Ethical issues in longitudinal surveys

Carli Lessof, National Centre for Social Research[1]

1. Introduction

Concerns about the ethics of medical research were raised – albeit unsuccessfully - in the 18th century when Jenner developed vaccination against smallpox. But a much more widespread concern developed in the aftermath of the Second World War and with the rapid growth of medical research in the 1950s, as a substantial number of experiments of very doubtful ethical validity were carried out without informed patient consent. In "Human Guinea-Pigs: A Warning", Maurice Papworth wrote evocatively about these ethical failures (1962, 1969). For the first time in the UK, medical ethics and patient's rights were put to the forefront of medical education and practice. Although the criticisms were not primarily directed at surveys, the concerns that were aroused and the codes of practice which were developed have presented both medical and social scientists with guidelines to be met both by investigators and by the Ethics Committees that are now the gatekeepers for research.

There are many publications on professional ethics but, as an example, an International Statistical Review by the Institute (1986) produced a Code of professional ethics that is still topical. It was concerned with maintaining ethical collaborations and professional standards of objectivity. It sought to extend the scope of statistical enquiry for the benefit of the community, while guarding against predictable misinterpretations or misuse of various types of data. Recognising the intrusive potential of some of their work, the Institute also emphasized the need for freely given informed consent whenever the active participation of human subjects was involved. In considering the need for confidentiality, dealing with information provided by proxies, and in the secondary use of records, the Code provided standards which still apply. Since that time the British Government has produced its own code of practice for statistics and social research (GSS, 1984) as has the Market Research Society (1985) and more recently the Economic and Social Research Council (2005). The ESRC guidelines provide a valuable contemporary summary as shown in the box below.

Box 1: Ethical Guidelines from the ESRC

1. Research should be designed, reviewed and undertaken to ensure integrity and quality.
2. Research staff and subjects must be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. Some variation is allowed in very specific and exceptional research contexts for which detailed guidance is provided in the policy Guidelines.
3. The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected.
4. Research participants must participate in a voluntary way, free from any coercion
5. Harm to research participants must be avoided.
6. The independence of research must be clear, and any conflicts of interest or partiality must be explicit.

Practitioners designing longitudinal studies face many of the same issues that present themselves in the cross-sectional studies upon which many of these

[1] Add thanks to Borbala Nagy, MHL, reviewers.

recommendations are based. By definition, however, longitudinal studies face an additional dimension, since they are centrally interested in measuring change or in specific outcomes over time. The time dimension in longitudinal research means that study teams carry out certain activities that extend and sometimes deviate from standard practice for cross-sectional studies. For example, longitudinal studies have to concern themselves with panel maintenance and attrition, they increasingly use techniques such as dependent interviewing which introduces references from one wave to another. Even the concepts of avoiding harm, or of informed consent (to participate generally and to agree to specific activities such as data linkage), which have been so central to the development of medical ethics may need to be considered in a different light. Similarly, efforts to maintain participant confidentiality and protecting respondents' data may also be more challenging.

If it were possible, this chapter might set out some key guidelines for the ethical conduct of longitudinal social research that could be applied to any new study about to begin. Of course, the complexity of many studies prevents such a simplistic approach. Paradoxically, moreover, the fact that longitudinal studies continue over a long time period mean that it is impossible to provide a definitive statement about what will and will not be ethical for the life of a particular research project. In medical research, it is acknowledged that the balance between the known benefits and risks of a study may change over time and may lead to a study being stopped. The examples are less stark in social science research that involves personal interviews, but various circumstances may still affect the ethical balance of a study or of an individual's participation in it:

a) Over time the study investigators or funders can change and new social issues and hypotheses may emerge. As a result, the nature or focus of a study can evolve over time. For example, the National Child Development Study (the British birth cohort study that began in 1958) started life as a study of mothers and infant health but over time has concerned itself with the acquisition of basic skills.

b) Respondents can change in relation to the study, especially when children in cohort studies become adult, or when adult participants age. And a participant's interest or confidence in the study can grow or subside as personal experiences affect its salience. The circumstances of a couple or household who form the subject of the research may also change, for example splitting and forming new partnerships.

c) What is considered best practice in ethical research can itself change over the course of a study. In recent years there has been a trend towards regulation with increasing demands for formal procedures such as written consent for surveys. At the same time, there has been a growth in new opportunities in research such as developments in technologies for genetic analysis and for linkages to administrative data. These raise new ethical questions that cannot be foreseen at the outset of any study.

