answers to *other social and lifestyle data* held in the SAIL database. In V2 respondents could choose to sign against one request but not the other. Both versions of the consent form are included in Appendix D.

The cognitive interviewing also aimed to explore the utility of a flowchart explaining the linkage process. This flowchart was printed on the back of the respondent copy of consents, which was included as a separate insert. Screen-shots of the flowchart are included in section 6.3.

Finally, the cognitive interviewing aimed to explore some of the content included in the WHS information leaflet. The material tested included an existing paragraph on how WHS data is used and a new paragraph about the data linkage. Appendix B shows the text that was tested.

2.3.4 Documents tested in round two

In round two, respondents were only asked for one signature to link their individual survey answers to all the sources of data held on them. This was found to be sufficient based on findings from round one (as opposed to splitting out the sources and requesting separate signatures for *health* and *other social lifestyle* data held in the SAIL database). A decision was made to test two versions of the consent form in round two.

1. One consent form **within** the WHS questionnaire, printed on the final page; and
2. One consent form as a **separate** document, printed on carbon copy paper but paper clipped to the back of the WHS questionnaire to emphasise the connection.

Half of the sample was randomly assigned the 'within' questionnaire version of the consent form whilst the other half was assigned the 'separate' consent form. We use these descriptors as shorthand to refer to the two versions of the consent form throughout the rest of this report. The wording in the two versions of the consent form was almost identical; the only variation was in the instructions to the respondent of what to do with the form if they signed it. The two versions of the consent form are included in Appendixes F and G.

As with round 1, the cognitive interviewing also aimed to explore whether a flowchart might assist in explaining the linkage process; however for round 2 there were two

versions of a flowchart. Interviewers randomised the order in which respondents received the versions of the flowchart: half of the sample was first shown flowchart version A (a newly designed flowchart) and the other half was first shown version B (the flowchart from round 1 but with some revisions). Once the respondent had considered the flowchart, the alternative was then shared with them and they were asked to compare and contrast and state a preference. Flowcharts were shown as separate documents and not until right at the end of the cognitive interview. Copies of the two flowcharts can be found in Appendix I and J.

Finally, the cognitive interviewing aimed to explore some revised content included in the WHS information leaflet. The material tested included an existing paragraph on how WHS data is used and some new paragraphs about data linkage. Appendix H shows the text that was tested.

Advance mailing of the consent documents

In round 2 we decided that it would be beneficial if respondents were able to digest the materials in advance of the interview, to allow them time to reflect on the request. This was a different process from round one when interviewers took the materials along with them to the interview. The reasons the respondents were sent this pack containing these documents prior to interview in this round were to:

1. Reduce time-pressure: Having the packs in advance meant that respondents had more time to look over the materials on their own before the interviewers arrived so there was no pressure for them to read through the documents quickly.
2. Replicate the WHS context: in the real life context, some respondents will receive the WHS packs without having any contact with the interviewer and either way, it is most likely that respondents will be on their own when they actually come to consider the data linkage request.

Respondents were sent the data linkage consent form along with a blank copy of the WHS questionnaire, the leaflet and a cover letter explaining that if possible we would like them to read through the documents in advance of their interviewer's visit. As mentioned above, half of the sample were sent the 'within' questionnaire consent form and the other half were sent the 'separate' consent form, paper-clipped to the back page of the WHS questionnaire.

2.3.5 Interview protocols for round one and round two

All cognitive interviews in both rounds were conducted by three of NatCen's core team; a group of survey interviewers highly experienced in conducting cognitive interviews³. In round one, interviews were conducted in three areas of Wales; Cardiff, Monmouthshire

³ Two of the interviewers who worked on round one worked on round two, so were familiar with the aims of testing. The other interviewer is very familiar with the WHS since she is a survey interviewer on this survey working in Lancashire.

and Conwy. In round two, interviews took place in three different areas of Wales, these being: Swansea and the surrounding areas; Wrexham and the areas around the Welsh border; and Brecon and the rural areas which surround it. All the interviews for this study were conducted in English.

Interviews in both rounds were conducted face-to-face in the respondent's homes or another location of the respondent's choice. The Interviews lasted approximately one hour. All respondents received a £20 High Street Voucher to thank them for their help in round one and round two.

A copy of the interviewer protocols for round one is included in Appendix C and for round two in Appendix E.

2.4 Report structure

As mentioned in chapter 1, this report consists of three parts. Part one provides background information on the study and the methods used. Part two presents findings from the first round of testing and the recommendations made and part three presents findings and recommendations from the second round of testing. Key issues and action points are summarised in a box at the end of each section. The field work documents used in both rounds of testing can be found in the appendices (B to J). The table below provides a detailed summary of what is covered in Parts two and three of this report.

Table 2.1 Chapter contents for parts two and three

Part 2: Findings from round one	Part 3: Findings from round two
<ul style="list-style-type: none"> • Chapter 3 gives findings related to placing the documents at the start of the interview. • Chapter 4 gives findings on respondents' initial reactions to the consent form, whether they would sign it and why. • Chapter 5 gives findings on probing respondents further about the consent form. In particular it gives looks at: <ul style="list-style-type: none"> → How respondents felt about the inclusion of a consent form, and whether this could influence their decision to take part in the WHS. → Whether respondents understood the 	<ul style="list-style-type: none"> • Chapter 9 gives findings related to respondents reading the documents. • Chapter 10 gives findings on respondents' initial reactions to the consent form, whether they would sign it and why. • Chapter 11 gives findings on probing respondents further about the consent form. In particular it gives looks at: <ul style="list-style-type: none"> → How respondents felt about the inclusion of a consent form and whether this could influence their decision to take part in the WHS. → Whether respondents understood the consent form.

<p>consent form.</p> <p>→ Whether any information was missing from the consent form.</p> <p>→ Whether respondents had a preference between the two versions of the consent form and why.</p> <ul style="list-style-type: none"> • Chapter 6 gives findings on the insert i.e. the copy of the consent and the flowchart. • Chapter 7 gives findings on the respondent information leaflet. • Chapter 8 gives findings on, after going through all the documents in more detail, whether or not respondents would sign the consent form and why 	<p>→ Whether any information was missing from the consent form.</p> <p>→ Whether respondents had a preference between the two versions of the consent form and why.</p> <ul style="list-style-type: none"> • Chapter 12 gives findings on the respondent information leaflet. • Chapter 13 gives findings on the flowchart. • Chapter 14 gives findings on the administration of the procedure to get informed consent for data linkage; and • Chapter 15 gives findings on, after going through all the documents in more detail, whether or not respondents would sign the consent form and why.
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PART TWO: ROUND ONE REPORT

3 Placing the documents

3.1 Background

In the first stage of each interview, interviewers spent a few minutes talking to the respondent to remind them about what taking part in the WHS involves. Respondents were given all the survey documents and asked to read through the WHS questionnaire to remind themselves of the sort of questions it contains. Respondents were not required to fill in the questionnaire.

Whilst respondents were doing this, interviewers made observations on what documents respondents actually looked at (the WHS questionnaire, the copy of consents/flowchart and the WHS information leaflet).

3.2 Key findings

Not all respondents recalled taking part in WHS 2009; some thought the questionnaire may have been completed on their behalf by a partner or a parent living at the same address. Although, it is possible that these respondents had originally completed the questionnaire themselves (and had forgotten about it). This demonstrates the utility of collecting a signature to gain consent. Without a signature it is possible that other household members may give 'proxy' consent which would be inappropriate in the majority of cases.

Respondents varied in terms of whether they looked at all the documents provided straight away. Some only focused on the WHS questionnaire, ignoring all other documents, some looked at some of the documents but not others, whereas others looked through all the documents provided.

It should be noted that some respondents spent a few minutes giving the documents a thorough read through whereas others only gave them a cursory glance over. The flowchart was not always noticed by respondents as it was printed on the back of the insert (see chapter 6).

At the debrief interviewers noted it would be good for field interviewers to have some direction as to how documents should be placed i.e. whether the copy of the consent form should be inside the questionnaire or kept separately. Likewise, if multiple copies of

the documents are required at each household (with one set given to each household member) something may be needed to keep documents together to prevent extra sheets being misplaced once the interviewer has left. Interviewers suggested an envelope of documents for each respondent.

An alternative suggestion was to have the information on the insert printed elsewhere. For example, the copy of consents could be included as a tearaway section of the questionnaire (see section 6.2) and the flowchart could be included in the leaflet or the questionnaire (see section 6.3). Interviewers also questioned whether information leaflets should be provided *per household* or *per householder*.

3.3 Action points

- Data linkage forms should continue to require a signature to minimise the likelihood of respondents giving consent by proxy.
- Once all survey documents have been finalised some thought needs to be given on how they will be placed i.e. if inserts are used what can be done to minimise their being misplaced?

4 Initial reactions to the consent form

4.1 Background

After being given time to familiarise themselves with the documents respondents were directed to look at the data linkage consent form which was printed in the back of the WHS questionnaire. Respondents were asked to pretend they had just finished completing the questionnaire and had reached the consent form. They were asked to take as much time as they wanted reading it, whatever they would do if they were looking at it by themselves after filling in the questionnaire. Whilst respondents were doing this the interviewers made observations on:

- A) Whether respondents appeared to read the entire consent form
- B) What other documents, if any, respondents referred to when looking at the consent form.

Respondents were encouraged to articulate what they were thinking 'out loud' as they read through the consent form

Respondents were asked to give their first reaction as to whether they would sign the consent form or not and why this was the case.

4.2 Interviewer observations

Interviewers were asked to observe whether they thought respondents had read the entire consent form or not at this stage. Interviewers were confident that fourteen of the respondents had read through the entire form. Interviewers were unsure whether the remaining three respondents had read the entire form or not: it was not clear whether these respondents were quick readers or whether they just skimmed through the material. On probing one respondent stated they had 'skim read' the form (Female, 65+, Other qualifications). It is likely having an interviewer present encouraged respondents to read the consent form more carefully than they would have under survey conditions.

Respondents varied as to what documents they referred to when reading the consent form. Some did not refer to any of the documents at all, these tended to be respondents who had also originally ignored the extra documents on placement. Some respondents looked at the flowchart for the first time when it was referred to in the text of the consent form, other respondents continued to ignore the flowchart. Again, respondents varied in terms of whether they looked at the documents in detail or whether they just flipped through them.

Respondents made a number of comments about the consent form whilst reading. Respondents either commented that the form was:

- Straight forward; or
- Over-wordy, long and hard to follow.

Level of qualifications appeared to have no impact on how respondents initially viewed the form. However, it should be noted that on probing a number of respondents who had described the form as ‘straight forward’ had not in fact understood it (see 4.2).

4.3 Would respondents give consent? Why?

After reading the consent form respondents were asked whether or not they would sign it.

In this test the majority of respondents thought they would sign the form. It should be noted that the sample was not representative and we have already noted in 1.2 that the respondents who volunteered to take part in this study may be more willing to sign a consent form than members of the general population. Therefore it likely this type of reaction would be more prevalent in the WHS main stage fieldwork than it was in the cognitive testing. What is important here is the reasons given for not signing or signing the form.

The one respondent who felt he would not sign the consent form said this was because he thought the consent form was a:

“...huge block of text which is not very clear...asking me to give confidential information.”

(Male, 16-30, Degree Level or above)

This respondent stated that after completing a 30 minute questionnaire he would not want to spend any time puzzling over this form. He read the form and, seeing that it was optional, stated he would not sign it.

Those respondents who thought they would sign the form included people who agreed to sign it without reading either the leaflet or the flowchart. Respondents varied in terms of the reasons they given for being willing to sign. There were 5 broad reasons respondents agreed to sign the form. These were:

1. **Wanting to help.** Respondents who gave this reason described how they wanted to help the people running the survey or that they wanted to be part of improving the Health service.
2. **Having nothing to hide.** Respondents described how they personally had nothing to conceal and that they weren’t being asked to provide anything ‘worrying’ such as bank details.

3. **Knowing the data is confidential.** Respondents were reassured by the fact that they ‘could not be identified’ and that everything was covered by the ‘data-protection act.’ Likewise, respondents were reassured that they could withdraw consent if they changed their mind.
4. **Wanting data to be used.** Respondents described how there was no point completing a questionnaire and then not signing a consent form. These respondents felt that if they did not sign the linkage consent form their answers could not be used at all (see section 5.2.)
5. **Data linkage would make their contribution more worthwhile.** These respondents mentioned that researchers having a ‘bigger picture’ could lead to more worthwhile results, and it could be useful to have information all in one place.

Therefore respondents may sign the form for various reasons that are not directly related to what the request is about. A number of respondents stated they did not fully understand the form but trusted it, as it looked professional and mentioned buzz words around confidentiality. Respondents discussed how they would be influenced by the demeanour of the interviewer:

“I would make up my mind from the person coming to visit me.”

(Female, 31-64, Other qualifications)

If interviewers appear trustworthy and professional they would be more inclined to sign without looking into the details. Respondents described how they felt that by signing it they might make a difference to improving the NHS. This indicates an underlying problem that respondents will sign the form even if they don’t fully understand its content. These issues are discussed further detail in section 5.2 on comprehension.

4.4 Key issues and action points

- Respondents will not always read the other survey materials prior deciding whether or not to sign the form. Therefore all key information needs to be on the consent form. Further direction to the other documents could be made more prominent.
- The quantity and density of the text may put off some people from reading the consent form in full. Key messages may be lost due to the volume of text, therefore, where possible, the text should be made shorter to encourage fuller reading and improved spacing should be considered.
- Respondents may sign the form as they feel they want to be helpful and they see no harm in doing so but may not have fully understood the consent form so consideration needs to be given to how to make the information more accessible and understandable.

5 Probing on the consent form

After being asked for their initial reactions on whether they would sign the form respondents were asked a number of follow-up probes on:

- How they felt about being asked to fill in a consent form
- What they understood the consent form to mean
- Whether there was information missing from the form
- Whether respondents preferred a 'one signature' version of the consent form or a 'two signature' version of the consent form.

This section goes on to describe key findings arising from this element of the testing.

5.1 Sensitivity

Background

The cognitive testing was intended to explore how respondents would feel about a consent form being included in the WHS. In particular, the cognitive testing wanted to establish whether being asked to sign a consent form would put people off from taking part in the WHS and could lead to lower response rates.

How did people feel about signing a form?

Respondents had mixed feeling about being asked to sign a consent form as part of the WHS. Respondents either had:

- no feelings about being asked to sign a consent form, or
- positive feelings about being asked to asked to sign a consent form.

No one in the cognitive testing sample had negative feelings in principle to signing a form. The one respondent who thought he would not sign stated this was not due to an objection to consent forms per se, but rather that he couldn't be bothered to read the details.

Respondents who had no feelings about the consent form stated they were used to signing forms and it did not influence them on way or another. Respondents who felt positive about the inclusion of a form felt this was because:

- it added a reassuring sense of 'legitimacy' to the research,
- it explained what would happen to your information,
- it provided the address of the people to contact if you had questions, and
- it proved that you had answered the questionnaire yourself.

When talking about sensitivity respondents mentioned a couple of points that suggested the consent form had not been understood as intended. For example, one respondent (Female, 16-30, Other qualifications) discussed how she felt happy to sign but she might feel differently if she had a serious condition that might get back to her employers. This suggested the respondent had not fully understood who the data would be released to and the fact it was anonymous. Another respondent (Female, 31-64, No qualifications) stated she did not mind signing the form as she had 'told the truth.' This suggests this respondent thought either:

- she was signing to confirm everything she said was accurate; or
- she felt the data linkage was part of a 'checking up' exercise.

Both interpretations of the purpose of data linkage are incorrect. Further issues related to comprehension are discussed in 4.2.

Could adding a consent form influence WHS response rates?

All respondents who took part in the cognitive interview stated they would be happy to return their WHS questionnaire. However, on probing interviewers discovered an issue that could potentially impact on response rates. A number of respondents misunderstood the consent form, and thought that by signing it they were agreeing for their WHS data to be used, not consenting to data linkage (see 4.2 and 6.3). These respondents thought that if you did not sign the consent form your questionnaire would be 'destroyed' when you returned it as it could not be used for anything. Therefore these respondents felt there was no point returning the questionnaire if you had not signed the consent form.

This suggests that respondents, if they don't understand the nature of the consent form, may not return their questionnaire if they chose not to sign it. This in turn could have a negative influence on response rates and highlights the importance of making the consent form clearer in that:

- 1) It is not asking for consent to use WHS data, we are making a separate request to respondents about adding their WHS survey answers into the SAIL database.
- 2) Completed questionnaires can be used regardless of whether or not respondents chose to sign the form.

At the debrief it was suggested that the consent form should be printed separately from the WHS questionnaire so that there was more of a physical separation between the WHS questionnaire and the consent form.

Whether or not the inclusion of the consent form could significantly influence response rates can only be verified using a quantitative field-test. Given the fact the cognitive testing suggests response rates could be affected we would highly endorse the use of a

field test with a sufficiently large sample to draw statistically robust conclusions about impacts on response rates.

5.2 Key issues and Action Points

- The cognitive testing found no evidence that people would react negatively to the inclusion of a consent form in the WHS. In fact some respondents viewed it positively as it gave the survey a sense of 'legitimacy'. Therefore including a consent form is not in itself problematic.
- Some people misunderstood what the consent form is for and felt that if they did not sign the consent form their questionnaires would be destroyed. This is problematic as it means that if people do not wish to sign the consent form they may not return their WHS form at all. Therefore it needs to be made clearer that the consent to data linkage is a separate request and respondents can return their questionnaire regardless of whether or not they sign the consent form. One approach could be providing the questionnaire and consent form as two separate documents.

5.3 Comprehension

Background

The cognitive testing aimed to establish whether respondents understood the consent form. Respondents were asked to explain 'in their own words' what they thought the form was asking their permission for and what would happen to their information if they chose to sign. The key issue under investigation was whether or not respondents understood the form sufficiently well to be able to give 'informed consent.'

General

A number of respondents commented that the consent form was difficult to understand as the language used was too technical and contained too much jargon. These comments were made by respondents who varied in terms of their qualifications, including respondents who had degree or higher level of qualifications. Respondents felt that the information leaflet should be written in 'plain English'. It was thought even the phrase 'data set' sounded like jargon.

It was noted that the length of the consent form actually detracted from the clarity. By presenting so much information on one page it becomes more likely that respondents will lose the gist of what is being said:

"By this time I've forgotten what the link is, what are they talking about?"

(Male, 31-64, Other qualifications)

Respondents felt that some bits of the text were repetitive e.g. 'confidentiality' and 'not being identified' are mentioned several times. Respondents felt the information would be clearer if fewer words were used and only 'key points' were mentioned. Additional details should be included elsewhere (i.e. the leaflet) so respondents can look-up anything else they want to know or that they think is unclear. The leaflet should be clearly referenced in the consent form and respondents should be encouraged to read the leaflet prior to signing. However it should be noted that there were respondents who did not read the leaflet when first given all the documents so, as noted above, any crucial information needs to be contained in the consent form itself.

Respondents felt the text in the leaflet was easier to understand, partially as the information was giving in smaller chunks clustered under sub-headings (see section 7.3). This could be one strategy to help improve the current consent form.

One respondent (Male, 31-64, Degree level or higher qualifications) commented that people may overlook the fact that full name, including the middle name, is required. He suggested the answer boxes should be separated into three, one for first name, middle name and one for surname.

