EXERCISE 1A: CONSENT - QUALITATIVE DATA


BACKGROUND TO THE STUDY

The 2001 foot and mouth disease outbreak had an enormous effect on the economic, social and political life of rural areas in the UK. This research project, which was funded by the Department of Health, produced evidence about the human health and social consequences of the epidemic.

The study recruited a standing panel of 54 local people from the worst affected area (North Cumbria). This panel wrote weekly diaries over a period of 18 months describing how their lives had been affected by the crisis and the process of recovery they observed around them. The panel was recruited to reflect a broad range of occupations including: farmers and their families; workers in related agricultural occupations; those in small businesses including tourism, hotel trades and rural business; health professionals; veterinary practitioners; voluntary organisations; and residents living near disposal sites.

The panel members produced 3,200 weekly diaries of great intensity and diversity over the 18-month period. The data were supplemented by in-depth interviews with each respondent, focus group discussions, and 16 other interviews with stakeholders.

The research team gained consent from participants for primary participation in the project, but did not initially consider consent for sharing or archiving their data. When the project was finished they wanted to archive their data, so had to gain retrospective consent. They sought expert advice from copyright law specialists to help draft terms of agreement which would give respondents a series of options about how their diaries, copies or portions of diaries, and/or their audio material would be archived.

The exercise includes three consent forms to discuss. The first consent form is the initial consent that the researchers used. The second and third are the retrospective consent forms.
The Institute for Health Research
Lancaster University

CONSENT FORM

Name ____________________________________________

Address __________________________________________
___________________________________________
___________________________________________

I consent to participating in the health and social consequences of the 2001 foot and mouth outbreak project, which involves:

- Completing a weekly diary for a period of 18 months
- Competing a questionnaire about my quality of life (3 times during the study)
- Individual and group interviews about my life experiences, my work and my health.

I understand that:

1. Everything that I tell you will be held in the strictest confidence. Some of the information that I give you may be used in reports and articles, but my identity will remain anonymous (my name will not be given).

2. I am free to withdraw from the project at any time.

Signature ____________________________ Date _____________
Archiving Depositor Consent Form
(Diary –Economic and Social Data Service, UK Data Archive)

Terms of Agreement

Below are sets of statements that give you the depositor, a series of options in terms of how you wish your diary, copy of your diary, or portion of your diary, to be archived. For each numbered statement, please delete the part that is not applicable. Please note that ‘diary’ refers to ‘anonymised diary’ (you are not named).

By signing below:

1.1 I agree to deposit the whole/a portion of my diary (or copy of my diary) with Economic and Social Data Service, UK Data Archive.

1.2 I agree that my diary/or the agreed portion of my diary will be available from………………………to researchers and the public for scholarly and educational purposes.

By giving my permission I also:

2. I do/do not agree that the Economic and Social Data Service, UK Data Archive may use this diary/portion of the diary, including making a copy or copies of it or a part or parts of it, in any form or medium, and may authorise others to do so, without any further approval on my part.

3. I do/do not agree that a part or parts of the whole diary/portion of the diary may be published from……………………………as long as I am not identified.

4. I hereby assign ownership of the diary/copy of the diary/portion of the diary to Economic and Social Data Service, UK Data Archive. I understand that I nevertheless retain copyright, subject to the rights which I have granted Economic and Social Data Service, UK Data Archive to make copies and publish and to grant permissions to others to do so.

Signature of depositor……………………………………………………………………Date———

Name of depositor (print)……………………………………………………………….

Witnessed By ……………………………………………….[name, print]

Signature of Witness……………………………………………………………….
Archiving Depositor Consent Form
(Audio material – Economic and Social Data Service, UK Data Archive)

Terms of Agreement

Below are sets of statements that give you the depositor, a series of options in terms of how you wish your audio material, or extract of your audio material, to be archived. For each numbered statement, please delete the part that is not applicable. Please note that ‘audio material’ refers to ‘anonymised’ audio material (you are not named).

By signing below:

1.1 I agree to deposit the whole/ extracts of my audio material with Economic and Social Data Service, UK Data Archive

1.2 I agree that my audio material / or the agreed extracts of my audio material will be available from ..................... to researchers and the public for scholarly and educational purposes.

By giving my permission I also:

2. I do/do not agree that the Economic and Social Data Service, UK Data Archive may use this audio material / the agreed extracts of my audio material, including making a copy or copies of it or a part or parts of it, in any form or medium, and may authorise others to do so, without any further approval on my part.

3. I do/do not agree that a part or parts of the audio material / the agreed extracts of the audio material may be published from ........................... as long as I am not identified.

4. I hereby assign ownership of the audio material / the agreed extracts of the audio material to Economic and Social Data Service, UK Data Archive. I understand that I nevertheless retain copyright, subject to the rights which I have granted Economic and Social Data Service, UK Data Archive to make copies and publish and to grant permissions to others to do so.

Signature of depositor-------------------------------------------- Date-------------------

Name of depositor (print)------------------------------------------

Witnessed By .................................................[name, print]

Signature of Witness-----------------------------------------------
When gaining retrospective consent the researchers spoke to their participants about archiving their data. Researchers often worry that participants will be reluctant to share their data, but when this research team went back to their participants, only seven (out of 54*) panel members declined archiving their data. Forty interview and diary transcripts are archived and available for re-use by registered users. Three interviews and five diaries are embargoed until 2015.

* Figures here do not total exactly, due to interviewees also being diarists.

The retrospective consent forms were well-thought through and the researchers used an individual approach to discussing archiving with respondents (one-to-one discussions on whether interviewees wanted their interviews and diaries archived or not), giving the respondents the opportunity to decide.

The research team sought expert advice from a copyright specialist to help draft terms of agreement which would give respondents a series of options about how their diaries, copies or portions of diaries, and/or their audio material would be archived.

A large dataset of sensitive, confidential information was archived with minimal anonymisation (only names, addresses, dates of birth and company names were removed).

The drawbacks of using many different forms within a small-scale project are that:
- additional paperwork puts a greater burden on respondents who have to complete them and on the research team who have to administer them
- there is a danger of making the final collection difficult to access as a whole if the various elements have different consent agreements

The second and third consent forms offer multiple choice text answers. This allows greater freedom for participants to record their wishes. However, too many permutations of consent could affect what is being made available and could potentially distort the final body of research that is being made accessible.

On the diary consent form, respondents are given the option to select a date for their data to become available. We recommend that if this is to be offered then guidance should be given about setting a date - in case an arbitrary date is set. The data is usually best set by the research team as they will have a better sense of when the project will be completed and when the data should be accessible.

These forms are very official and formal. This may put some participants off. They read more like legal documents. The first consent form was less formal, but did not gain consent for archiving the diaries and audio. The researchers later went back to respondents to gain retrospective consent, by which time the political and legal situation surrounding this issue had changed. There was more public awareness and sensitivity to the issue. They therefore employed legal experts to help design the consent form. This makes it very formal and perhaps intimidating. Some projects may benefit from a more rigorously laid out form. Others may require a more informal looking agreement.

Respondents could have been offered an information sheet which explains archiving.

The form states that the respondent ‘assigns ownership’ to the UK Data Archive. The Archive does not assert ownership of research data so instead this could be phrased ‘I hereby license the diary...’