To give an example, we can imagine that the Millennium Cohort Study whose study members are now five years old, will continue to follow these children into their sixties, as the National Survey for Health and Development which started to collect data in 1946 is about to do. A simple thought experiment of this kind shows how challenging it would be to predict all the ethical requirements that might be needed in 2060. The consequence of this is that studies must be subject to regular review to ensure that appropriate ethical controls are in place, and must be given some protection from the 'changing winds' of contemporary preferences.

This paper sets out some of the ethical issues that are faced specifically by longitudinal studies. We review four of the key ethical principles identified by the ESRC; informed consent, voluntary participation, avoidance of harm and confidentiality (points 2, 4, 5 and 3 above) and provide illustrations based on particular aspects of the longitudinal survey research process. The first and last issues raised by the ESRC (integrity and quality; resolution of conflicts of interest) are considered more generally in the conclusions.

2. Informed consent

> "Research staff and subjects must be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved." (ESRC, p)

One of the fundamental requirements of ethical research is to gather informed consent. There have been occasions where consent was not gained, for example in the notorious case of the Tuskegee Syphilis Study, which began in the 1930s and studied the natural history of syphilis, and which breached every notion of what is ethical in clinical research. A few legitimate exceptions also exist and are discussed further below. In the great majority of longitudinal studies, however, informed consent must be acquired, and at several points in time.

Initial consent

First, a study requires consent for initial participation. In some respects this is no different to seeking consent for a cross-sectional study. However, the questions raised are whether, when and how eligible individuals should be told that they have been selected to be a member of a longitudinal study. This is not always known from the outset of a project (for example in the case of the Health Survey for England which followed up respondents as part of the English Longitudinal Study of Ageing) but arguably it should be revealed whenever possible. Where this is done, it is important to stress the voluntary nature of future stages. That said, in studies where the extent to which a sample is representative of the population is crucial, researchers can fear 'putting off' respondents who need only make a commitment to the first stage of a study for their input to be valuable, and may avoid revealing its longitudinal nature. The study team hopes, of course, that commitment will grow once the participant has established a connection with the study. In other studies, the extent to which the sample is representative of the total population is less important. Here, the key issue is to ensure that participants remain in the study indefinitely (Swerdlow) and this may mean that clarifying the long-term goals of the project, which is compatible with the most open dialogue with respondents, is considered crucial to ensure maximum commitment at the outset.

Continuing consent

Having gained initial consent, further issues arise about informed consent future stages of the research. Data protection legislation has meant that it has become increasingly common practice in cross-sectional surveys to ask for permission to revisit the household in the future (and in some instances for personal information to be given to organisations should a sponsor wish to transfer fieldwork to another contractor). But once individuals have been recruited to a longitudinal study, practitioners are understandably reluctant to seek positive consent for a future visit. Instead, they may include a final item expressing the intention to revisit the respondent in one, two or more years in the future, which asks for a stable-address should they move. This provides the respondent with a clear opportunity to

spontaneously record the fact that they do no want to be approached again, yet leaves the decision about participation for most to be made at the time of the next interview. The rationale is that even if someone gave a full commitment at the end of an interview, this could only be for permission to be re-approached. And an individual that feels they have 'had enough' at the end of an interview in one year may feel quite differently before the next stage of fieldwork arrives.

When asked to participate in a study committed respondents tend to agree to almost any interventions and requests because they trust the investigators and the study. The investigator's interests may seem to be aligned with those of participants, but this may not always be the case, or this may change over time. Continuing consent may not therefore be taken for granted in a continuing study.

It should be acknowledged that however committed any study member may be, longitudinal research that has a number of data collection activities inevitably involves the respondent in a series of separate decisions rather than a continuous obligation. Consent to participate can only, therefore, be seen as valid for a particular wave of activity. Each time a study member is asked to take part in a new wave of data collection their agreement to take part is implicitly or explicitly required. In some studies, such as the Millennium Cohort Study (MCS), the Multi-Centre Research Ethics Committee (MREC) insists that the study member sign a written document agreeing to participate. Written agreements of this kind may become a norm in future social surveys but it goes beyond the current standard in large-scale surveys in Britain. Indeed many would argue that it is unnecessary and disregards the relationship of trust that has been established in the early stages of the study.