Variations in Understanding

Probing revealed that respondents held disparate ideas on what they were actually agreeing to by signing the consent form. Analysis of the survey data shows that respondents fell into 5 distinct groups. A description of these groups, and whether or not *informed* consent to linkage was actually given, is summarised in the table below.

Table 5.1 What were respondents consenting to and was informed consent given?

Group	Description	Informed consent?
1. Open consent	<p>Respondents felt they were giving consent for researchers to use the information in any way they saw fit.</p> <p>Respondents did not have a clear concept of what the form was asking, they felt by signing it they were giving open consent for the data to be used in any way required.</p> <p>These respondents felt they did not need to know the ins and outs of how the data was used. The form had been designed by '<i>higher-</i></p>	?

	<i>ups</i> ' who knew more about these things. They just hoped by signing they were helping.	
2. Consent that WHS survey answers could be 'used'	<p>Respondents thought they were agreeing for their WHS survey answers '<i>to be used</i>' i.e. they thought they were consenting to the main WHS analysis.</p> <p>These respondents felt that if they did not sign the consent form there was no point returning the questionnaire as it would not be used for anything.</p> <p>Respondents who were looking at V2 questionnaire (with separate consents for health linkage and social and lifestyle linkage) thought the first signature meant that they agreed for the WHS survey answers they had given on 'health related' things e.g. medical conditions to be used. They thought that the second signature meant their WHS survey answers on other things e.g. fruit and vegetable consumption could be used.</p> <p>Respondents thought 'NHS Wales' would be the ones doing the analysis. One respondent (Male, 31-64, Degree Level Qualification) felt that his 'DATE OF BIRTH' was necessary so the researchers could check his age.</p>	x
3. Consent that WHS survey answers could be collated with other surveys	<p>These respondents understood they were consenting to something more than the WHS main-stage analysis. Respondents felt they were agreeing to their survey answers being shared with other organisations and collated with information other surveys. Respondents gave examples of previous years of WHS data or with other surveys that asked similar questions.</p> <p>Respondents did <u>not</u> understand they were agreeing for their answers to be added to a database holding administrative information about members of the population including them.</p>	x
4. Consent to data linkage: <u>Unclear</u> on information held	<p>These respondents did understand they were giving consent for their survey answers to be added to a database that held other information on them.</p> <p>However these respondents did not understand what types of information this database contained or where this information came from. Some respondents thought that the information in the database would come from other surveys they completed in the</p>	x

	future. Respondents felt by signing the consent form they were giving consent to take part in these future surveys i.e. they were agreeing to take part in a longitudinal panel. These respondents did not understand that the database already contained information on them from other sources.	
5. Consent to data linkage: <u>Clear</u> on information held	<p>These respondents appeared to understand the nature of the request.</p> <p>Respondents described the fact that other information on them was stored in a database somewhere e.g. information from NHS records and GP surgeries. They were giving their consent for their WHS answers to be added to this database. The database could be accessed by a range of people e.g. health researcher and economists.</p> <p>Respondents appeared to understand the database was anonymous but did not fully understand the mechanisms of how this worked.</p>	✓

Therefore, in its current format, signing the form is not an indication that informed consent is being given.

Respondents who fall into groups two and three (consent that WHS answers can be 'used' and consent that WHS answers can be 'collated with other surveys') thought they were agreeing to something that happens in WHS already but does not require signed consent. By completing and returning a WHS questionnaire it is assumed respondents are willing for the data to be analysed and collated with previous survey results. Data collected on the WHS is publicly available to authorised researchers via the UK data archive.

Respondents did not always realise that they were agreeing for their WHS survey answered to be added to a larger database that already stores information about them. Even respondents who had grasped this concept were sketchy about what the database would contain and how this information got there. The idea that the database already held information on them was alien to some. This led to people assuming that by signing the consent form they were actually agreeing to become part of a survey panel.

"I had assumed...that once consent is given I would do [the questionnaire] regularly. "
(Female, 31-64, Other qualifications)

A number of respondents who misinterpreted the consent form originally still did not understand the database after it was explained to them by interviewers. Therefore, even with further explanation respondents could be in group four rather than group five. This indicates that respondents should be given more explicit information on what types of data are stored in the database. It should be made clear that, although it is stored anonymously, this information is about *them as an individual* (see suggested wordings given overleaf).

Example of new wording to clarify consent

“I give consent for my WHS survey answers to be added to any health information about me stored in the Health Information Research Unit for Wales (HIRU) database.”

“I give consent for my WHS survey answers to be added to any social and lifestyle information about me stored in the Health Information Research Unit for Wales HIRU database.”

What types of information did respondents think their survey answers could be linked to?

Even when respondents understood that their survey answers were being added to a larger database, respondents struggled to think what this database could contain. Respondents who were given the V1 consent form tended only to think of information related to the NHS such as GP records and hospital visits.

Respondents who were given the V2 consent form thought about NHS records when thinking about ‘health related’ datasets. However, respondents were at a loss to understand what was meant by ‘social and lifestyle’ data-sets. Respondents were also puzzled over who held the other dataset, as they thought HIRU would only be likely to store health records (as they are the Health Information Research Unit).

When asked to give examples of what other social and lifestyle data could be respondents either:

- Could not give an example of what this meant
- Thought the information could be on behaviours that were related to health e.g. smoking, drinking or fruit and vegetable consumption.
- Thought the information could be on education or current employment.
- Thought that the data-sets could be on ‘anything’ at all.

During probing respondents became more concerned over what other types of information could be included in the database. Some respondents started to wonder

whether areas such as benefits, expenditure, retail habits or anything from social services could also be stored. Respondents who initially said they would sign both parts of the V2 consent form began to have second thoughts at this stage and felt that greater clarity needed to be provided in this area, including more examples of the types of data currently stored.

Consent to linkage to future datasets

After probing on all the documents interviewers were specifically asked to probe on whether respondents were aware that their WHS surveys answers could be linked to future (and therefore currently unknown) sources of data.

Having not grasped the current content of the database, it is not surprising respondents did not understand the fact the database is still growing. Interviewers felt that none of the respondents had taken on board the fact that by giving their consent now they had also given consent for their WHS surveys answers to be linked to any future sources of information added to the database.

Respondents reacted to probing in this area in various ways. Some stated they wouldn't mind the future linkages as the dataset was still anonymous and they had 'nothing to hide.' Others thought they would not mind as they could always refuse to answer more surveys. These respondents incorrectly thought, by not giving more survey information, no more information on them could be added to the database:

"...just because I have agreed to this survey does not mean I will naturally agree to any other." (Female, 65+, A-Levels)

Other respondents did object to the idea of future data linkage as it appeared to be giving researchers 'carte blanche' to do whatever they wished:

"It's giving your consent to something that might change drastically in the future... to something you don't know about."
(Male, 31-64, Degree or above)

Respondents were particularly concerned by what could be added under the bracket of 'Social and Lifestyle' data, who could have access to this data and what it would be used for (see above, section 5.3 and section 5.4).

Respondents, on probing, felt the issue of future data linkage should be clarified. Respondents suggested there should be more information on:

- How long the data will be stored for (i.e. indefinitely)
- What types of information are currently held in the database, with more information on what is meant by 'social and lifestyle datasets.'

Respondents felt there should be a clear acknowledgement that the database is still growing and could contain different types of information in the future, not just on health but across all sectors. Ideally there should be a link to a website that contains the most up to date list of what information is stored in the database. This link should be included on the respondent's copy of the consent form along with details of how to opt out.

One respondent suggested getting reminders every few years to see if consent still ongoing, and for an update on what the database contains. However this is likely to be unfeasible as the database itself is anonymous and therefore orchestrating repeated contact would be difficult and have to involve multiple organisations.

5.4 Key issues and action points

- Currently respondents are signing the consent form without understanding it and are therefore not giving informed consent. The length and the complexity of the form could be contributing to poor understanding. The form should only cover key points and should be written in plain English. Sub-headings might be useful at breaking the information down into smaller chunks.
- Further details on how the data linkage should be provided in the respondent information leaflet. This leaflet should be clearly referenced on the consent form and respondents should be encouraged to read the leaflet prior to signing.
- It needs to be made clear to respondents that this is a separate request from using their WHS survey answers for the WHS main analysis. It is assumed that completion of the questionnaire in itself provides consent for use of the data.
- Respondents did not all understand the idea that the SAIL database could expand in the future. Among those who did understand this there was some concern about what they were agreeing to. Provide respondents with more details on what the SAIL database is and the types of information it contains. This information should specifically specify that the database is growing and could include different types of information in the future (with examples of what this could be provided).

5.5 Missing Information

Background

In addition to probing on sensitivity and comprehension, interviewers also asked respondents whether or not they thought anything was currently missing from the consent form, and, if so what should be added.

Key findings

Respondents varied in terms of whether they felt the consent form was missing any information. Some thought precisely the opposite i.e. the consent form contained too much information and the content should be reduced (see 4.2).

Other respondents felt that some information was missing. Respondents suggested three things they would like to add to the consent form:

- 1) **An explanation of why data linkage is important.** Some respondents felt they would like more concrete examples on what the purpose of the exercise was and what the linked information would be used for. Other suggested it would be nice to have an internet link to reports that had used WHS data.
- 2) **More information on what is currently stored in the database.** As has been discussed (see 4.2.) respondents did not have a clear idea of what sort of information was currently stored in the SAIL database. Therefore respondents did not know what their survey answers would be linked to if they gave consent. A number of respondents felt that if a web-link were provided it they would use this to check out the most up-to-date list of data-sets held.
- 3) **A phone number to call for more information.** Respondents noted that they could withdraw their consent in writing but they felt phoning someone would be quicker and more convenient. Likewise respondents felt it would be useful to have a helpline if they had any queries about what the consent form was about. Some respondents also suggested having a help email address.

The above suggestions are all worth considering in the revised version of the documents. To reduce the length of consent form some of the details could be provided in the respondent leaflet instead. However, if this approach is adopted a clear reference should be made to the leaflet in the consent form text. Details of who to contact to opt out should always be provided on the consent form rather than the leaflet.

5.6 Action points

- Consider adding an explanation of what data linkage is and why it is useful in the documents for respondents.
- Provide respondents with more details about what types of information are included in the SAIL database.
- Consider adding a helpline and email address to the consent form. Consideration should be given as to who would be best to host this helpline i.e. NatGen, HIRU or someone else.

5.7 One signature or two signatures?

Background

During the cognitive testing respondents were shown two different versions of the consent form. Respondents were randomly allocated to which version of the consent form they saw first (i.e. which version was printed at the back of the WHS questionnaire provided). During probing they were then shown the alternative version of the consent form on a showcard.

The first version (V1) required respondents to sign *once* for their WHS survey answers to be linked to all the information held in the SAIL database. The second version (V2) asked respondents to give permission to link their WHS survey answers to *health data* held in the SAIL database, and secondly for their permission to link their WHS survey answers to *other social and lifestyle data* held in the SAIL database. In V2 respondents could choose to sign against one request but not the other. The cognitive testing aimed to explore whether respondents had any preference between the two versions and why.

Preferences

The cognitive testing found respondents had no clear preference between the two versions of the consent form. Respondents fell into one of the following three groups:

- 1) **No preference between the two versions.** These respondents felt they were happy to sign either version and it did not make a difference what their survey answers were linked to as they had 'nothing to hide' and 'everything was anonymous.'
- 2) **Preferred V1.** These respondents felt the V1 form was clearer in terms of where you needed to sign whereas in the V2 version it would be easier to make a mistake i.e. accidentally only sign once when you would be happy for all the linkages to be made.
- 3) **Preferred V2.** These respondents felt the second form was more explicit in terms of what data was being linked to and gave more choice and control over what you agreed to.

It should be noted that respondents did not always understand what was meant by 'social and lifestyle data' as mentioned in V2 version of the consent form (see 4.2). On probing some respondents felt this would deter them from signing the second part of the V2 consent form.

5.8Key issues

- Respondents had no clear preference between the two versions of the consent form versions.
- Whilst the two signature version, was preferred by some respondents, it also confused respondents who didn't understand 'social and lifestyle data' and those didn't understand why they had to sign twice. There was a concern that using two signatures could reduce the percentage who agreed to data linkage

6 Copy of consents and flowchart

6.1 Background

The WHS questionnaire given to respondents contained a single sheet insert. This insert had a 'copy' of the consent on one side and a flowchart, explaining the data-linkage process on the other. The aim of the cognitive testing was to:

- Explore whether respondents know what the copy of the consent form is for.
- Explore whether respondents would keep their copy of the consents.
- Explore whether respondents find the data linkage flowchart useful or not in terms of understanding the data linkage process.

Results relating to testing the insert are discussed below.

6.2 Findings on the copy of consents

Did respondents notice the copy of consents?

Respondents did not always look at the insert at all and some had to have it pointed out to them on probing. Respondents who did notice the insert tended only to give the copy of the consents a passing glance. Respondents felt they did not have to read it as it was clearly marked as a 'copy' so would contain the same information as the consent form in the questionnaire. A number of respondents discarded the insert upon seeing the word 'Copy' on the front. This was problematic as it meant the flowchart was also discarded and overlooked (see section 4.2.). This suggests the flowchart should be included elsewhere, rather than the back of the copy.

Did respondents understand what the copy was for?

Respondents varied in terms of whether they understood what the copy was for. Respondents either:

- Were unsure who the copy was for; or
- Understood the copy was for their own records;

Respondents who were unsure about what the copy was for queried whether they would have to sign this document as well, and asked why the researchers wanted them to sign the consent form twice. These respondents felt the form could be made clearer if it said 'Copy for your records' rather than just 'Copy.'

Would respondents keep a copy of the consent form?

Respondents varied as to whether they would keep a copy of the consent form. Some felt that they would not use it and that it was a waste of paper. These respondents stated that once they had agreed to something they were unlikely to change their mind at a later date and they could not think of what would trigger them to change their mind.

Other respondents felt it was good practice to keep a copy of anything that you had signed and that they would try to hang on to the copy. The copy was felt particularly useful as it contained the contact details of who to get in touch with if they changed their minds or if they had any further questions. Likewise, if necessary they might need to refer to the copy at a later date to provide proof of what they had agreed to. As noted in section 5.3 respondents felt a helpline would be a useful addition to their copy of the consent form.

One respondent commented that the 'Copy' provided was not strictly a copy at all as it did not require a signature. Another respondent felt it would be better to have the copy attached to the back of the original consent form as a tear-away slip. This would establish a clearer link between the two documents so there was no room for confusion.

No respondents felt that having a copy of the consent form was off-putting or would detract from their taking part in the WHS

6.3 Action points

- The watermark used should be amended, if possible, to say 'Copy for Your Records' rather than just 'Copy.'
- Consider having the respondent copy of the consents on carbon paper attached to the back of the original consent form- this would alleviate confusion over whether or not the copy needs to be signed. It may also encourage respondents to keep their copy of the consent form rather than bin it.
- The flowchart should not be included on the back of the copy, as this encourages respondents to overlook it.

6.4 Findings on the flowchart

The cognitive testing aimed to look at whether the respondents used the flowchart or not and, if so, whether it was useful. Interviewers checked whether respondents understood the flowchart and also asked them for their views on how it could be improved.

Did respondents notice the flowchart?

Respondents varied as to whether they looked at the flowchart. Respondents:

- noticed the flowchart immediately, on placement,
- referred to the flowchart when prompted to by the consent form, or
- did not look at the flowchart at all.

A number of respondents, who tried to look for the flowchart when prompted to by the consent form, could not find it. These respondents looked for it on the back of the actual consent form (rather than the copy) or asked the interviewer for assistance in locating it. These respondents had either not noticed the insert at all or had put it to one side thinking they did not have to read it. As discussed in 5.2 respondents discarded the insert as they saw the word 'Copy' written across it, and did not notice something was printed on the back.

Did respondents find the flowchart useful?

Respondents varied as to whether or not they found the flowchart useful. Respondents either:

- were not used flowcharts and therefore found them confusing, or
- were used to flowcharts and found them helpful.

Respondents who were not used to flowcharts stated that they did not understand this flowchart and it looked over-complicated. They felt they would not use the flowchart when making their decision on whether or not to sign the consent form.

Respondents who were more familiar with flowcharts felt including a flowchart is useful because it:

- helps to visualise the process,
- is easier to follow than a large block of text,
- clarifies the information that has been given elsewhere, and
- reassures the reader some thought had gone into the processes involved.

Interviewers went on to explore whether or not respondents actually understood the flowchart. Results on this are reported in the next section.

Did respondents understand the flowchart?

Regardless of whether or not they used it respondents who were more familiar with flowcharts seemed to have a good understanding of what the flowchart was for. Respondents felt the aim of the flowchart was to illustrate:

- who has access to the information you provide,

- what information is passed from one organisation to another, and
- how data is kept anonymous i.e. that your name/ address/ date of birth are deleted

Therefore, for respondents who were familiar with flowcharts the 'big picture' given in the current flowchart was clear. However, on looking at the flowchart in more detail during probing respondents felt the flowchart did not always make sense. Respondents were unclear about:

- 1) The terminology used
- 2) The organisations named
- 3) What 'other data' referred to
- 4) Who had access to the data; and
- 5) Aspects of the process shown.

Each of these issues will now be discussed in turn.

Problems with terminology

A number of respondents commented that they were unsure what was meant by the term 'unique reference.' Part of this issue was due to the consent form referring to respondents being giving a 'personal identification number.' Respondents questioned whether these two things were the same or different. This indicates that terminology should be consistently used between the two documents.

One respondent (Male, 31-64, Degree level or above) was unclear about the word 'match' referred to. It should be noted the consent form uses the word 'link' throughout but the flowchart calls this 'matching.' Again, this indicates that terminology needs to be used consistently between documents to minimise the risk of confusion. A number of respondents also questioned how this match could be made.

Problems with the named organisations

Respondents who used the flowchart felt it was useful as it illustrated the different organisations that would have access to the information. The flowchart helped to clarify who was involved, for example one respondent (Male, 31-64, Other qualifications) on reading the consent form had thought that the NHS Wales Informatics Service and HIRU were part of the same organisation. The colour-coding on the flowchart helped this respondent to realise the two organisations were separate.

However, respondents noted that they had not heard, or were not familiar with, the organisations named on the flowchart (including NatCen) and this should be expanded

upon elsewhere. Currently there is no explanation of who the different organisations are in any of the survey materials. Therefore, it may be desirable to add more information on the organisations in the WHS respondent leaflet, so respondents can refer to this if they chose to. One respondent felt the NatGen abbreviation should not be used and instead the documents should refer to the 'National Centre for Social Research.'

Lack of understanding of 'other data'

As discussed previously, respondents found it difficult to imagine what sort of information would be held in the SAIL database (see 4.2). This became apparent again when respondents were asked to review the flowchart. Respondents questioned what the 'other data' box referred to.

"Where is this other data coming from?"

(Male, 31-64, Degree Level or above)

At this point it was apparent that some respondents were still unclear that the information held on the database could be about them. Respondents who understood the database held information about them were unclear about how the data already had a unique reference on it that allowed the WHS data to be added it.

It should be noted again terminology is being used inconsistently in that the flowchart refers to 'other data' whereas the consent form and the leaflet refer to 'Datasets' and 'information.'

Problems with 'other authorised researchers'

The biggest issue respondents had with the flowchart was in relation to who had access to the data at the end of the process. Respondents were surprised by the fact the information in HIRU gets passed again to 'Other authorised researchers' at the end of the process. This had not been made clear to respondents in any of the other documents they had seen.

Respondents varied as to whether they minded that the data was passed on to other people. Some stated they did not mind as it was "*all anonymous*" but others had reservations.

"It could anybody at all. This needs to be clarified."

(Female, 65+, Degree or Above)

Respondents questioned whether advertising companies or market researchers could make use of the data. A number of respondents felt there should be something that clarified the type of people who could use the data and how authorisation was granted.

It should be noted that currently other authorised researchers have access to WHS data through the UK data archive, regardless of whether or not respondents agree to consent to data linkage. Again this is not made explicit in any of the existing survey materials.

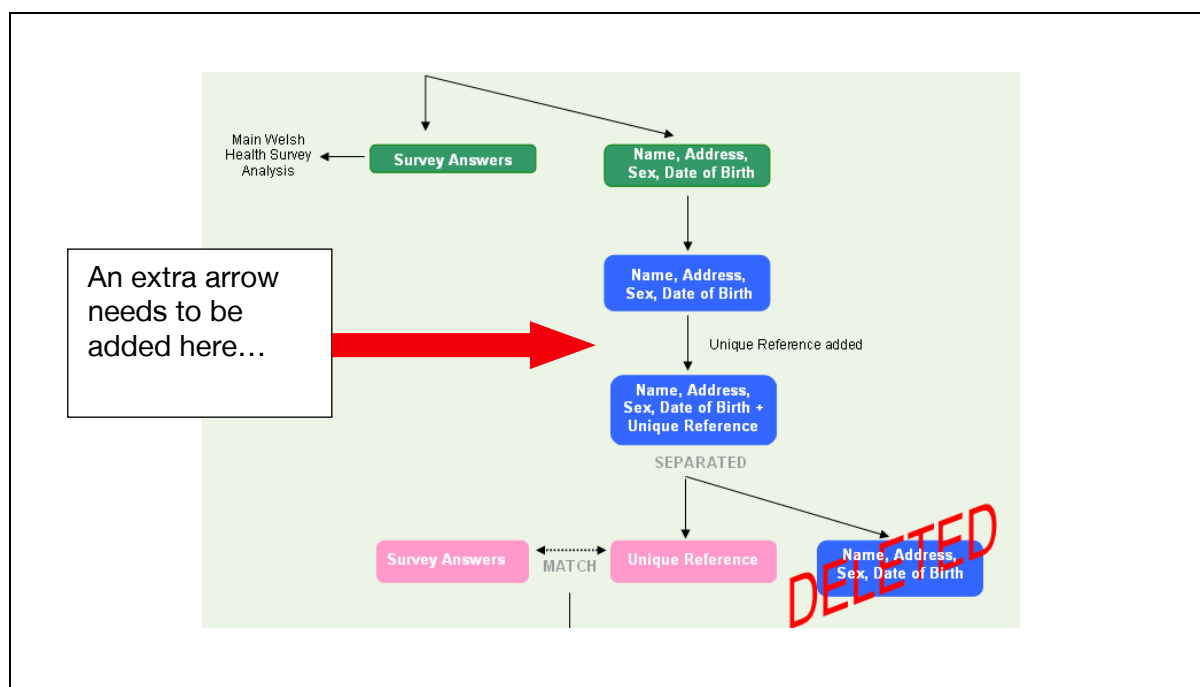
Cognitive testing revealed a problem with the way this information was presented in the flowchart. Some respondents felt that the word ‘anonymous’ was referring to the researchers who had access to the data rather than to the information stored in SAIL database. Naturally respondents found this concerning as they thought the information was being deliberately withheld. It needs to be made clearer that the data held is anonymous, rather than the researchers.

Other areas of the process that lacked clarity

Respondents picked up on four other areas of the process that they did not understand on the flowchart.

Firstly, respondents noted the flowchart does not show that the survey answers go from NatCen to HIRU. An extra line needs to be added to the flowchart to demonstrate this (see figure 6.1 below).

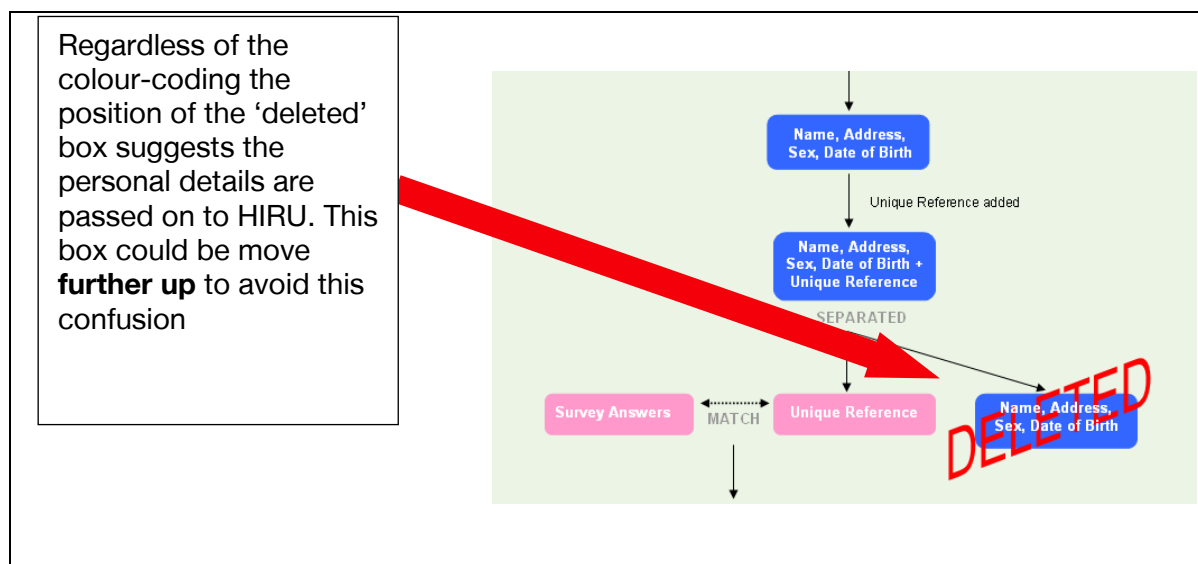
Figure 6.1: No link between NatCen Survey answers and HIRU



Secondly, respondents were unsure about what happened to the data when it was passed on from the NHS Wales Informatics Unit to HIRU. Respondents were not always clear why two organisations were involved, and why they had to pass on their personal details if they were going to be deleted. The current system is in place so that personal

details are not accessible to HIRU and are not part of the SAIL database; however this was not clear to respondents. Respondents noted that the placement of the 'deleted box' made it look like the deletion could have been carried out by HIRU as it is on the same level of the other HIRU boxes (see figure 6.2. overleaf).

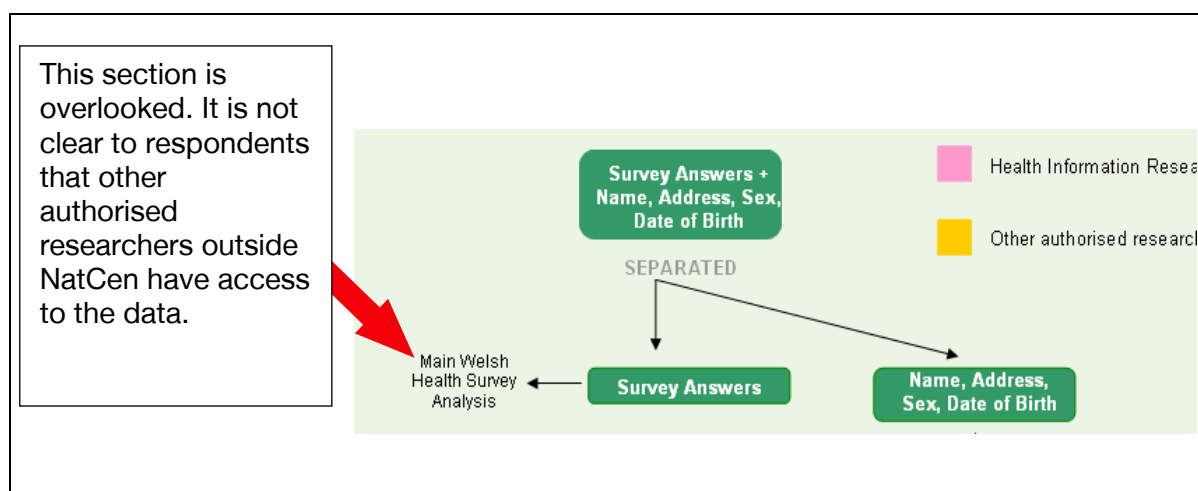
Figure 6:2 The positioning of the deleted box caused confusion



In addition currently the flowchart states 'sex' is deleted. However, this is not likely to be the case as sex is not a disclosive variable and would be needed for analysis. Therefore the reference to 'sex' being deleted should be removed.

Thirdly, respondents did not understand what would happen to their answers if they did not consent to linkage. There is an argument that this needs to be made more explicit on the flowchart (see figure 6.3. below).

Figure 6:3 Unclear what happens in main WHS analysis



Finally, a number of respondents questioned how a 'match' could be made from the unique reference number back to the WHS survey answers if there was no longer anything that could be used as a cross reference. In actuality, a second number is used to do this (the WHS serial number) which is not shown on the flowchart. It is unclear whether this information should be added to the flowchart, on one hand it could explain how the link is made, on the other it could add an extra degree of complication to what is an already busy flowchart.

1.2 Key Issues and action points

- A flowchart will be useful to some respondents so it is recommended one is used.
- Terminology used in the flowchart needs to be consistent with that used in the other documents i.e. the flowchart should use the term 'identification number' rather than 'unique reference' and 'link' rather than 'match'.
- The flowchart should not be included as a separate insert as this will mean it is more likely to be overlooked. It should be either with the actual consent form or in the information leaflet.
- The changes in format illustrated in Figures 6.1, 6.2 and 6.3 need to be implemented.
- Remove the reference to 'sex' on the flowchart and any other explanations (including the consent form) as this variable would not be excluded from the SAIL database.
- On probing, the flowchart caused respondents to question a number of issues related to data linkage. Not all of these issues should be addressed on the flowchart itself as this would decrease its readability. However, the questions respondents asked need to be addressed somewhere in the other documents provided:
 - Consider adding a couple of sentences about each of organisation involved in the data linkage into the respondent information leaflet.
 - More information needs to be included somewhere in the documentation on what information is held in SAIL and how that information came to be there.
 - More information needs to be included somewhere in the documentation on who can use the SAIL database and how authorisation is given.

7 The information leaflet

7.1 Background

The final document examined in the cognitive testing was the WHS respondent information leaflet. The sections of the leaflet examined were:

- 1) The existing leaflet sections that explain what happens to WHS survey answers in the main-stage analysis.
- 2) The new leaflet section on what happens to WHS surveys answers if respondents agree to data linkage.

The text tested is shown in Appendix B.

The aims of the cognitive testing were to:

- To establish whether respondents would read the information leaflet
- To explore whether respondents understand the material provided in the leaflet.

Results from testing the respondent leaflet are shown below.

7.2 Did respondents use the leaflet?

Respondents varied as to whether they used the leaflet. Respondents:

- did not look at the leaflet at all,
- briefly glanced through the leaflet; or
- read all the relevant leaflet sections.

During the cognitive testing the leaflet was the document least likely to be referred to by respondents. There is only a brief mention of the leaflet at the end of the consent form where it is described as a source of '*further information.*' To encourage respondents to read the leaflet the consent form should explicitly *recommend* that respondents refer to the leaflet, and give details of the sort of information it contains. Furthermore, interviewers could also encourage respondents to refer to the leaflet if they have any questions.

7.3 Did respondents understand the leaflet?

General understanding

A number of respondents stated they found the information leaflet easier to understand than the consent form. This may be due to the fact that respondents did not always look at the leaflet in detail until after they had been probed on their understanding of the consent form and therefore had more time to reflect on the information.

Nonetheless, respondents gave some convincing reasons why the content of the leaflet was easier to understand. Firstly, respondents felt the style of the leaflet was more simple and 'to the point.' Secondly, respondents felt that the leaflet was easier to read as it was broken up using a series of subheadings. Therefore, although a lot of information was given it was easier to digest.

Respondents liked the fact that the information was given as a series of 'Frequently Asked Questions' and described how they could read through the headings and then choose to read the answers to the questions they were most interested in. One respondent (Male, 31-64, Other qualifications) suggested the leaflet should have a contents page to help him find the information he was looking for.

What did respondents think would happen if they did not sign?

Even after reading the consent form, the flowchart and the leaflet a number of respondents still had not grasped the distinction between the WHS mainstage analysis and the consent for data linkage to the HIRU database. These respondents continued to think the consent form was asking for their permission to 'use' their WHS survey answers for the main analysis and felt their questionnaires would be destroyed if the consent form was not signed.

"If you don't give consent nobody can use it."

(Male, 31-64, Degree Level or above).

Currently, the leaflet subheadings do not clearly differentiate between the main survey analysis and the data linkage and could be made more explicit e.g. they could read 'If I return the questionnaire, who will have access to the information I provide?' and 'What will happen to my information if I sign the data linkage consent form?' It should be made clear in the information leaflet that the data linkage consent form is an additional optional request that they can sign if they are happy for their survey answers to be used in additional ways.

Did respondents understand who would have access to the data?

Prior to looking at the leaflet there had been no discussion on who had access to the data for the WHS mainstage analysis. Furthermore, respondents did not always appreciate there was a difference between the mainstage analysis and the analysis done using the linked data (see section 5.2). Therefore, respondents did not realise until looking at the leaflet that certain groups had access to their survey answers. Respondents expressed surprise on probing that 'universities' and 'other organisations' could have access to their survey answers regardless of whether or not they signed the consent form. They felt that the whole issue of who had information if the form was not signed had been glossed over.

Respondents noted that the organisations mentioned in the leaflet were different to those on the flowchart. For example, the leaflet mentions WAG, NHS organisations and universities, none of whom were mentioned on the flowchart. Some respondents came to incorrect conclusions about access because of this, for example they thought that HIRU was part of WAG, and that NHS organisations meant the NHS Wales Health informatics. This indicates the flowchart should be clear in terms of what happens to data in the WHS mainstage analysis as well as after data linkage.

Finally, it was noted that the terminology used between the leaflet and the flowchart differed, for example the leaflet talks about 'statistical researchers' and 'registered researchers' whereas the flowchart talks about 'other authorised researchers.' Terminology used should be consistent between documents (see also section 6.3).

Passing on postcodes to WAG

Respondents varied in terms of whether they noticed the statement that said their postcode could be shared with researchers at Welsh Assembly Government. Respondents who did notice it did not raise an objection to it. Respondents felt the postcode would be useful to researchers i.e. it could show what health services were available in their area and it could show whether people in different areas were more healthy than others.

Missing information

The main thing respondents felt was missing in the leaflet (and elsewhere) was information was held in the HIRU database (see 4.2).

Web address

As part of the cognitive testing respondents were asked whether or not they would go to the web address mentioned in the leaflet. Respondents varied in terms of whether or not they would use this link.

Some stated they would not look at the web page as:

- they did not have any questions

- it would be easier to ask questions of their interviewer
- the web page would just contain the same information as the leaflet
- they did not normally go on line or they did not like using computers.

However, other respondents felt a web-link would be useful if they had any unanswered queries. Respondents noted that the advantage of a website is that it could be kept more up-to-date than a leaflet i.e. it could include more details of the latest research findings and an up-to-date record of the types of dataset held in SAIL. Therefore, a website could prove a useful addition to the leaflet provided the content is different to that included elsewhere and it is kept up-to-date.

7.4 Key issues and action points

- The consent form should explicitly encourage respondents to look at the information leaflet and outline what additional information it contains.
- Interviewers should encourage respondents to refer to the leaflet if they have any questions when all the documents are placed.
- The information in the leaflet should continue to be laid out as a series of 'Frequently Asked Questions' as this format broke information down into small chunks that were easier for respondents to read.
- Consider adding a contents page to the leaflet so respondents can quickly locate the information they are looking for.
- The leaflet subheadings need to clearly differentiate between the main survey analysis and the data linkage, as currently the distinction between the two is blurred or overlooked entirely.
- The leaflet and the flowchart should use consistent terminology. The flowchart should be updated to include details of who has access to the information if the data linkage consent form is not signed.
- Respondents felt the leaflet should include more information on what types of data are currently held in the HIRU database.
- No respondents in the testing appeared to mind that their postcode could be given to researchers at WAG.
- A web address would be useful for some respondents, mainly as an up-to-date source on what sort of information is included in the SAIL database and an up-to-date resource on survey findings.

8 Respondents' views post-probing

8.1 Background

After interviewers had been through all the documents with respondents, and answered any extra questions raised, respondents were asked again on their views as to whether they would sign the consent form, and why this was the case.

8.2 Did respondents change their mind about consent after probing?

By the end of the interview four respondents felt, now they had discussed the documents with the interviewer in more detail, they would no longer give consent.

Reasons for withdrawing consent were:

- Not feeling confident they had understood the form.
- Confusion over what the data would be linked to and what it could be used for. This was particularly the case for 'social and lifestyle' data.
- Realising third parties could have access to their answers and not being aware of whom these were.

The other respondents stated they would still give consent to the data-linkage even when they were more aware of what was involved. Respondents gave the following reasons for consenting:

- Knowing everything in the database is confidential/ anonymous
- Knowing they can 'opt-out' if they choose to
- Wanting to contribute to the research and to make a difference to the future of the NHS (some were still concerned that their WHS questionnaire would not be useful if they did not sign the consent form).

The final point is concerning as it demonstrates that even with one-on-one reassurances from interviewers that signing is optional respondents may feel obliged to sign the consent form.

8.3 Key issues and action points

This above indicates the priorities for improving the consent to need to be:

- 1) Improving the general clarity of the consent form. Make it more concise and filled with less jargon. Non-essential information should be included in the leaflet instead. There should be clear sign-posting to the leaflet in the body of the consent form.
- 2) Provide more information on what types of information are held in the SAIL database, particularly the sorts of things that could be considered as 'social and lifestyle' data.
- 3) Provide more information on what is meant by an 'authorised researcher' and in what circumstances the information could be accessed i.e. how the data would be used.

In addition the documents need to:

- Continue to reassure respondents that the database is anonymous.
- Continue to provide contact details respondents can use to ask questions or to withdraw consent.
- Stress that the consent to data-linkage form is an 'optional extra' and is separate from the questions and that their survey data could still be used without them consenting to linkage.

PART THREE: ROUND TWO REPORT

9 Reading the documents

9.1 Background

In the first stage of each interview, interviewers spent a few minutes talking to the respondent to set the context. This involved describing the format of the interview, finding out if the respondent recalled taking part in the WHS in 2009, and checking if the respondent had received and read the pack of information (the WHS questionnaire, consent form, and information leaflet) sent prior to the interview. Respondents were not required to fill in the questionnaire.

9.2 Key findings

In testing not all respondents recalled taking part in WHS 2009. There was one respondent who thought their parent living at the same address had filled in the self completion for her. Although, it is possible that the respondent had originally completed the questionnaire herself and had forgotten⁴.