Consent to trace respondents
A key objective of all longitudinal studies is to maintain response over time and a vital part of achieving this involves tracing any respondents who move address. This topic is covered in more detail in the next section, but it is relevant to ask here whether study members should be asked to consent for their names and addresses to be sought out by various means should they move.

Consent for unanticipated activities or analyses
The issues raised thus far, relate primarily to informed consent for the study as a whole, but there will often be additional elements to a study that demand specific additional consents or unanticipated analyses that may require more permissions. Some argue that the whole study should be revealed to the study member at the outset and that it is unethical to reveal further elements at a later date. However this is often unrealistic for longitudinal social research, where future research questions and funding are uncertain, and the opportunity for a nurse visit, analysis of genetic material, or other additions, may not be anticipated at the outset. In some respects there is no difference between the issues here for cross-sectional and longitudinal research but there is a greater likelihood that there will be additional interventions in the future, and there are also added opportunities to return to subjects to seek additional consents if necessary.

If an individual undergoes a transition that affects consent
The circumstances described above all assume that the individual respondent or the household remains static over time. In some instances, however, the issue of informed consent is complicated by changes in the circumstances of the individual respondent or by changes in household composition. For example, in birth cohort studies, the parent initially consents on behalf of the child and answers questions

about themselves and their family[2]. As the child grows old enough to exercise some preferences, the child assents to physical or cognitive measurements but is not considered able to give informed consent. When the child becomes older, decision making shifts from the parent to the child. This transition is a difficult one and is exacerbated by the fact that it takes place at a time when the young person is establishing a separate identity. It is not entirely clear to what extent these children are able to disregard the commitment offered by their parents, and refuse to take part. Nor is it clear whether the parents understood at the outset that their role would diminish. These issues have already been faced by the first three birth cohort studies, and are a current concern for the Avon Longitudinal Study of Parents and Children (ALSPAC).

There is an equivalent problem at the other end of the age spectrum where individuals who have participated in a study may lose the ability to give informed consent as they become physically, cognitively or mentally impaired. At this stage, it is important to find the correct balance between representing these individuals in the study by reducing the burden of the questionnaire or by involving proxy informants, and between accepting their loss to the panel with the consequent increase in non-response bias. ELSA acknowledges this issue by inviting respondents to nominate a relative, friend or carer to act as an informant on their behalf in the future. This person can either act as a proxy interview for a living ELSA respondent who cannot take part themselves, or as an informant for an End of Life Interview after their death. An ethical issue that is raised here is whether the request should go further, and rather than ask for a preferred nominated proxy, ask people whether they consent to having a proxy interview or End of Life Interview conducted on their behalf.

If a household undergoes a transition that affects consent
Another particular case is provided by studies where a household is selected to take part (as in the case of the British Household Panel Study) or a partnership is the focus of study (as in the case of ELSA). In these instances new entrants are often invited to join the study and all eligible individuals are normally followed if a split occurs. In practice, it can be difficult to gain access to all individuals after a household has broken down, and it may be ethically appropriate and practically important to make the intention to follow all individuals clear from the outset. Another issue this raises concerns the use of data collected from a household that changes composition over time. This is discussed further in Section X below.

Consent for linkages to administrative data
Another area that requires informed consent in many longitudinal studies is linkage to of survey and administrative data. Administrative data can provide detailed information about a respondent that could not be collected in any other way. This data may provide historical information stretching back many years, as with National Insurance Contributions made over a working lifetime. It can also continue to be collected indefinitely, for example data on the receipt of disability or carers benefits or the receipt of hospital care. Given the appropriate consent, administrative data can be linked to survey data for earlier periods and also after an individual leaves the study or after it stops collecting primary data. It can provide supplementary information for all responding individuals but can also provide basic information about non-responders, which can be used as proxy data or to understand non-response bias.