Four of the 18 respondents had not received the pack posted to them, despite it being posted to the correct address 4 days before the interview. Respondents who *had* received the pack tended to either have:

1. read *both* the consent form and information leaflet; or,
2. read/ skim read/glanced at the consent form *only*; or,
3. skimmed read *both* documents; or,
4. not look at either document.

Just three of the 18 respondents said they had read through all of the documents and five said that they had read the consent form but not the leaflet (either because they felt they didn't need to or because they hadn't noticed it inside the envelope). Two respondents said they had briefly skimmed/glanced over the documents and the remaining eight respondents (four of whom reported not receiving the pack in the post) had not read anything before the interview.

It should be noted that there were two respondents who had received the materials but had not noticed the consent form or the information leaflet in their pack. In testing, when the consent form *had not been noticed* it was because:

- it was clipped to the questionnaire and it was assumed it was a copy of the advance leaflet or,
- it was not seen at the back of the questionnaire.

Both these reasons had only been observed once in testing.

A reason why the consent form was *not read* when noticed was because it appeared to be very similar to the information leaflet or that the respondent had read the instruction 'Thank you for completing the questionnaire' on page 21 and assumed they had finished. When the information leaflet was missed or not read it was because it was not clipped to the other documents and or had fallen to the bottom of the envelope.

For respondents who had not read the documents (either because they had not received the documents before the interview or choose not to read them) the interviewers asked the respondents to briefly read through these two documents. It was observed in testing by both respondents who had looked at some of the materials prior to their interview and those who had not, that when the information leaflet was not referred to, it was because the respondent felt they understood the consent form so did not need further information.

9.3 Action points

- In the main survey there will be respondents who do not read the material fully prior to signing the consent form. To assist respondents to read both the consent form and the leaflet we would advise that the consent form should be more noticeable and distinct from the questionnaire. To achieve this it needs to be visually different, so not printed on green paper/with a green background.
- The data linkage documentation should be clipped together so it does not get missed and are seen as belonging together and given to respondents with sufficient time to read through the documentation. We discuss in the following chapters how the different documents could be improved to assist 'skim readers' (those looking for key messages) and 'readers' (those who read the documents properly) to understand each document.
- In addition it would be helpful if the questionnaire refers respondents to the consent form and supporting leaflet. This can be achieved by slightly amending the thank you message on page 21 of the WHS questionnaire to something along the lines of "Thank you for completing the questionnaire. Now please refer to the Information leaflet and consent form (both printed on ... colour paper)".

⁴ This had also been observed in round one.

10 Initial reactions to the consent form

10.1 Background

After being given time to familiarise themselves with the documents respondents were directed to look at the data linkage consent form and encouraged to refer/read the consent form (again) if they wanted to.

Two ways of administering the consent form were tested in round two. These were having the consent form printed:

1. 'within' the questionnaire: on the final page; and
2. as a 'separate' document, on carbon copy paper.

Both versions were tested, with eight respondents in group (1) and ten respondents in group (2). Respondents were asked to imagine they had just finished completing the questionnaire and had reached the consent form. Respondents were asked to give their first reaction as to whether they would sign the consent form or not and why this was the case.

10.2 Would respondents give consent? Why?

Respondents were asked if they had read the consent form and asked to give their first reactions as to whether or not they would sign it. In testing there were respondents who had:

1. read the consent form and said they would sign it;
2. read the consent form and said they would *not* sign it;
3. *not* read the consent form and said they would sign it; and,
4. *not* read the consent form and said they did not know whether they would sign it.

We look firstly at the reasons why respondents said they would not sign the form and then discuss the reasons why respondents said they would.

10.2.1 Reasons why respondents would not sign the consent form

In testing only rarely did a respondent say they would not or did not know whether they would sign the consent form. These respondents had a fairly good grasp of the essence of the request and understood their survey answers would still be used. This only occurred for respondents who had been given the version of the consent form within the WHS questionnaire. The reasons why respondents would not sign the consent form or did not know if they would were:

- concerns about confidentiality; or,
- that paragraph three in the consent form was confusing and not understood; or
- they did not know the reason why the Welsh Government wanted to link the data.

When the first reason was given it was underpinned by concerns that linking to other records would mean their data were no longer confidential or concerns about the recent phone hacking scandal. One respondent said:

“Happy to fill in the questionnaire and to help but when other things get involved, I am not keen” (Female aged 16-30 Other qualification).

There was one occasion in testing when a respondent who answered that she would sign the consent form said later in the cognitive interview that if she had spent time filling in the questionnaire and then came across the consent form she would think “what, more?!” (Female 65 or over, with a degree) and put the form aside and forget about it. This suggests that within the group of respondents who said yes in the cognitive interview they may actually decline in the survey context.

10.2.2 Reasons why respondents would sign the consent form

Those respondents who thought they would sign the form included respondents who agreed to sign it without reading the form or the leaflet. Respondents varied in terms of the reasons they gave for being willing to sign. There were six broad reasons respondents agreed to sign the form. These were:

1. **Wanting to help.** Respondents who gave this reason described how they wanted to help the people running the WHS or that they wanted to be part of improving/helping the NHS or health Services to understand and improve people’s health. One respondent said he will always help if he can whatever he is asked to do.
2. **Personal reasons.** Due to personal or family health issues and a willingness to do anything they can to help the NHS or health-related research.
3. **Having nothing to hide.** Respondents described how they personally had nothing to conceal or that they were not a private person and that they were not being asked to provide anything ‘worrying’ as far as they could see.
4. **Knowing the data are confidential.** Respondents were reassured by the fact that the data would be anonymised, personal identifiers such as name and address are removed, and that the research is covered by the Data Protection Act.
5. **Wanting data to be used.** Respondents described how there was no point completing a questionnaire and then not signing a consent form. These

respondents felt that if they did not sign the linkage consent form their survey answers could not be used at all (see Chapter 4).

6. **No harm.** Respondents described how they could not see any harm to them as the survey answers would be used only to provide statistics.

All respondents who agreed to sign the consent form did not mention that their data could be linked to other data sources. Exploration of respondents' understanding of the consent form revealed that there was a group of respondents in testing who assumed they would be giving their permission for their survey answers to be used only (we explore this further in Chapter 4). Therefore respondents may sign the form for various reasons that are not directly related to the information that they have been provided with

10.2.3 Sensitivities

Irrespective of whether respondents answered that they would or would not sign the consent form, respondents almost all felt it was not sensitive to be asked to sign a consent form. As a respondent who answered No responded "*It is up to me to say whether I will or not*" (Female, 65 or over, with other qualification). Other, respondents felt it was not sensitive because:

- they could say no to data linkage; or,
- they thought it was not sensitive to ask if their survey answers could be used; or,
- NatCen or the Welsh Government would not pass on their name and contact details to commercial organisations.

Occasionally a respondent checked with the interviewer or expressed concern even though they said they would sign. When the respondent had checked it was to verify that:

- only NHS Wales would have their name, address and date of birth; or,
- their data would not be sold to commercial organisations.

The one occasion when a respondent had expressed a concern it was because the respondent was worried that how he answered the questions could be referred to later if he has health problems. The respondent gave the example that all the health questions are about the last week, so if he went to a party and got very drunk this would skew his medical records. He was concerned that if these records were referred to at a later date this could affect any future treatment he may require.

This indicates a fundamental problem that there could be respondents who will sign the form even if they do not fully understand its content.

10.3 Key issues and action points

- Testing showed that respondents will not always read the other survey materials prior to deciding whether or not to sign the form. Therefore all key information needs to be on the consent form in an attractive, easy and quickly digestible form so respondents are encouraged to read it and even respondents who skim read get the key messages. Further direction to the other documents could be made more prominent so respondents are encouraged to refer them for example to find out about confidentiality and data access. (We provide an example of wording changes at the end of chapter 11)
- Respondents may sign the form to be helpful, and they see no harm in doing so, but they may not have fully understood the consent form so consideration needs to be given to how to make the information more accessible and understandable.
- To assist respondents to read and understand the purpose of the consent form consider changing the title of the consent form so it explicitly refers to seeking permission for data linkage. A possible wording for the title is: **Permission to link your survey answers with other health and educational data records**

11 Probing on the consent form

After being asked for their initial reactions on whether they would sign the form, respondents were asked a number of follow-up probes on:

- what they thought the form is asking permission for;
- why they thought the Welsh Government wanted to link the data;
- what would happen if they signed and did not sign the form, and;
- clarity of the information provided on the self-completion questionnaire.

This section sets out key findings arising from this element of testing.

11.1 Comprehension of the data linkage request

11.1.1 Background

The cognitive testing aimed to establish whether respondents understood the consent form. Respondents were asked to explain in their own words what they thought the form was asking their permission for and what would happen to their information if they chose to sign. The key issue under investigation was whether or not respondents understood the form sufficiently well enough to be able to give ‘informed consent.’⁵

11.1.2 Variations in understanding

On the whole respondents did not understand why they were being asked to sign the consent form well enough to give informed consent. Analysis of the survey data shows that respondents fell into five distinct groups irrespective of which version of the consent form they had received. A description of these groups, and whether or not *informed* consent to linkage was actually given, is summarised in the table 11.1.

⁵ Informed consent refers to providing sufficient information to respondents so they can make an informed decision about whether or not to agree to data linkage. This involves understanding the stages of data linkage and the implications of the linkage i.e. its uses.

Table 11.1: What were respondents consenting to and was informed consent given?

Group	Description	Informed consent?
1. Consent given to use WHS survey answers only.	Respondents thought they were agreeing for their WHS survey answers to be used <i>only</i> .	✗
2. Permission given to be re-contacted for future surveys	Respondents in this group thought they were being asked to give contact details to take part in future health surveys.	✗
3. Consent that WHS survey answers could be used and other information looked up	These respondents understood they were consenting for their survey answers to be used and other information referred to such as health records. However, they did <u>not</u> understand they were agreeing for their answers to be added to a database holding administrative information about members of the population including them.	Partial understanding
4. Consent to data linkage: <u>Unclear</u> on information held	<p>These respondents thought they were giving consent for the NHS to be contacted to get more information about them.</p> <p>These respondents did not understand the different types of information this database contained about them from other sources. The respondents also did not know who would have access.</p>	Partial understanding
5. Consent to data linkage: <u>Clear</u> on information held	<p>These respondents appeared to understand the request correctly.</p> <p>Respondents described that their details and survey answers would be linked to NHS records or Education records to help get a better picture of the respondent and of people in Wales. Respondents appeared to understand that the linking process involved different organisations, that there was a database, and that researchers could access the data.</p>	✓

Respondents in group 1 (those who thought they were consenting to their survey answers being used) thought that if they did not sign the consent form their questionnaire could not be used for anything and so there was no point returning the questionnaire if they did not sign the consent form. Respondents with this understanding did not understand the second bullet point and in particular, the words 'In another way'. This raised questions as to what the 'another way' could be, which was not clarified by the other bullet points in the consent form. This could lead to reduced WHS response rates. It is therefore important that the consent form is made clearer that:

1. completed WHS questionnaires can be used *regardless* of whether or not respondents chose to sign the form; and,
2. the form is not asking for consent to use WHS data, we are making a separate request to respondents about adding their WHS survey answers into the SAIL database.

Whether the inclusion of the consent form could significantly influence response rates can only be verified using a quantitative field-test. Given the fact the cognitive testing suggests response rates could be affected however, we would advise the use of a field test with a sufficiently large sample to draw statistically robust conclusions about impacts on response rates.

Currently the variation in understanding of the purpose of the consent form shows that, signing the form is not an indication that informed consent is being given.

11.1.3 Understanding of reasons for the data linkage request

Considering that respondents have not consistently understood the purpose of the request it is not surprising that respondents have also not consistently fully understood the reasons for the request i.e. to add their data to a larger database that already stores information about them. Respondents thought that the Welsh Government wanted to link the data to:

- improve health services generally, or to get a better understanding of health issues to be able to appropriately target services or to produce health statistics or to plan for future needs (correct understanding); or,
- make them look good that they are doing something helpful (incorrect understanding); or,
- give the government insights into people claiming sickness benefits and see if they should be claiming them (incorrect understanding); or,
- help someone somewhere (understanding unknown).

11.1.4 What respondents believed would happen if they did or did not sign the consent form

Irrespective of whether respondents said ‘no’, ‘don’t know’, or ‘yes’ to Form outcome 1 (a question which established whether they would sign the consent form), on the whole respondents did not understand the outcome of signing or not signing the form. There was a variety of misunderstanding of the outcome. Saying this, there was a group of respondents who either retained their correct understanding or seemed to be developing an idea of the process by this stage of the interview. Below we discuss how respondents who had answered ‘no’, ‘don’t know’, or ‘yes’ to Form outcome 1, understood the implication of signing and not signing the consent form.

In testing one respondent answered ‘no’ and another said ‘don’t know’ when asked ‘Form outcome 1’. The respondent who answered ‘no’ understood that by signing the form she was agreeing for her survey answers to go to Swansea University and then the Welsh Government who would take it further. How it would be taken further was not understood. This respondent understood that her survey answers would be used even if she did not sign the form. She felt this would be a good thing because it would not have been a waste of her time filling in the questionnaire and also did not make her feel bad to say to refuse the data linkage request. The respondent who answered ‘don’t know’ to ‘Form outcome 1’ believed that by not signing the form it prevented the Welsh Government contacting the NHS to take the process further. The respondent did not know what would happen to her survey answers by not signing.

Table 11.2 below illustrates how respondents who had originally said ‘Yes’ at the start of the interview to ‘Form outcome 1’ understood the process.

Table 11.2: How respondents who answered Yes to ‘Form outcome 1’ understood the implication of signing and not signing the consent form.

Understanding	Whether understanding was correct or not
Permission to link records such as health records in the respondent’s past and survey answers and that the data will be compared to other people. There were respondents who had this understanding who also understood that even if they did not sign the consent form their survey answers will be used for research. However, some other respondents were not sure what would happen to their survey answers if they did not sign the consent form.	✓ & ✗
If the consent form is not signed the survey answers could still be	Partial

Understanding	Whether understanding was correct or not
used but not signing prevents the Welsh Government approaching the respondent again for further information.	understanding
If the consent form was not signed, the survey answers would still be used but only by the Welsh Government and not shared with other organisations.	Partial understanding
If the consent form was not signed, the questionnaire would be destroyed or that there was no point returning the questionnaire.	✗
Permission to look at survey answers to identify if the respondent needs particular support service e.g. if drinking too much to receive help to reduce the his/her alcohol consumption.	✗

11.1.5 Understanding of the phrase ‘Your survey answers and other information will be used for research purposes only’.

This phrase is included in the fifth bullet point on the consent form. Respondents were asked how they understood this phrase. On the whole respondents seemed to have some idea of what is meant. Even when it was not understood exactly as intended respondents’ understanding was not far from the mark. The table below illustrates how it was understood.

Table 11.3: How ‘Your survey answers and other information will be used for research purposes only’ was understood.

Understanding	Whether it was correct or not
Research focused understanding	
To set up a health data base/ To produce statistics/ for medical research only	✓
To look at health problems prevalent in the population/ get a picture of Wales	✓
To plan for future needs	Partial understanding
<i>“To research how I use the NHS or how it has behaved towards me”</i> (Male, 65 + with other qualification, received the version with the consent form within the questionnaire)	✗

Understanding	Whether it was correct or not
To see if hospitals and GPs are dealing with issues as they should	x
Compared to commercial organisations	
Saying this to encourage survey participation	Partial understanding.
Details would not be shared with commercial organizations selling things	

11.1.6 Clarity of consent form

In testing, the clarity of the consent form was explored with respondents by exploring with them how clear they found the information and if anything should be made clearer in the form. In testing respondents fell in two groups in regards to how they found the clarity of the consent form. There were respondents who felt the consent form was fine (group 1) but there were others who felt the consent form could be clearer (group 2). Respondents in group 1 felt the information in the consent form was:

- fine and very clear;
- pretty concise and liked the bullet points;
- clear enough for them to sign the form.

Respondents who described the consent form as ‘fine and very clear’ on the whole had not understood the purpose of the consent form. It was (wrongly) understood by them as asking permission to use their survey data only; or to look at their data to see if they needed help for example to claim the correct benefits or to access addiction services. There were some respondents who found it ‘fine and very clear’ and did correctly understand the consent form. These respondents were male or female aged 31-64 and education to degree level or other. Respondents in this group had received both versions of the consent form so this does not seem to be a factor in understanding or how respondents found the clarity of the consent form. Respondents who felt it was clear enough for them to sign the form had a fair understanding of the consent form.

There were respondents of all ages and education backgrounds in group 2. Respondents in group 2 felt the consent form:

- could benefit from simplification to make it clearer, as it was found to be “*a little bit confusing*” (Male 65 or over with other qualification).
- needed to be read 2 or 3 times to understand it and by scanning it you could only get a gist or a feeling that you have understood the form when actually you have not.

- could benefit from making bullet point 2 and 3 clearer and that these points generally could flow better into one other. It was felt that bullet point 3 introduces a new topic for the first time.

In group 2, there were respondents who started to understand the purpose of the consent form once they had read the form a few times and also the information leaflet. However, in the main stage respondents may not go through this effort especially if they have assumed they have understood it correctly on first reading.

11.2 Missing information

11.2.1 Background

In addition to probing on sensitivity and comprehension, interviewers also asked respondents whether or not they thought there was too much or too little information and if anything was currently missing from the consent form, and, if so what should be added. Interviewers also explored what respondents would do in the survey context if they were unsure about the consent form for example if they would look for more information.

11.2.2 Amount of information given in the consent form

Respondents varied in terms of whether they felt the consent form was missing any information. On the whole respondents thought that either the amount of information provided on the consent form was about right or felt it was too wordy. On a rare occasion a respondent had felt that the consent form could provide more information on how the information collected in the survey would be used in research. This respondent was very clear in her mind that the consent form was asking for her permission to use her survey answers only (so had not understood it was asking for permission to link her data).

Respondents who felt the information was about right commented that all the information was relevant, that the bullet points answered questions that they had in their mind or that they did not need any extra information. Within this group were respondents who understood that they were being asked permission to link their data as well as respondents who were very clear in their mind that the consent form was asking permission to use their survey answers only (an incorrect understanding). There was one respondent who after reading the consent form three times at this point of the interview concluded that he now realised that irrespective of whether he signed the form his data would be used. However, he also thought that by signing the consent form he would be giving permission for his survey answers not to be anonymised and by not signing, his survey answers would remain anonymised (male respondent aged 65 + with no qualifications given the version of the consent form attached to the questionnaire). This shows that despite reading the form multiple times there potentially could be still a group

of survey respondents who do not understand what they are agreeing to when they sign the form and also the implication of not signing. Respondents who sign the consent form may not actually be giving informed consent for data linkage and those who do not may not realise their 1) survey answers may still be used and 2) that they have not agreed to the data linkage request.

There were respondents who thought there was too much information in the form. They felt it was too wordy, needed to be simplified or felt that although there was a lot of information the detail was about right with a clear start, middle and end. Within this group were respondents who understood that they were being asked permission to link their data as well as respondents who understood they were being asked permission to use their survey answers only (an incorrect understanding). It was suggested by some respondents that although all the information was necessary, if it could be condensed further this would be helpful as people may not read the consent form properly. When respondents highlighted areas that could be taken out or were irrelevant it was in reference to bullet point 2 “there is another way you can help us....” which was felt to be superfluous or the website link because the respondent did not use the internet.

Interviewers explored with respondents what they would do in the actual survey context if they were unsure about anything in the form. Respondents felt they would:

- refer to the leaflet; or,
- use the website; or,
- phone the number on the consent form.

The website was considered a source of information as well as a tool to verify the survey was bona fide as it was felt that any one could produce a leaflet.

11.3 Impact on response rates

Interviewers explored with respondents whether the consent form would negatively affect response rates. On the whole respondents did not feel that seeing a form like this would make them less likely to return their WHS questionnaire. However as discussed above most respondents did not understand the purpose of the consent form and this should be borne in mind before drawing conclusions about the impact on the WHS response. There was one occasion in testing when a respondent did feel it could affect whether she returned the form. This respondent had correctly understood what the purpose of the consent form was and she felt that it may make her less likely to complete and return the survey.

As noted above although in testing generally respondents have felt that the consent form would not negatively impact them returning their WHS, there is slight evidence that in the main survey this may not be the case if they have understood the purpose of the consent

form. Within the group who said it would not negatively influence them returning the WHS questionnaire, there were respondents who retained their understanding that it was solely asking their permission to use their survey answers only. In addition there were rare occasions when a respondent now was wondering if the consent form was seeking their permission to publish their data or take part in future WHS surveys.

11.3.1 Process for returning the form

Before the section ‘Your consent’ on the consent form there is an instruction in italics about signing and what to do about returning the consent form. Generally respondents did not see the italic instructions in both versions of the consent form, even if they had read all the other bullet points and/or had understood the consent form. This is a concern since the sentence has a dual purpose: 1) to instruct the respondent to complete the section below, i.e. sign their consent and 2) to instruct the respondent around what to do with the form once they have signed it. Respondents had to study the form to see this sentence in italics and an implication of missing this in the cognitive testing was that there was a respondent who understood that the purpose of the consent form was for data linkage wrongly signed it when she did not want to give consent. This is worrying because in the main survey this would be interpreted that consent had been given.

Respondents correctly assumed that the consent form would go in the envelope provided even if they had not read the instruction. There was variation in understanding of whether they should post the consent form (to NatCen offices) or if the interviewer would pick it up with their questionnaire. What respondents should do once they have put it in the envelope should be clearly stated in the instruction.

Respondents generally understood the carbon copy was for them, if they saw there was a carbon copy. For those respondents who received the version of the questionnaire with the consent form on the last page, all thought the questionnaire should remain attached (i.e. they missed the perforation sign).

11.4 Key issues and action points

- There were respondents who retained their misunderstanding of what the consent form is for and felt that if they did not sign the consent form their questionnaires would be destroyed or there was no point returning it. This is problematic as it means that if people do not wish to sign the consent form they may wrongly think that their survey answers will not be used. Therefore it needs to be made clearer in the text that the consent to data linkage is a separate request and respondents can return their questionnaire regardless of whether or not they sign the consent form. To assist this message to be conveyed this could be added to the flow chart too so respondents can also visually see this as a distinct step.
- Currently respondents are signing the consent form without understanding it and are therefore not giving informed consent. The amount of text and looking at three documents (consent form, leaflet and flow chart) could be contributing to poor understanding especially for skim readers who look for key messages. Sub-headings would be useful to break the information down into smaller chunks. This will help skim readers and readers alike to be sign posted through the key messages.
- The leaflet should be clearly referenced on the consent form and respondents should be encouraged to read the leaflet prior to signing.
- It needs to be made clear to respondents that *this is a separate request* from using their WHS survey answers for the WHS main analysis (which is the default outcome of completing the questionnaire) and that taking part in the WHS will result in their data being used irrespective of whether they sign the consent form or not. Consider amending the title to 'Permission to link your data to other health and educational data records' so it is explicitly clear to respondents what the request is about. Consider adding an instruction on the consent form to direct respondents to read the leaflet. This leaflet should be focused just on data linkage only and should be separate from the survey leaflet. Again this will help reiterate the message that this is a separate request.
- We would suggest that the text in italics is not in italics and actually placed as a bullet so it is read as part of the other bullet points.
- Clearly inform respondents whether they should post the consent form back or keep it safely until the interviewer comes to collect it with their self completion forms.
- On the next page we illustrate possible wording amendments to the consent form in red font to help it to perform in the intended way.

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Permission to link your survey answers with other health and educational data records

Please read this form carefully before signing this form.

- The Welsh Government would like to be able to link your survey answers **which you have provided in this survey to other** information that the NHS and other public organisations hold about you (e.g. your GP, hospital, and education records.) **Linking records in this way** will help us get a better picture of the lifestyles and circumstances of people in Wales.

How will my data be linked to other records about me?

- If you agree to this, we will need to send your name, address, sex and date of birth to the NHS in Wales. They will work with a Welsh Government funded research unit at Swansea University to link your survey answers to other information about you.
- Your personal details will be kept completely confidential **at all times**. Once the link has been made between your survey answers and other information about you, your name, address and postcode will be removed so that you cannot be identified. Your survey answers and other information will be used for research purposes only.

Do I have to sign this form and agree to my survey answers being linked?

- No** this is completely voluntary. We do rely on people's voluntary co-operation and hope you will be willing to help as this will help to give an accurate overall picture of the health of people in Wales. You can withdraw consent at any time by contacting us at the address shown in the leaflet provided.

What happens if I don't give my consent?

- If you don't, **that's fine**. Your survey answers **will still be used** for health research *without them* being linked to other information.

Where can I get further information?

- Further information about data linkage can be found on our website www.natcen.ac.uk, in the leaflet provided, by contacting us on 029 2082 6685 **or by talking to your survey interviewer**.
- If you agree for us to link your survey answers to other information as described above please complete the section below and put this consent form in the envelope provided **and your interviewer will collect this**. The copy beneath is for your own records.

Your consent

I agree that NatCen can pass on my name, address, sex and date of birth to the NHS in Wales so that my survey answers can be linked with other information held about me.

Full name: _____
Signature: _____
Date of birth: ____ / ____ / ____ (dd/mm/yyyy)

12 The leaflet

In the context of the cognitive interview, respondents were asked to read through the leaflet. Interviewers then probed on anything which the respondent commented on, and this did not necessarily refer to the text about data linkage. This chapter deals with the information in the WHS leaflet, looking at both information which is and is not related to data linkage.

12.1 General impressions of the survey leaflet

On the whole respondents found the information in the leaflet “*straightforward*” and easy to follow and there were often comments that suggested that the information could not be made any clearer. The way the leaflet is laid out, in a series of question and answer sections, was liked by certain respondents in the sample though there was the odd respondent who said the information presented on pages 4 and 5 was irrelevant and not helpful. This did not cause any problems; it seemed to be a case of preference.

There appeared to be particular pieces of information which stood out to respondents as these were often referred to in probing:

- participation in the WHS was voluntary;
- postcodes are used to identify people, and not names;
- the answers would be treated anonymously;
- confidentiality and the reference to the data protection act;
- even if you did not sign the form, the information would still be useable;
- the information would not be shared with marketing or market research companies.

Respondents were asked in the interview who they believed would have access to their survey responses. Generally, respondents talked about how the National Centre for Social research (NatCen) would have access and occasionally respondents suspected, or assumed, that NatCen would pass their answers to the Welsh Government. There were respondents who also talked about authorised researchers (beyond NatCen and the Welsh Government) having access, through the data archive, and also anyone trying to improve health services.

12.1.1 Data archiving

The cognitive interviewers were asked to explore whether respondents understood the final paragraph on page 7 (boxed below).

Each year, like many other major national surveys, a dataset with information from the Welsh Health Survey is archived with the UK Data Archive so that it can be analysed by registered researchers who have agreed to certain terms and conditions. This anonymised dataset does not contain detailed information about the areas people live in or personal details like name, address, or postcode. (page 7)

There were mixed reactions to this text: some thought it was clear and understood it, whilst others found it unclear.

Those who seemed to understand the general gist of the paragraph talked about how the answers would go into a library somewhere, where this data is kept and updated on a yearly basis. It was apparent that there were some respondents who did not seem to click that the anonymised answers were accessible to others, for example one respondent assumed the data archive to be the place where his and all the other answers to the WHS were kept.

Occasionally, on reading this paragraph, respondents became confused about the data linkage request/process. This confusion either arose because:

- Previously the respondent had assumed that they had understood the data linkage request (and their comments to interviewers had more or less confirmed this) but now they questioned how, if they did not sign the consent form, their answers would still go into a data base.
- The respondent did not understand how we could link the information without the knowledge of who they were or where they lived (possibly confusion added because of reference to postcodes).

12.2 Understanding of text about data linkage

The sections which explicitly refer to the process of data linkage were also seen as straightforward however it was apparent that respondents had not always understood the detail and in some cases, on reading it, they became confused (see below).

The information in the leaflet was described as clear, good for those who would want to read through it all, contained the small details which were not in the consent form, but also as a repetition of what was in the consent form. There were mixed feelings around the necessity of the text, in clarifying or providing more detail on data linkage. Some thought that they would read through everything thoroughly in a 'real life' context, and before deciding to sign or not, whilst others said they would not read it and would use the wording on the consent form alone as this was ample and made them comfortable enough in choosing whether or not to sign.

Those who understood the data linkage request (either fully or more or less so) either said that they found the leaflet helpful in clarifying what would happen (note these respondents did not necessarily need the leaflet text to assist in their understanding of the linkage), or they said that the leaflet did not make any difference and felt they would not need to read it as the consent form was sufficient. Additionally, those who had said they would sign the consent did not change their mind having read closely the detail in the leaflet.

12.3 Understanding of the data linkage process

Whilst difficult to ascertain whether the information in the leaflet added to the understanding of the process, since respondents had already seen the consent form, interviewers asked respondents to explain in their own words what they thought would happen to the questionnaire responses if they signed the consent form, specifically relating to the information in the leaflet. The sample comprised broadly of three groups of respondents. Those who, at this point, either:

1. were able to clearly explain the whole process correctly (i.e. that responses are passed to Swansea University who add the other information to the survey answers);
2. appeared to understand what was going to happen but did not verbalise the process, instead talked more generally or in terms of the outcome:
 - i.e. that by signing the consent form, they would be authorising access to their GP and other record); or,
 - that the answers would be linked to other health or educational information and used for analysis to build a better picture of me; or,
 - that the survey answers would be linked to other information on them but that their name and address would be removed so that they could not be identified.
3. or still assumed that the whole process was asking for consent to use the survey answers only:
 - i.e. they could not understand why there was so much information in the leaflet as it seemed intuitive: *“if one completes the a consent form to provide information to the survey then they are giving their permission for whatever purpose might be considered appropriate”* (Male,65+, degree, separate); or,
 - that your answers could be used by public research if you sign the form.

12.3.1 NHS Wales involvement in the data linkage process

In terms of NHS Wales' (the NHS Informatics Service) involvement in the linkage, there were respondents who did understand why they were necessary (i.e. to make the link possible) and these tended to be people who understood the whole process, either fully or more or less. There were also those who had not understood the data linkage request but still assumed, when probed, that NHS Wales removed names and addresses.

12.3.2 What kinds of information could be held in the SAIL database?

In terms of what sources the survey data could be linked to, the following suggestions were made by both respondents who did and did not understand the data linkage process:

- the city council;
- social services (to retrieve information from someone's childhood);
- purely the NHS: so information about health conditions that people have, conditions being treated for etc;
- schools and educational records;
- only the government.

Others said that they could not think what the answers could be linked to, beyond GP and hospital records. Almost universally respondents mentioned health related data, either exclusively or in combination with other information (i.e. those listed above).

The HIRU website link was noticed by certain respondents in the sample (all ages, with differing levels of education), who said they would, might (out of curiosity) or probably would not visit it, whilst other respondents said they had not noticed it and were not sure what it would contain or they assumed it would list the kinds of things that are researched.

12.3.3 Who would have access to the linked data?

In terms of accessing the linked data, there were respondents who had not understood the data linkage request and therefore unsurprisingly assumed the Welsh Government and/or the National Centre for Social research would be the only organisations to have access to the linked data. Other respondents who did not understand the data linkage request, and assumed that the request was to consent to the survey answers being used only, and thought the following organisations might have access:

- Health researchers;
- The NHS and the government; or,
- Swansea University and the government.

There were also respondents (notably those who did understand the data linkage request, either in full or in part) who assumed access to the linked data would be given to those in government or (registered) researchers who would sign a confidentiality agreement to use it. People interested in health research, or wanting to carry out their own research, were also mentioned.

12.3.4 Understanding of what would happen to the survey answers (even if the consent form was not signed)

The understanding of the usual WHS procedures (i.e. that the survey responses will be archived) depended on whether or not the respondent had understood the data linkage consent request.

Where respondents did understand the data linkage request, they thought that the survey answers would still be usable. One respondent, for example, said the survey responses would *“still go into the pool of information and will help research”* (Female, 65+, degree, received consent form separately). Occasionally respondents said that the answers would still be used even if the consent form was not signed and that:

- their personal details/medical records from their GP, hospital records, and/or educational records would not be accessed.
- they would be used to plan for the health of the future / to provide a picture of Wales;
- the survey answers would be accessible only in an anonymous format and that the name would not be linked to any other information;
- the *“other stuff”* would not happen;
- they (the Welsh Government) would just not be able to use the questionnaire answers in another way
- they (unknown which organisation was being referred to) will not be allowed to share this with other organisations (although the information will still be used).

Of course, as noted already earlier in this report, there were respondents who incorrectly assumed that if they did not sign the consent form their self completion answers would not be used: they would be destroyed; the questionnaires would not be of any use.

Occasionally, on reading the leaflet, respondents who were initially confused on first glance of the documents, still were and said that they now thought that by not signing, the answers could still be used but only by the National Centre for Social Research. Similarly there were respondents who thought in this way but instead that the Welsh Government would have sole access and use of the answers (and they could not pass them onto other researchers and universities).

12.3.5 Ways to clarify the leaflet

Generally there was not a feeling that the leaflet could be made clearer in any way, and respondents on the whole thought the detail here was appropriate, occasionally commenting that none of it should be moved into the consent form. There were however a few points made by respondents in the sample in relation to the leaflet, and having considered the information in it and in the consent form:

- People should be encouraged to read the leaflet before signing the consent form and there should be a direct link to the pages of the leaflet to read;

- The leaflet should list the kinds of people who would have access to the linked data;
- The leaflet should also list the public organisations who hold information about you;
- The section on page 9 (What if I change my mind about my survey answers being linked?) should have a telephone number as well as an address since people may not feel inclined to want to write a letter.

12.4 Key issues and action points

- To avoid any confusion around what happens to the survey responses (archived in an anonymous way, where even postcode level detail is not available), we would strongly advise that all of the text about data linkage is removed from the survey leaflet and put into a separate leaflet which is dedicated towards data linkage and administered separately. The survey leaflet may want to signpost respondents to 'refer to the data linkage leaflet for information about the consent form and the data linkage process' however it should not contain any details about this.
- To avoid confusion around who could, in theory, have access to the linked data, we would recommend that a couple of hypothetical examples are given. So, one example might be an example of someone in government gaining authorisation to look at the association between alcohol consumption and cardiovascular health nationally, whilst the other example might be a PhD university student wanting to explore something at a more local/regional level.
- Since there were two important pieces of information which were conveyed here in the flowcharts, but had not been elsewhere (replacement of personal details with a personal reference number to make the link possible and which organisations get which pieces of information – see below), we would advise that these are spelled out in the data linkage leaflet.

13 The flowcharts

13.1 Key findings

Respondents were shown two versions of the flowcharts (see appendix I and J for versions). The purpose of testing the two versions was to explore two very different ways of presenting visual information. There were respondents who found the flowchart useful in showing the process and also the end result. Respondents occasionally picked up on the removal of the name and address once the link had been done (in version B) but in one case, a respondent pointed out that it is hard to see what is beneath the word 'DELETED'.

Although this is a very small sample, there was an observed preference for version B out of the two (see table below). Comments on version A included that it was too messy, confusing, not useful, chaotic with arrows going all over the place and hard to take the in. There were occasions where initially version A was seen as overwhelming, at first glance, however when they read it in more detail it was described as more informative than version B (suggesting that the visual design detracted from the content). There were respondents who were distracted, within version A, by the survey question "Have you had a flu jab in the last 12 months?" (notably these were older respondents).

Regardless of which version was preferred, it was still quite common for respondents to say they either found the flowchart did not clarify or add anything they had already understood in relation to the data linkage. Occasionally bullet points were mentioned as a better way of getting the flowchart information across in a simplified way. This said and there were respondents who **did** find a flowchart useful in clarifying the process.

There were two extra pieces of information that people were given in the flowchart, seen as useful, which was new to them (i.e. had not been covered elsewhere):

1. the fact personal details are replaced with a personal reference number (both versions); and,
2. who (which organisations) get what information.

13.1.1 Older respondents and flowcharts

There did seem to be an age effect in relation to usefulness of a flowchart. There were respondents in the 65+ quota group (of all education groups) who said they were unfamiliar with flowcharts, said they could not understand them at all, said they were "*muddling*" and could not work out what the boxes or arrows were referring to. This group of respondents also occasionally referred to how they had not been taught with flowcharts at school but that young people might find them usefully or acceptable.

"just to come out with a straight statement rather than this silly business"
(Female, 65+, degree, separate, version B).

“not useful and contributed nothing”
(Male, 65+, other qualification, within, version B)

The older respondents, who were unfamiliar with flowcharts, held mixed views on which version was better: some thought version A was simpler (though could not always say why) whilst others considered version B to be easier to understand.

There was evidence from the cognitive interviews to suggest that the unfamiliarity with flowcharts was not exclusive to the older respondents. One young female said she was *“not good with flowcharts”*, and did not find either version useful (Female, 16-30, other qualification, within, version A).

13.1.2 Flowchart preference

Table 13.1 below summarises the preferences of the respondents in the sample.

Table 13.1 Version preferences expressed by respondents

Version A preference	Version B preference	R characteristics and which version (V) they got first
	<i>“more straightforward”</i>	Female, 31-64, other qualifications, within, VA.
	Clearer though unable to say why (found both confusing)	Female, 65+ no qualifications, within VB.
	No reason given (and did not think either added to the understanding)	Male, 65+, other qualifications, within, VB.
	Easier on the eye (though neither were useful)	Female, 16-30, other qualifications, within, VA
	More obvious than version A	Male, 65+, degree, separate, VB
	Allowed you to read down the page and follow the process	Female, 16-30, other qualifications, separate, VB.
	Easier set out, neater and easier to read. You can use the colours [key code] to work it all out	Female, 16-30, other qualifications, within, VB.
	Clearer and less going on and also shows which organisations are involved. Also clearer that they are putting your WHS answers with other records	Male, 16-30, other qualifications, separate, VA.
	Easier to follow but still confusing	Male, 65+, no qualifications, separate, VB.
Gives the name of someone (i.e. a respondent) and shows how the process works, however likes the way the name and address are shown as DELETED in version B.		Female, 16-30, degree, separate, VA.

Gets across what happens from the start to finish (plus includes the consent form, which version B doesn't) and is less formal		Male, 31-64, other qualifications, within, VA.
A mix of the two		
Version B easier to look at though version A provides a clearer understanding of the process		Female, 31-64, no qualifications, separate, VA.
Neither (no preference)		
Neither useful as flowcharts don't provide anymore information which isn't already elsewhere		Female, 65+, other qualifications, within, VA.
Neither useful as flowcharts as confusing		Female, 65+, degree, separate, VB
Neither flowchart was useful: both confusing. Quite stressful to look at a bunch of boxes and arrows		Male, 65+, no qualifications, within, VB
Neither were helpful and both would take time to work out		Female, 31-64, other qualifications, within, VB.
None were of any help: never seen anything like this before		Male, 65+, no qualifications, separate, VA.
Neither helpful but version B does not look as scary and is good in how it shows the process of replacing your person details with a personal number (most important part of the process)		Male, 31-64, degree, within, VA.

Those who thought the flow char would be useful made the following suggestions:

- have a link to the flowchart on the website;
- have the flowchart on a separate A4 piece of paper with the other documents; and,
- include the flowchart in the leaflet, as A5.

13.2 Key issues and action points

- Whilst there were respondents who found the visual display of the data linkage process useful, there will always be respondents who either do not like information being presented in this way, or do not need it.
- We would advise, however and for those respondents who do find it useful, that a flowchart is included in the supporting documents and that this could come on the final page within the new data linkage explanatory leaflet.
- We would advise that the flowchart takes the form of version B but with some of the detail from within version A also included.

14 Consent form administration

In the final stage of the interview interviewers explained that they were going to show the respondent a different version of the form. They showed the respondent the alternative version to the one the respondent had been sent/shown first. Interviewers explained the difference between the two versions (i.e. one is printed within the questionnaire and one is a separate and has a carbon copy). Interviews then sought to establish which version of the consent form respondents preferred: printed in the questionnaire or separately, on carbon paper.

14.1 Why respondents liked each version

The table below shows the reasons why respondents liked each version. One of the reasons why the within questionnaire version was liked was because it clearly showed the consent form was asking permission to use their survey answers (shown in the grey cell in the table below). This suggests that having the consent form as physically separate from the questionnaire might help respondents to realise that the consent form is asking about something else

Table 14.1: Why respondents liked each version of the consent form

Separate with a carbon copy	Within the questionnaire
<ul style="list-style-type: none">• Good to have a copy even if the respondent would bin/lose the copy	<ul style="list-style-type: none">• Did not want a copy and it saves paper being attached
<ul style="list-style-type: none">• Liked this version because it was physically separate from the questionnaire and so showed it was something different from the questionnaire.	<ul style="list-style-type: none">• Liked this version because it was attached to the questionnaire and so showed a link to the questionnaire i.e. to use survey answers.
<ul style="list-style-type: none">• Felt the text was clearer	<ul style="list-style-type: none">• Used to reading to the end of a document because of exams so preferred this version.
	<ul style="list-style-type: none">• Because it does not suggest something legal which the carbon version does.

14.2 Key issues and action points

- The evidence from different elements of the cognitive interviews suggests that the separate version with the carbon copy has worked better because it was seen. It should be borne in mind that the 'thank you message' on page 21 of the questionnaire may have discouraged respondents to refer to the back page which contained the consent form. Nevertheless, with this note of caution, we would advise that the separate version with a carbon copy is used because it helps to convey the message that this is about a different request and not about using their survey answers per se.
- Consider using the separate version with the carbon copy but consider not printing it on green paper but on another colour so it is visually seen as different from the questionnaire. A possibility would be to print the consent form on yellow paper. The font may also be clearer for readers against a background such as yellow which will assist respondents to read the form. If this decision is implemented, the data linkage leaflet could also be printed on yellow paper, in an A5 booklet or on a crib sheet.

15 Respondents' views post probing

After interviewers had been through all the documents with respondents, respondents were asked again on their views as to whether or not they would sign the consent form, and why this was the case.

15.1 Did respondents change their mind about consent after probing?

By the end of the interview only one respondent had not changed his mind about giving consent. Having previously said that he would give consent he felt, now that he had discussed the documents with the interviewer in more detail that he did not know if he would give consent. The reason for this was that he was now suspicious of the use of his survey answers. Respondents who had declined or did not know at the start of the interview retained this view because they were:

- still concerned about confidentiality and data being passed around;
- happy to be involved in WHS but did not want “*others to get into other stuff*” (Female, aged 16-30 with other education qualification).

The other respondents stated they would still give consent to the data-linkage even when they were more aware of what was involved. Respondents gave the following reasons for consenting:

- knowing everything in the database is confidential/ anonymous/not passed on to commercial organisations; or,
- happy to help any research to do with health or the NHS.

There were respondents who only understood the consent process at the end of the interview when the interviewer took them through it. On understanding universally respondents did not have any concerns about agreeing. This highlights that if the information is easy for respondents to assimilate they can give informed consent and this will not impact the WHS response.

Respondents gave a number of suggestions in addition to what had been already been discussed in the interview in regards to the consent form, leaflet and flow chart and also gave general feedback. These are summarised in table 15.1 below.

Table 15.1: Respondent suggestions and other feedback about all data linkage documents

Consent form	Leaflet	Flow Chart
<ul style="list-style-type: none"> There should be a note on the top of the consent from saying “<i>have you read the information leaflet before signing this form</i>” (Female, aged 16-34, with no formal qualifications). 	<ul style="list-style-type: none"> Liked the Q & A as it was helpful to find an answer for each point 	<ul style="list-style-type: none"> Did not help at all and “<i>reduced the dignity of the questionnaire</i>” (Female, aged 65 or over, with a degree qualification)
<ul style="list-style-type: none"> Make it clearer: <ul style="list-style-type: none"> that is for linking; what the information would be used for. 	<ul style="list-style-type: none"> Wordy but necessary 	<ul style="list-style-type: none"> Should be on the last page of the leaflet.
<ul style="list-style-type: none"> that it is voluntary should be on the consent leaflet 		
<ul style="list-style-type: none"> Make it stand out more e.g. different colour background and larger font 		
<ul style="list-style-type: none"> In the questionnaire there should be a reference to please sign the form. 		
<ul style="list-style-type: none"> Having an on-line version would be easier for the generation used to working with computers and would save paper 		
General Feedback		
<ul style="list-style-type: none"> To provide examples to clearly show how the data linkage can help. 		
<ul style="list-style-type: none"> Stress direct benefits to people to sign, such as better and or more efficient health services. 		
<ul style="list-style-type: none"> Data Protection should be in bold. 		
<ul style="list-style-type: none"> Interviewers should be able to answer any questions respondents may have about giving consent for data linkage. 		

15.2 Key issues and action points

- To assist respondents to give informed consent ensure that interviewers fully understand the data linkage process so they can talk the main householder through it and explain to them the two requests, 1) namely to fill in the questionnaire and 2) to agree to data linkage.
- To help respondents understand that there are two requests consider separating out the material so the message is reiterated. So interviewers should give respondents two piles of documents, 1) the questionnaire and its supporting documentation and 2) the consent form and its supporting documentation.

Appendix A Round 1 and 2 Cognitive Methods

Cognitive interviewing methods, which are derived from cognitive psychology, allow researchers to examine the processes by which people make decisions. This form of testing helps to identify problems with information provided to people and also helps to illuminate possible solutions to these problems.

The two most frequently used cognitive interviewing techniques are think aloud and probing. In this study both techniques were used. In the think aloud technique, respondents are encouraged to say out loud what they are thinking. For this project respondents were encouraged to articulate any thoughts they had about the data linkage documents as they looked through them.

In the probing technique the interviewer asks specific questions or probes which provide information on how respondents interpret wordings and what processes they go through when deciding on a course of action. The probes used are partly pre-scripted and provide a guide to the topics to be covered in the cognitive interview. However, as cognitive interviews are qualitative in nature, interviewers also have the freedom to probe on an issue that may be unique to the respondent and issues that have not been foreseen in advance.

Probing during this testing was carried out retrospectively in both rounds of testing, after respondents had been given the opportunity to look through the documents and decide whether to not to give their consent to data linkage. In addition to collecting information using Think Aloud and probing, interviewers were also instructed in both rounds to collect observational data on when (if at all) respondents referred to the different sources of information i.e. the flowchart and the leaflet.

All the interviewers made detailed notes on each of their cognitive interviews in a structured 'notes-template' document, with reference to the recording of the interview. The notes template is organised by interview stage. All notes contained verbatim references to the original interview recordings. These notes and the recordings of the interviews were reviewed as part of the analysis process.

Notes were analysed using a content analysis or 'Framework,' approach. A separate matrix was set up for each round. Each matrix listed the areas under investigation *across* the page and cases *down* the page. The matrix included a summary of the characteristics of each respondent; such as their sex, age, and educational attainment. Thus data could be read horizontally, as a complete case record for an individual, or

vertically, by area under investigation, looking across all cases. Once the matrix was completed the data were reviewed. In reviewing the matrix the full range of problems with the documents were explored and appropriate recommendations made.

Appendix B Round 1 Leaflet text

What will happen to the information I provide?

Your answers will be treated in the strictest confidence in accordance with the Data Protection Act. Along with the answers of everyone else who takes part, the results will be anonymised and published at a later date. You will not be identifiable from the published results in any way. The information is being collected for statistical purposes only.

Who will have access to the information I provide?

Unless you let us contact you again for future health-related research, or agree to your data being linked, access to your name and address will be restricted to the research team at the National Centre for Social Research and only used for carrying out this study.

We will share your data (the information you provide) and postcode with a limited number of statistical researchers in the Welsh Assembly Government. Your postcode will be used just to assign your information to the area where you live, in order to provide results which represent the people living in your area. These statistical researchers will follow the Code of Practice for Official Statistics.

Other statistical researchers, for example from NHS organisations and Universities, sometimes ask us to share detailed but anonymised data from the study for their research in health matters. If we agree to share data with an organisation it is on condition they sign a confidentiality agreement prohibiting them from passing the information on to anyone else.

Each year, a Welsh Health Survey dataset with information from the survey is archived so that it can be analysed further by registered researchers. This anonymised dataset does not contain personal details, like name, address or postcode and detailed information about the areas people live in are also not available in the archived anonymised dataset.

What will happen to my data if I give my consent on the consent form?

If you agree, your full name and date of birth, along with your address, will be sent to the NHS Wales Informatics Service. They will replace your personal details with a unique anonymous number and give this number to Health Information Research Unit for Wales (HIRU).

HIRU will then be able to use this number to link your responses to the survey with other datasets that they hold, without being able to see any of your personal details. This increases the value of the information you have given as further research can be conducted into the lifestyles, circumstances and health of people in Wales.

HIRU holds a wide range of datasets. These are mostly health-related administrative data sets from GP practices and hospitals. They also include administrative and survey datasets collected by publicly funded organisations on other social and lifestyle topics.

Your information will be treated in the strictest confidence and will be used for research only and no data which can identify you will be released. To get access to the data, authorised researchers must meet strict confidentiality rules.

More information about the databases held by HIRU and on the process of linking your survey data to other data can be found on NatCen's website:

www.natcen.ac.uk

What should I do if I change my mind about linking my survey responses?

If you change your mind about allowing your survey responses to be linked with other data, then you can withdraw your consent at anytime by writing, quoting your name, address and date of birth, to:

National Centre for Social Research,
Kings House, 101-135,
Kings Road,
Brentwood,
Essex CM14 4LX.

Appendix C Round 1 Interviewer protocol

Testing Welsh Health Survey Data Linkage Consents

The Main Objectives for the interview

- To examine whether respondents understand the data linkage consent forms
- To examine which version the consent form is most appropriate to use: A one signature version, or a two signature version.
- To explore respondent's reaction to the consent forms i.e. and whether they would consent to data linkage and, if not, whether the request would influence whether or not they returned the WHS questionnaire.
- To explore whether respondents find the data linkage flowchart useful in terms of understanding the data linkage process.
- To explore whether respondents read and understand the information on data linkage provided in the WHS respondent leaflet.
- To get general feedback on what, if anything, could be done to encourage respondents to give their consent to data-linkage

Stage One: Introduction

- Introduce **yourself, the National Centre, and the study**
- The National Centre for Social Research carries out a survey called the Welsh Health Survey (WHS) on behalf of the Welsh Assembly Government.
- Explain they have been approached to take part in this study as they took part in the Welsh Health Survey in 2009 and kindly agreed we could contact them again in relation to future projects.
- Explain that this year we will be making some changes to the WHS. Before we roll out these changes we would like to test them on a small number of people to see what they think of them.
- Explain that you will be asking them to look over the questionnaire to remind themselves about the sort of questions that are asked in the Welsh Health Survey. They do not have to fill the questionnaire in.
- Explain you will then be asking them to look at some new survey documents and then asking them to give their views on them. These new documents are a **consent form** and an **information leaflet** about the consent form.
- Explain we are interested in whether they understand the form and whether or not they would fill it in. Stress there are no right or wrong answers and this **isn't a test**. If they have any issues with the form it is likely that other people will too and this will need to be looked at before the questionnaire is sent to thousands of people.
- Stress the confidentiality of the process; all the findings will be reported anonymously. The respondent's name will not be on any of the notes you write up. Everything they say will be used to help us improve our documents in the future.
- Remind them that the interview will last up to one hour.
- Explain that you will be recording the interview so that you don't have to make lots of notes. Check this is OK with the respondent. If they ask who will have access to the recording, tell them that only the small research team at NatCen

and yourself will, and that recordings are stored securely i.e. they are password protected.

- Ask whether they have any questions before you start.

Stage Two: Setting the Scene and placing the questionnaire

Aim: To set the context of the WHS survey and collect observations of how respondents react to the questionnaire prior to probing.

- Spend a few minutes discussing with the respondent whether they remember taking part in the WHS before (in 2009), and what they remember about it.
- Describe what taking part in the WHS involves:
 - Their household would have been sent a letter saying they had been randomly selected to take part in the Welsh Health Survey.
 - An interviewer would have come along and asked someone in the household a few questions about the people who live in the house.
 - The interviewer would have left paper questionnaires for all the adults in the house to complete and, if there are children in the household, left questionnaires for children and measured their height and weight. The questionnaires would come with an information leaflet.
 - A few days later the interviewer would have come back to pick up the paper questionnaires.
- Explain you would like respondents to imagine they have just received the questionnaire in this way and completed it by themselves...
- **Give the respondent the following documents:**
 - WHS questionnaire (which contains the consent form at the back)
 - WHS information leaflet
 - Respondent copy of the consent form
- Ask respondents to briefly read through the questionnaire to remind them what sort of questions it contains. They do not need to fill the questionnaire in for the cognitive testing. If respondents also look through the other documents (such as the consent form copy and leaflet), this is ok and let them do so. *Give respondents a few minutes to look through the documents.*

OBSERVATIONS 1

Do they look at their copy of the consent form?

1. Yes
2. No

Do they look at the flowchart?

1. Yes
2. No

Do they look at the information leaflet?

1. Yes
2. No

Did respondents comment on anything related to the consent form prior to probing? If so what?

WRITE IN BELOW:

Stage Three: Consent Form 1

Aims

- **To examine respondents' initial reactions to the consent forms...***Do they read it? Do they ask questions or look for further information?*
- **To explore whether respondents would sign the form or not, and why this is the case.**
- **To explore whether respondents understand the data linkage consent forms.**
 - *Do they understand the process sufficiently to be able to give informed consent?*
 - *Do they feel any information is missing from the consent form?*

- Explain to respondents you are now going to ask them to look at a specific document.
- Encourage respondents to say what they think of the document **out loud** as they look over it.
- Tell them to take as much time as they like reading the document- *whatever they would do if you were not there and they were looking at the document by themselves after filling in the questionnaire.* After they have finished you will ask them some questions.
- Ask respondents to turn to p22 of the questionnaire where the consent form is... Please note down any observations you make below.

OBSERVATIONS

Does respondent appear to read the whole consent form?

1. Yes
2. No
3. Unsure

Do they look at their copy of the consent form?

1. Yes
2. No

Do they look at the flowchart?

1. Yes
2. No

Do they look at the information leaflet?

1. Yes
2. No

Did the respondent ask you any questions? If so what?

WRITE IN BELOW:

Did respondents comment on anything in the form prior to probing?

WRITE IN BELOW:

Q1 Form Outcome

READ OUT: Imagine you had just completed this questionnaire, would you sign this consent form?

- 1) Yes
- 2) No
- 3) Don't Know

PROBES

Form outcome:

- Why would you sign the form/ not sign the form? Why are you unsure whether you would sign it or not? *In Version 2 explore whether respondents would sign against both sections, one section or neither section.*

Sensitivities and response

- How would you feel about being asked to sign a consent form like this? Why?
- *Explore any initial concerns the respondent might have about signing the form and why these occurred.*
- Would seeing a form like this influence whether or not you returned your WHS questionnaire? Why?

Comprehension

- In your own words what do you think this form is asking for?
- VERSION 1: In your own words what do you think would happen if you signed this form?
- VERSION 2: In your own words what do you think would happen if you signed the first section? And what would happen if you signed the second section?
- In your own words what do you think would happen if you didn't sign this form?
- How clear is the information that is provided on the consent form? Could anything be made clearer? If so what?
- *Explore if specific words or phrases should be changed – i.e. suggestions for ways to make the form clearer or make them more likely to feel comfortable about giving consent.*

Too much or too little (i.e. missing) information

- Would you say that all of the information in the form is necessary? Does it feel too wordy or is the level of detail, and the explanations given, about right?
- Is there any information that you didn't read, or didn't take in, that could be taken out (i.e. because it doesn't really add to the form)
- Are there any areas you would like more information about? If so which areas? *Explore what respondents would do in the survey context if they were unsure about the form. Would they look for more information? If so from where/whom? Would they explore a website link, or rely on the information provided in the consent form or leaflets?*
- How would they feel about NOT giving consent? Would they be happy to return their questionnaire if they did NOT give consent?

Stage Four: Consent Form 2

Aims:

- **To establish which version the consent form respondents prefer: A one signature version, or a two signature version.**

→ Explain you are now going to show the respondent a different version of the form. Hand over the alternative version and ask them to read it.

PROBES

- In your own words what do you think this consent form? How is it different to the first consent form I showed you?

Prompt if necessary:

- What is the form asking you to consent? What is the other form asking you to consent to?
- Why do you think this form separates out the signatures? Can you think of situations where someone might want to sign one part but not the other?
EXPLORE THIS
- Which form would you be more likely to sign? Why? *In Version 2 explore whether respondents would sign against sections, one section or neither section.*

Stage Five: Respondent copy of consents and the flowchart

Aims

- **To explore whether respondents know what the copy of the consent form is for**
- *Would they keep their copy of the document?*
- *Would they find having their own copy reassuring or off-putting?*
- **To explore whether respondents find the data linkage flowchart useful or not in terms of understanding the data linkage process.**
- *Should this flowchart be included?*
- *If so could it be improved in anyway?*

- Explain you are now going to talk about the respondent about the insert that comes with the questionnaire (the copy of the consents and the flowchart).
- Ensure respondents have the correct document in front of them.

PROBES

- Did you look at this sheet when deciding whether or not to give consent? Why? *Check whether respondents saw the information on the front and the back.*
- Was this sheet helpful or not? Why? How could it be improved?

Copy of consents

- What do you think this document is for?
- *Explore whether respondents feel having their own copy of the consent form is important or not. Would they keep hold of this form after the survey?*

Flowchart

- Did you use this flowchart when deciding whether or not to sign the consent form? Why?/ Why not? How useful do you find this flowchart in helping you understand the data linkage process? Why? Could it be made clearer? How?
- In you own words what is this document trying to illustrate? *Explore whether respondents can talk you through each stage of the flowchart.*
- Should a flowchart be provided at all? *Explore whether respondents found the flowchart useful or off-putting.*

Stage Six: Information Leaflet

Aims:

- **To establish whether respondents would read the information leaflet**
- **To explore whether respondents understand the material provided in the leaflet.**
- **To establish whether the leaflet is useful in addressing any concerns they may have.**

- Explain you are now going to talk about the respondent about the information leaflet that comes with the questionnaire.
- Ensure respondents have the information leaflet in front of them turned to page 6-8. Give respondents time to read through the appropriate section before probing.

PROBES

- Did you look at this section of the leaflet when deciding whether or not to give consent? Why?/ Why not?
- How clear is the information on data linkage that is provided in the leaflet? Could anything be made clearer? *Explore if specific words or phrases should be changed.*
- Are there any areas you would like more information on? If so which areas? *Explore what respondents would do in the survey context if they were unsure about the form. Would they look for more information using the web-link provided?*
- *If would look on the web:* What would you expect to find on a website that isn't on the leaflet/consent form and other documents?

General understanding of the information in the leaflet

- Can you explain to me, in your own words, what you think would happen to your survey data irrespective of whether you chose to consent to your survey data being linked?
- Who do you think has access to what?
- Did you notice that 1) the Welsh Assembly Government has access to postcodes to assign information to areas, and 2) that other researcher may have access to anonymous data?
- Did you notice the reference to codes of practice such as confidentiality agreements?

Stage Seven: Overview and Summary

Aims:

- To check whether, after discussions, respondents would consent to the data linkage. To explore how outstanding concerns might be addressed.
- To get general feedback on how consents to data linkage could be improved
- To explore whether respondents have fully understood the consequences of giving consent (i.e. that their survey data could be linked to datasets HIRU acquire in the future)

- Tell respondents you are now going to ask them to sum up their feelings about the data consent process.
- Explain that at this point you can try to answer any questions they might have about the data linkage process and how it would work.

Q2 Form Outcome 2

READ OUT: After all the discussions we have just had would you sign this consent form if you were to complete the WHS questionnaire again?

- 1) Yes
- 2) No
- 3) Don't Know

Did the respondent ask you any further questions? If so what do they ask?
WRITE IN BELOW:

PROBES

Q2: Form outcome 2:

If R said Yes:

- Can you talk me through why you would sign the form
- Would anything in the documents I have shown you today need to change to make you feel that you definitely would sign the form, or are they ok as they are?

If R said No:

- Can you talk me through why you would (still) not sign the form?
- What concerns do you still have, and how could these be overcome?
- INTERVIEWER EXPLORE: whether R would not consent because of one sole reason (i.e. not wanting to allow anyone to access their anonymous survey answers) or more than one reason (i.e. because there are too many parties involved in the linkage process and because they don't like the idea of people having access to their answers).

If R said Don't know

- Can you talk me through why you don't know whether you would sign the form?
- What are you unsure about, if anything?
- What concerns do you still have, and how could these be overcome?
- If we were to make changes to the documents I have shown you today, do you think you would sign the form?

Q3 Future dataset linkage

READ OUT: If you were to give consent to your survey answers being linked to datasets held by HIRU's, it is likely that more datasets would be added to HIRU's database in the future. Therefore consenting to your survey data being linked now would not only cover current data held by HIRU, but also future datasets that they may well add.

Has this possibility been made clear to you in any of the information you have seen today?

1. Yes
2. No
3. Don't know

PROBES

Q3: Future dataset linkage:

- How would you feel about the idea of not only consenting to links to current datasets held by HIRU but also to links with future, and unknown, datasets?
- Can you suggest any ways in which the consent form and materials could make this clearer?

General feedback

- What information, if any, would you add to make the data linkage request clearer?
*Review all the documents and explain outstanding queries to the respondent.
Explore if overall approach should be altered and if so, in what way?*
- *Explore where this information should be added i.e. should it be on the consent form itself, the flowchart, the information leaflet or elsewhere?*
- What could be done, if anything, to encourage people who take part in the WHS to consent to the data linkage?
- Do you have any other ideas on how the WHS could be improved for the people who take part in it?

End of interview:

THANK YOUR RESPONDENT

ANSWER ANY QUESTIONS THEY MAY HAVE AND REASSURE CONFIDENTIALITY.

Remember to give the £20 High Street Voucher and thank you leaflet

Appendix D: Consent Forms Round one

V1



SERIAL NUMBER
(interviewer write in):

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Welsh Health Survey Linking your answers to other data sources for research purposes Consent form

- Thank you for the information you have provided in the questionnaire about your health.
- The Health Information Research Unit for Wales (HIRU) holds a number of datasets that are stored in such a way that information about individuals cannot be identified. The datasets held by HIRU are mostly health-related administrative datasets from GP practices and hospitals but they also include administrative and survey datasets collected by publicly funded organisations on other social and lifestyle topics e.g. education.
- With your permission, we would like to link your survey answers to health and other social and lifestyle data held by HIRU so that further research can be carried out about the lifestyles, circumstances and health of the people of Wales. Giving your permission is entirely voluntary and we will not link your survey answers to other information without your consent.
- To link your survey answers we need to send your name, address, sex and date of birth to the NHS Wales Informatics Service so that they can make the link possible. NHS Wales Informatics would not be given your survey answers, but provide a personal identification number for each person so that HIRU can link the data belonging to an individual without knowing who that person is.
- Your information will be treated in the strictest confidence. The data created by linking your survey answers and the information already held by HIRU data will not include personal details that could be used to identify you and will be used for research purposes only. If they want access to the linked data, authorised researchers must follow strict confidentiality rules.
- For more information about how the linking is done and how your confidentiality is protected, please see the flowchart on the back of the copy of this form, for your records, included with this questionnaire.
- You can cancel your permission at any time by writing to us at the address below quoting your name, address and date of birth:
National Centre for Social Research, Kings House, 101-135, Kings Road, Brentwood, Essex CM14 4LX.
- Further information about linking your survey answers to other sources can be found on our website (www.natcen.ac.uk) or in the leaflet provided.

A copy of this form is included with the questionnaire for your records.

Your consent

By giving my full name and date of birth, I agree to NatCen passing my details to the NHS Wales Informatics Service so that my survey answers can be linked with data held by the Health Information Research Unit for Wales (HIRU) for research purposes.

Full name including Surname (e.g. Janet Mary Jones): _____

Signature: _____

Date of birth: / / (dd/mm/yyyy)

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Welsh Health Survey
Linking your answers to other data sources for research
purposes
Consent form

- Thank you for the information you have provided in the questionnaire about your health.
- The Health Information Research Unit for Wales (HIRU) holds a number of datasets that are stored in such a way that information about individuals cannot be identified. The datasets held by HIRU are mostly health-related administrative datasets from GP practices and hospitals but they also include administrative and survey datasets collected by publicly funded organisations on other social and lifestyle topics e.g. education.
- With your permission, we would like to link your survey answers to health and other social and lifestyle data held by HIRU so that further research can be carried out about the lifestyles, circumstances and health of the people of Wales. Giving your permission is entirely voluntary and we will not link your survey answers to other information without your consent.
- To link your survey answers we need to send your name, address, sex and date of birth to the NHS Wales Informatics Service so that they can make the link possible. NHS Wales Informatics would not be given your survey answers, but provide a personal identification number for each person so that HIRU can link the data belonging to an individual without knowing who that person is.
- Your information will be treated in the strictest confidence. The data created by linking your survey answers and the information already held by HIRU data will not include personal details that could be used to identify you and will be used for research purposes only. If they want access to the linked data, authorised researchers must follow strict confidentiality rules.
- For more information about how the linking is done and how your confidentiality is protected, please see the flowchart on the back of the copy of this form, for your records, included with this questionnaire.
- You can cancel your permission at any time by writing to us at the address below quoting your name, address and date of birth:
National Centre for Social Research, Kings House, 101-135, Kings Road, Brentwood, Essex CM14 4LX.
- Further information about linking your survey answers to other sources can be found on our website (www.natcen.ac.uk) or in the leaflet provided.

A copy of this form is included with the questionnaire for your records.

By giving my full name and date of birth, I agree to NatCen passing my details to the NHS Wales Informatics Service so that my survey answers can be linked with health data held by the Health Information Research Unit for Wales (HIRU) for research purposes.

Your consent

Full name including Surname (e.g. Janet Mary Jones): _____

Signature: _____

Date of birth: / /

(dd/mm/yyyy)

Appendix E Round 2: Probe sheet

P3028 Round Two Testing Welsh Health Survey Data Linkage Consents	
The Main Objectives for the interview	
<ul style="list-style-type: none"> To explore respondent's reaction to the consent forms and whether they would consent to data linkage. 	
<ul style="list-style-type: none"> To examine whether respondents understand the data linkage consent form: <ul style="list-style-type: none"> → <i>Do they understand we are asking for their permission to link their survey answers to other sources of information held on them?</i> → <i>Do they understand by doing this they are agreeing for their personal details (name, address etc.) to be sent to NHS Wales?</i> → <i>Do they understand the consent form represents a separate request i.e. their WHS survey answers can still be used if they don't sign the consent form?</i> To examine whether or not the consent form would influence whether or not they returned the WHS questionnaire. To explore whether respondents understand the information on data linkage provided in the WHS respondent leaflet. To explore respondents' initial reactions to the flowchart, whether they would be likely to read it as part of the standard survey, and if so whether it is likely to be understood correctly and if so which flowchart they prefer. To examine which version the consent form is most appropriate to use: One within the WHS Questionnaire or a separate one with a carbon copy To get general feedback on what, if anything, could be done to make the documents clearer 	

Stage One: Introduction

- Introduce **yourself, the National Centre, and the study**
- Explain that the National Centre for Social Research carries out a survey called the Welsh Health Survey (WHS) on behalf of the Welsh Assembly Government.
- Explain they have been approached to take part in this study as they took part in the Welsh Health Survey in 2009 and kindly agreed we could contact them again in relation to future projects.
- Explain that this year we will be making some changes to the WHS. Before we roll out these changes we would like to test them on a small number of people to see what they think of them.
- Explain we are interested in whether they understand the documents. Stress there are no right or wrong answers and this **isn't a test**. If they have any issues it is likely that other people will too and this will need to be looked at before the questionnaire is sent to thousands of people.
- Stress the confidentiality of the process; all the findings will be reported anonymously. The respondent's name will not be on any of the notes you write up. Everything they say will be used to help us improve our documents in the future.
- Remind them that the interview will last up to one hour.
- Explain that you will be recording the interview so that you don't have to make lots of notes. Check this is OK with the respondent. If they ask who will have access to the recording, tell them that only the small research team at NatCen and yourself will, and that recordings are stored securely i.e. they are password protected.

- Ask whether they have any questions before you start.

Stage Two: Setting the Scene and checking documents have been read

Aim: To set the context of the WHS survey and to ascertain whether respondents have read through the documents prior to your arrival.

- Spend a few minutes discussing with the respondent whether they remember taking part in the WHS before (in 2009), and what they remember about it.
- Describe what taking part in the WHS involves:
 - Their household would have been sent a letter saying they had been randomly selected to take part in the Welsh Health Survey.
 - An interviewer would have come along and asked someone in the household a few questions about the people who live in the house.
 - The interviewer would have left paper questionnaires for all the adults in the house to complete. The questionnaires would come with an information leaflet.
 - A few days later the interviewer would have come back to pick up the paper questionnaires.
- Explain you would like respondents to imagine they received the questionnaire in this way and have completed it.
- Explain you will then be asking for their views on some new survey documents. These new documents are a **consent form** and an **information leaflet**.

CHECK 1

READ OUT: Did you receive a copy of the documents we are going to look at today and did you had time to read them before I arrived?

- Yes → Go to CHECK 2 overleaf
 - No → Go though points below.
- **Give the respondent the WHS questionnaire, consent form⁶ and information leaflet.**
- Ask respondents to briefly read through the questionnaire to remind them what sort of questions it contains. They do not need to fill the questionnaire in for the cognitive testing. Then ask respondents to spend a few moments looking through the other documents: whatever they would do if you were not there and they had received the documents as a respondent to the survey.
- Do not answer any questions respondents have a about the consent form/ leaflet at this stage. Make a note of any comments they have below then go to **Stage three overleaf**.

OBSERVATIONS 1: Did respondents comment on anything related to the consent form or leaflet prior to probing? If so what? WRITE IN BELOW:

⁶ The consent form will either be printed inside the questionnaire or be a separate copy attached to the back. Please give respondent the correct version depending on what is on your sample sheet.

CHECK 2

READ OUT: Would you like to read through any of the documents again before we start?

1. Yes → Go though point below.
 2. No → **Continue to Stage three**
- Allow respondents to briefly read through the documents again. Do not answer any questions respondents have about the consent form/ leaflet at this stage. Make a note of any comments they have below

OBSERVATIONS 2

Did respondents comment on anything related to the consent form or leaflet prior to probing? If so what? WRITE IN BELOW:

Stage three: Consent Form

Aims

- **To explore whether respondents would sign the form and why this is the case.**
- **To explore whether respondents understand the data linkage consent forms.**
- *Do they understand we are asking for their permission to link their survey answers to other sources of information held on them?*
- *Do they understand why this would be helpful, and to who?*
- *Do they understand the process involves passing on their personal details (name, address, DOB) to NHS Wales?*
- *Do they understand that the consent form represents a separate request i.e. their WHS survey answers can still be used if they don't sign the consent form?*
- *Do they understand the request is voluntary?*
- *What do they understand by the sentence "Your survey answers and other information will be used for research purposes only"?*
- **To examine whether the consent form would influence whether or not they returned the WHS questionnaire.**

- Explain to respondents you are now going to ask them to look at a specific document.
- Show respondents the consent form.

READ 1

READ OUT: Did you read this form when going through the documents?

- 1) Yes
- 2) No
 - If necessary tell them to take as much time as they like reading (or re-reading) the consent form. Encourage respondents to say what they think of the document **out loud** as they look over it.

Form Outcome 1

READ OUT: If you had filled in the questionnaire, would you sign this consent form?

- 1) Yes
- 2) No
- 3) Don't Know

PROBES

Please do not explain the form to respondents at this stage.

Form outcome:

- Why would you sign the form/ not sign the form? Why are you unsure whether you would sign it or not?

Sensitivities

- How would you feel about being asked to sign a consent form like this? Why?
- *Explore any initial concerns the respondent might have about signing the form, why these occurred and whether what would make respondents feel comfortable about giving consent.*

Comprehension

- In your own words what do you think this form is asking your permission for?
- Why do you think the Welsh Government want to do this?
- What do you think would happen if you signed this form?
- What do you think would happen if you did not sign this form?
- What do you understand by the sentence "Your survey answers and other information will be used for research purposes only"?
- How clear is the information that is provided on the consent form? Could anything be made clearer? If so what?

Too much or too little (i.e. missing) information

- Would you say that all of the information in the form is necessary? Does it feel too wordy or is the level of detail, and the explanations given, about right?
- Is there any information that you didn't read, or didn't take in, that could be taken out (i.e. because it doesn't really add to the form)?
- Are there any areas you would like more information about? If so which areas?
Explore what respondents would do in the survey context if they were unsure about the form. Would they look for more information? If so from where/whom?

Impact on WHS response

- Would seeing a form like this influence whether or not you returned your WHS questionnaire? Why?
- What would you do with the form if you decided to sign it? *Explore whether it is clear how respondents should return the form.*

Stage Four: Information Leaflet

Aims:

- **To establish whether respondents used the information leaflet when deciding on whether to give consent**
- **To explore whether respondents understand the material provided in the leaflet.**

- Do respondents understand *who* will have access to *what* if they don't sign the consent form
- Do respondents understand *who* will have access to *what* if they do sign the consent form?
- **To explore whether respondents think any information in the leaflet should be made more explicit on the consent form.**
- **To explore whether respondents feel any information is missing from both the leaflet and the consent form**

- Explain you are now going to talk about part of the information leaflet that comes with the questionnaire.
- Ensure respondents have the information leaflet in front of them turned to page 7-10

READ 2

READ OUT: Did you read this part of the leaflet when going through the documents?

- 1) Yes
- 2) No

- If necessary tell them to take as much time as they like reading (or re-reading) the relevant section (page 4, and pages 7-10). Encourage respondents to say what they think **out loud** as they look over the leaflet.

PROBES

First impressions

- Did you use the information in the leaflet when deciding whether or not to give consent? Why?/ Why not?
- How clear is the information provided in the leaflet? Could anything be made clearer?

Understanding of what happens to WHS survey answers

*Information on this is included on **pages 4 and 7**.*

- Can you explain to me, again, what you think would happen to your questionnaire answers if you do not sign the consent form? *Check whether or not respondents understand that signing the form is voluntary and why they think this..*
- **Who** do you think will have access to your questionnaire answers?
- **What** information will people have access to?
- *Explore whether or not respondents understand that their answers are kept anonymous.*
- *Explore whether respondents understand the final paragraph on p7 about the UK data archive.*

If the respondent does not seem to understand ask them to read these pages 4 and 7 and then probe again. If the respondent still does not understand explain what will happen to their WHS answers and ask how the leaflet could be made clearer.

Understanding of data linkage

*Information on this is included on **pages 8, 9 and 10**.*

- Can you explain to me, what you think would happen to your questionnaire answers if you sign the consent form?

- What will happen to your **name** and **address** details?
- What types of information do you think your survey answers could be linked to? Could you give me some examples?
 - *Explore what respondents understand by records held by 'other public organisations.'*
 - *Explore whether respondents noticed the link to the HIRU website, and whether they would use it.*
- **Who** do you think will have access to the linked information? *Explore whether or not respondents understand that their answers are kept anonymous.*

If the respondent does not seem to understand ask them to read these pages and then probe again. If respondent still does not understand explain what will happen and ask how the leaflet could be made clearer.

Impressions after probing

- Now we have discussed the leaflet in more detail, how clear is the information provided in it? Could anything be made clearer?
- Is there any information you would like added to the leaflet?
- Is there any information on the leaflet that should be on the consent form itself? If so what?

Stage Five: Flowcharts

Aims:

- **To establish whether respondents would read a flowchart if they received one in the survey context.**
- **To explore whether respondents understand the flowcharts correctly.** Do the flowcharts make it easier or harder to understand what data linking is?
- **To establish whether respondents would they prefer to have a flowchart or not.** If they would like to have a flowchart, which version of the flowchart is preferred?

- Explain to respondents we are considering adding a flowchart to the information leaflet to help explain what happens if they agree for their questionnaire answers to be linked to other records held on them.
- Explain we have two different flowcharts we might use.
- Show the respondent the flowcharts *one at a time*. Please rotate the order in which you show the flowcharts between interviews, so respondents differ in terms of which flowchart they see first.

Reactions to the first flowchart

- In your own words what is this document trying to illustrate? *Explore whether respondents can talk you through each stage of the flowchart.*
- How useful do you find this flowchart in helping you understand what would happen if you signed the consent form? Why? Could it be made clearer? How?

Reactions to the second flowchart

- In your own words what is this document trying to illustrate? *Explore whether respondents can talk you through each stage of the flowchart.*
- How useful do you find this flowchart in helping you understand what would happen if you signed the consent form? Why? Could it be made clearer? How?

Reactions as both flowcharts

- Which flowchart did you find most useful in explaining what would happen if you signed the consent form? Why?
- Did the flowcharts help to clarify anything that wasn't clear before? If so what?
- Should a flowchart be provided at all? *Explore whether respondents found the flowchart useful or off-putting.*
- Would you read a flowchart if it was provided? Why?/Why not?
- *If the respondent thinks it would be helpful explore where the flow chart should be placed: in the leaflet, on a separate sheet, on a website with a link to it from somewhere?*

Stage Six: Consent Form administration

Aims:

- **To establish which version the consent form respondents prefer: Printed in the questionnaire or on carbon paper.**

Form placement

- How easy or difficult was it for you to find the form, when you were first given the pack?
- *Do any respondents initially not see the form when it is printed in the back of the questionnaire?*
- *Do any respondents misplace the form when it is paper clipped on as a separate document?*

- Explain you are now going to show the respondent a different version of the form. Hand over the alternative version and explain the difference between the two (i.e. one is printed in the back of the questionnaire and one is a separate form with a carbon copy).

PROBES

- Which type of form do you think would be better? Why?
- Would you like a carbon copy of this form if you had signed it? Why/ Why not?
Explore whether respondents feel having their own copy of the consent form is reassuring or off-putting.
- *Explore whether respondents would keep their copy after the survey.*
- *Explore whether having the consent form printed separately influenced whether or not respondents saw it as a separate request.*

Stage Seven: Overview and Summary

Aims:

- **To check whether, after discussions, respondents would consent to the data linkage. To explore how outstanding concerns might be addressed.**
- **To get general feedback on how consents to data linkage could be improved**

→ **Tell respondents you are now going to ask them to sum up their feelings about the data consent process.**

Form Outcome 2

READ OUT: After all the discussions we have just had would you sign this consent form if you were to complete the WHS questionnaire again?

- 1) Yes
- 2) No
- 3) Don't Know

PROBES

Form outcome 2:

If R said Yes:

- Can you talk me through why you would sign the form?

If R said No:

- Can you talk me through why you would not sign the form?
- What concerns do you still have, and how could these be overcome?
- *Explore whether respondent would not consent because of one sole reason (i.e. not wanting to allow anyone to access their anonymous survey answers) or more than one reason (i.e. because there are too many parties involved in the linkage process and because they don't like the idea of people having access to their answers).*

If R said don't know

- Can you talk me through why you are unsure about whether you would sign the form?
- What are you unsure about, if anything?
- What concerns do you still have, and how could these be overcome?
- If we were to make changes to the documents I have shown you today, do you think you would sign the form?

General feedback

- What information, if any, would you add to make the request clearer? *Review all the documents and explain outstanding queries to the respondent Explore where this information should be added i.e. should it be on the consent form, the information leaflet or elsewhere?*
- What could be done, if anything, to encourage people who take part in the WHS to sign the consent form?
- Do you have any other ideas on how the WHS could be improved for the people who take part in it?

End of interview:

THANK YOUR RESPONDENT

ANSWER ANY QUESTIONS THEY MAY HAVE AND REASSURE CONFIDENTIALITY.

Remember to give the £20 High Street Voucher and thank you leaflet

Appendix F Round 2 Consent form (Carbon copy)



SERIAL NUMBER
(interviewer write
in):

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Making your survey answers even more valuable

- Thank you for taking part in the Welsh Health Survey. Your answers will be very valuable to help plan health services and look at ways of improving people's health.
- There is another way you can help us that would make your survey answers even more valuable.
- The Welsh Government would like to be able to link your survey answers to information that the NHS and other public organisations hold about you (e.g. your GP, hospital, and education records.) Linking records in this way will help us get a better picture of the lifestyles and circumstances of people in Wales.
- If you agree to help, we will need to send your name, address, sex and date of birth to the NHS in Wales. They will work with a Welsh Government funded research unit at Swansea University to link your survey answers to other information about you.
- Your personal details will be kept completely confidential. Once the link has been made between your survey answers and other information about you, your name, address and postcode will be removed so that you cannot be identified. Your survey answers and other information will be used for research purposes only.
- It is up to you whether you give your consent. If you don't, your survey answers will still be used for health research without being linked to other information. You can withdraw consent at any time by contacting us at the address shown in the leaflet provided.
- Further information about data linkage can be found on our website www.natcen.ac.uk, in the leaflet provided, or by contacting us on 029 2082 6685.

If you agree for us to link your survey answers to other information as described above please complete the section below and put this consent form in the envelope provided. The copy beneath is for your own records.

Your consent


I agree that NatCen can pass on my name, address, sex and date of birth to the NHS in Wales so that my survey answers can be linked with other information held about me.

Full name: _____

Signature: _____

Date of birth: ____ / ____ / ____ (dd/mm/yyyy)

Appendix G Round 2 Consent form (Within the questionnaire)



NatCen
National Centre for Social Research

SERIAL NUMBER
(interviewer write in):

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Consent F

Making your survey answers even more valuable

- 1 Thank you for taking part in the Welsh Health Survey. Your answers will be very valuable to help plan health services and look at ways of improving people's health.
- 2 There is another way you can help us that would make your survey answers even more valuable.
- 3 The Welsh Government would like to be able to link your survey answers to information that the NHS and other public organisations hold about you (e.g. your GP, hospital, and education records.) Linking records in this way will help us get a better picture of the lifestyles and circumstances of people in Wales.
- 4 If you agree to help, we will need to send your name, address, sex and date of birth to the NHS in Wales. They will work with a Welsh Government funded research unit at Swansea University to link your survey answers to other information about you.
- 5 Your personal details will be kept completely confidential. Once the link has been made between your survey answers and other information about you, your name, address and postcode will be removed so that you cannot be identified. Your survey answers and other information will be used for research purposes only.
- 6 It is up to you whether you give your consent. If you don't, your survey answers will still be used for health research without being linked to other information. You can withdraw consent at any time by contacting us at the address shown in the leaflet provided.
- 7 Further information about data linkage can be found on our website www.natcen.ac.uk, in the leaflet provided, or by contacting us on 029 2082 6685.

If you agree for us to link your survey answers to other information as described above please complete the section below and tear off this consent form and put it in the envelope provided.

Your consent

I agree that NatCen can pass on my name, address, sex and date of birth to the NHS in Wales so that my survey answers can be linked with other information held about me.

Full name: _____

Signature: _____

Appendix H Round 2 Leaflet Welsh Health Survey 2011

What is the Welsh Health Survey?

The Welsh Health Survey is a major source of information about the health of people in Wales, the way the NHS is used, and the things that can affect people's health. Since 2003, the National Centre for Social Research (Britain's largest independent research organisation) has carried out this study on behalf of the Welsh Government.

How was my address chosen?

To call at every address in the country would take too long and cost too much money, so we select a sample of addresses. Your address was chosen at random from the Postcode Address File, which is held by the Post Office and is available to the public. This file only contains addresses. It does not contain any information about the people living at the address.

What are the questions about?

The study collects information about your use of health services, your health and well-being, and related factors. If you agree, the interviewer will also measure the height and weight of participating children aged 2 to 15 years.

Your rights under the Data Protection Act 1998

This list is not intended to be exhaustive:

- ❖ You have the right to ask the Welsh Government to provide you with access to and a copy of personal data it may hold about you
- ❖ You have the right, in specified circumstances, to ask the Welsh Government to stop processing personal data about you
- ❖ You have the right to seek compensation if you believe that you have suffered damage and/or distress because the Welsh Government has processed personal data about you in contravention of any of the requirements of the Data Protection Act 1998
- ❖ You have a right to ask the Information Commissioner to carry out an assessment of the way in which the Welsh Government has processed personal data about you

Individuals who wish to exercise any of these rights should contact the Welsh Government's Data Protection Officer on 02920 826770.

HOW WILL THE INFORMATION BE USED?

This information will be used to help plan health services in Wales, inform health policies, and look at ways of improving people's health. The information collected each year will make it possible to see whether the nation's health changes over time.

The Welsh Government and its partner organisations cannot get this information in any other way.

Is the study confidential?

Yes. All information that you give will be strictly confidential and will only be used for the purposes described in this leaflet. There's more information on this on page 7.

Do I have to take part?

No, but we rely on people's voluntary co-operation and hope you will be willing to help. It is important that as many people as possible take part to ensure that all types of people are represented. We need to talk to people in good health and those with less good health. This will help to give an accurate overall picture of the health of people in Wales.

What will happen to the information I provide?

Your answers will be treated in the strictest confidence in accordance with the Data Protection Act. Along with the answers of everyone else who takes part, the results will be made anonymous and published at a later date. You will not be identifiable from the published results in any way. The information is being collected for statistical purposes only.

DID YOU KNOW...?

(SOME FINDINGS FROM THE 2009 WELSH HEALTH SURVEY)

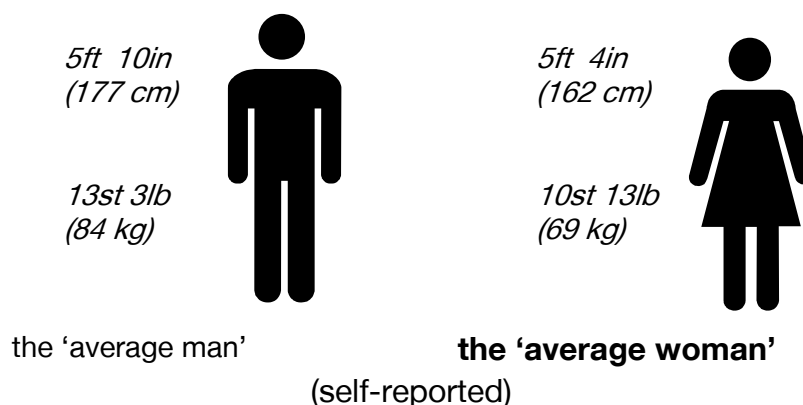
- ❖ 16% of adults reported that their **health in general** was excellent, 35% very good, 28% good, 15% fair, and 6% poor
- ❖ 27% of adults, and 6% of children, were reported as having a **long-term illness** that limits their daily activities



- ❖ 24% of adults reported that they **currently smoked**
- ❖ 35% of adults reported eating **five or more portions of fruit and vegetables** the previous day



- ❖ 57% of adults were classified as **overweight or obese**, including 21% classified as obese



Further information about linking data

For information about the records that are currently being held by the Welsh Government funded research unit at Swansea University, visit their website www.HIRU.ac.uk

Further information about data linkage can be found on our website www.natcen.ac.uk or by contacting us on 029 2082 6685.

Further information

If you have other questions, or would like to talk to someone about the study, please contact NHS Direct Wales on 0845 46 47. (A Minicom service is available on 0845 606 46 47.) When you phone, check firstly that you have reached NHS Direct Wales, and then ask to speak to someone about the Welsh Health Survey.

Or you can visit *<http://www.natcen.ac.uk/study/welsh-health-survey/participants>* for more information.

Or you can write to:

**Jan Bunce
Welsh Health Survey Administrator
Social Research Division
Welsh Government
Cathays Park
Cardiff
CF10 3NQ**

You can read more about the Welsh Health Survey at the following web address:
www.wales.gov.uk/statistics

What if I change my mind about my survey answers being linked?

If you agree now but change your mind later, all you need to do is to write to:

National Centre for Social Research,
Kings House,
101-135, Kings Road,
Brentwood,
Essex
CM14 4LX.

Please give your name, address and date of birth. We will then make sure that the link is removed between your survey answers and other information.

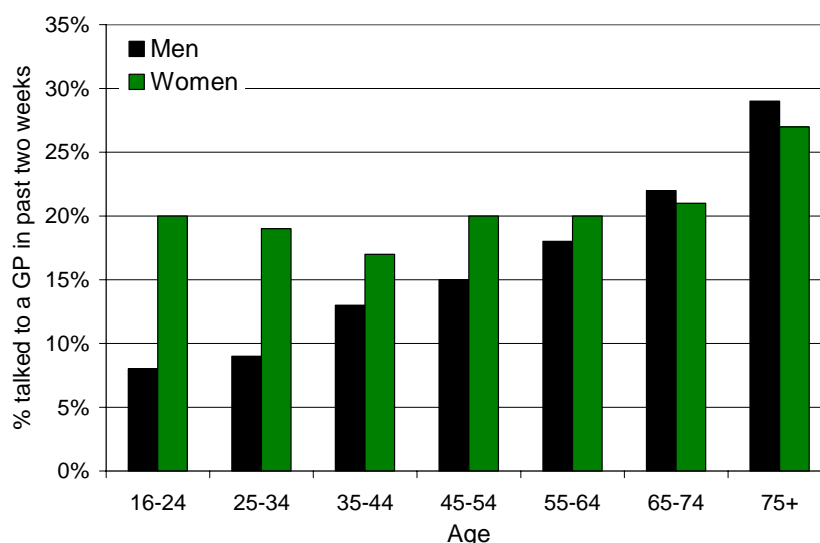
If I don't consent, will my survey answers still be useful?

Yes. Your survey answers will still be very valuable and will continue to be used for health research.

Linking your survey answers to other information is not the main purpose of this survey. The linking is simply another way you can help us that would make your survey answers even more valuable.

It is entirely up to you whether you give your consent for us to link your survey answers to other information.

Who talked to a GP about their health in the past two weeks?



- ❖ In all, 18% of adults reported having **talked to a GP** about their own health in the past two weeks



- ❖ 5% of adults, and 7% of children, were reported as having an **accident needing a visit to hospital** in the past three months



Who will have access to the information I provide?

Unless you sign the consent form enclosed or give us permission to contact you again for future health-related research, access to your name and address will be restricted to the research team at the National Centre for Social Research and only used for the purposes of carrying out this study.

In addition to the research team at the National Centre for Social Research, the answers you provide and your postcode will be provided to a small number of researchers in the Welsh Government. Your postcode will only be used to group together the answers for everyone living in a particular area in order to provide results for all the people in the area.

Other researchers, for example from the NHS and Universities, sometimes ask us to share detailed but anonymous data from the study for their research into health matters. If we agree to share data with an organisation they must sign a confidentiality agreement agreeing not to pass the information on to anyone else. We will not share any information with any marketing or market research companies.

Each year, like many other major national surveys, a dataset with information from the Welsh Health Survey is archived with the UK Data Archive so that it can be analysed by registered researchers who have agreed to certain terms and conditions. This anonymised dataset does not contain detailed information about the areas people live in or personal details like name, address, or postcode.

What is the consent form asking me?

The consent form asks your permission to link your survey answers to other information that the NHS and other public organisations hold about you (e.g. GP, hospital, education records).

Linking to other information is not the main purpose of this survey. This is an additional way to get a better picture of the lifestyles and circumstances of people in Wales.

To do this, the NHS in Wales will need your name, address, sex and date of birth. By signing the consent form, you agree to give us permission to pass this information to the NHS in Wales.

If I give consent, what will happen next?

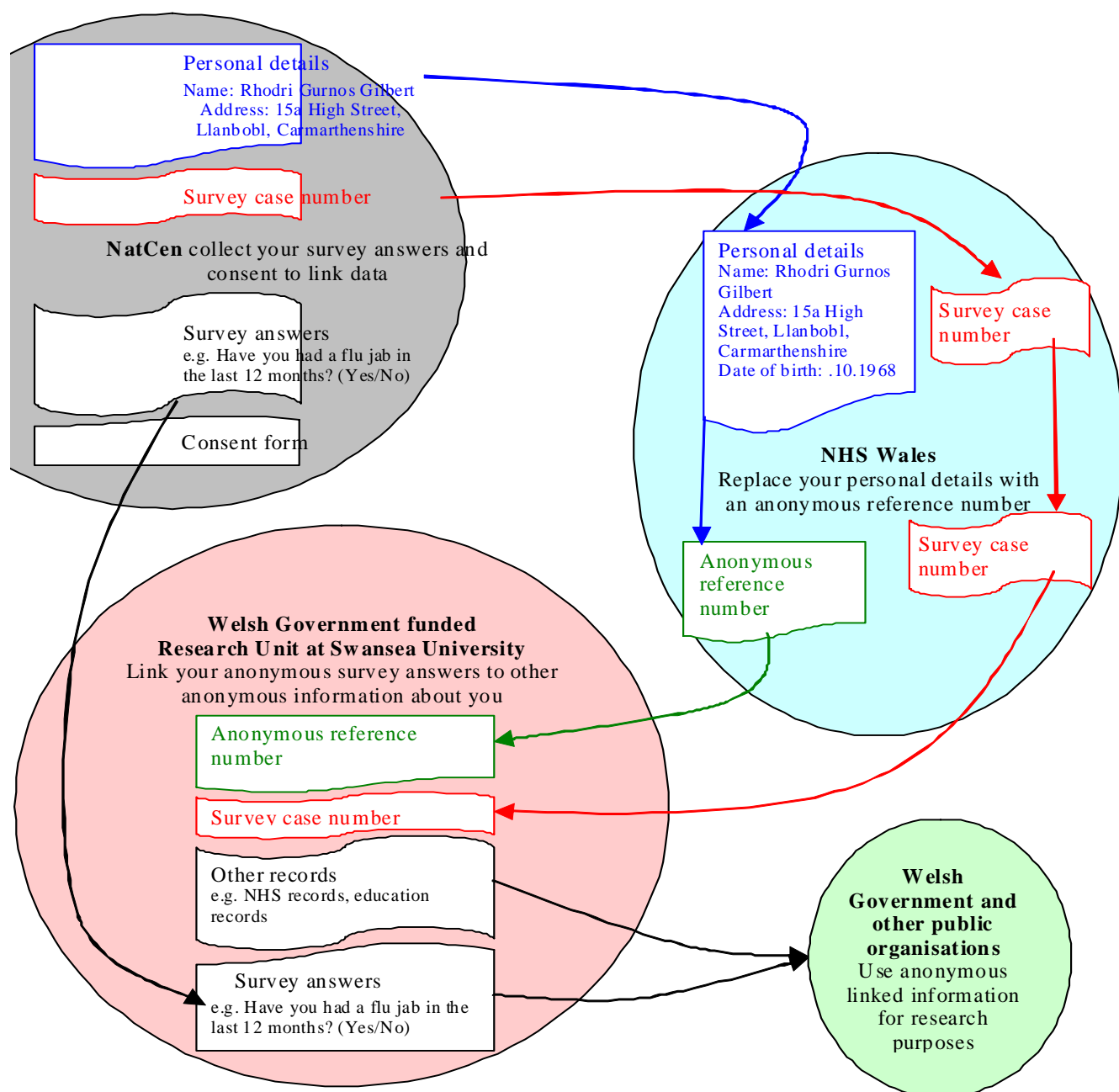
If you agree, the NHS in Wales and a Welsh Government funded research unit at Swansea University will work together to link your survey answers with information the NHS and other public organisations hold about you.

As soon as the link has been made, your name, address and postcode will be removed so that you cannot be identified. This means your survey answers and other details will be kept completely anonymous.

The anonymous linked information will be made available to researchers from public organisations like Universities and the Welsh Government. These organisations must sign a confidentiality agreement preventing them from passing the information on to anyone else. They will not be able to identify any individuals. Your survey answers and other information will be used for research purposes.

Appendix I Round 2 Flow chart (Version A)

How do we link your survey answers to other information?



Appendix J Round 2 Flow chart (Version B)

How do we link your survey answers to other records?