[2] As an aside, from time to time the child's two parents will disagree. The ethical and practical dilemmas that this presents are exacerbated where the family has taken part in the study and has subsequently split.

There has been a long history of using administrative data to aid research, for example in Doll's study of doctor's smoking habits, described in Chapter X. At the time of that study there were no ethical committees that scrutinised research designs and informed consent was not given for the linkage. Although there are still instances – as in the ONS Longitudinal Survey – where linkages to administrative data occur without the knowledge or consent of the study participants, these are now carefully regulated and only allowed under specific circumstances. Normally, consent for linkage to administrative data is now required. Researchers must explain to respondents what the administrative dataset is, the nature of the information that will be used, and the purpose to which the data will be put. Further assurances about confidentiality and the protection of the data are added.

The linkage of survey and administrative data has become much more widespread in recent years though its costs and benefits are still being explored. In the meantime, the procedure has raised a number of practical questions, some of which are specific to longitudinal studies. For example, how long can consent of this kind last? Can it be collected once, or should there be a cool-off period for example in the form of a check question at the next visit as is normally the case with ELSA respondents? Or, more stringently, should consent be recollected on every occasion that the respondent is interviewed as occurs with consent for linkage to the Hospital Episodes database for MCS? A final question, whether consent for linkage is automatically nullified if the participant leaves the study, is discussed further in the next Section.

Using administrative data for longitudinal research without full consent
A final question we can ask is whether it is ethical to draw the sample for a study from an administrative data source that allows eligible individuals to be tracked over time, regardless of their participation and consent. For example, in the evaluation of the New Deal for Lone Parents, approximately 70,000 individuals were identified from benefit records and their outcomes (in terms of exits from benefit) were observed. Explicit consent was only collected from those who were interviewed face to face so that their survey data could be linked to the administrative records that had been identified. This method is very effective in counteracting some of the problems thrown up by non-response and attrition, particularly in disadvantaged populations such as this one. It does, however, require 'silent' observation of a large group using administrative data only. But if permission to do this kind of activity is denied, a great deal of useful data collection will either be impossible or will be severely biased. In considering the ethical aspects (as in clinical studies) there is therefore one important question. The question is whether an individual's health, interests or confidentiality could be affected negatively.

Is fully informed consent realisable?
All of these separate considerations about informed consent may need to be addressed in the course of any longitudinal study. But informed consent can be a theoretical ideal that proves illusive. When defining informed consent, a Canada Council Consultative Group (1977) stated that:

> No research involving human subjects should be undertaken without their freely-given, informed consent, if possible in writing…. The information given should be complete and presented in a way which takes into consideration the level of (their) comprehension. An exact description should be provided of all aspects of the research project…..Subjects should always be apprised of any considerations which might lead them to refuse to participate..... Those participating in a research project should never, either before or after the experiment, have any reason for saying that they did not fully understand what was involved.

In discussing these guidelines Jowell (1986) pointed out that, clear and comprehensive though they may be, their fulfilment is not always a simple matter. As an example, he suggests that both consent and coercion can be informed, uninformed, or disinformed – that "informed coercion" is the condition under which many censuses are conducted and that "uninformed coercion" is the condition under which many observation studies are conducted - since the subjects are unaware of their participation. Furthermore, when the aim is to investigate anti-social or unlawful practices by those in positions of influence, informed consent could not be obtained. It could be argued that asking for it might, in any case, change the behaviour that the study was designed to investigate. Important though it is, it cannot therefore be argued that informed consent is the cornerstone of all research practice.

In considering informed consent, we need to understand what study participants actually believe with regard to the use of their data, and what they believe they do and do not need to know to make informed decisions about participation, especially if new issues emerge at a later date. The complexity of fully informed consent and the complexity of the studies that require it make it important to know that safeguards are provided. In practice, some respondents may take more assurance from the fact that there has been an ethical review of the study than from the detailed information with which they may feel they have been bombarded. That overview is now provided by ethical committees which involve lay people who are drawn from or are similar to the target group, working alongside independent academics and others who have an interest in ethical issues.

3. Free choice whether or not to take part

> "Research participants must participate in a voluntary way, free from any coercion" (ESRC, p)

Another important principle in carrying out ethical social research, separate from though related to informed consent, is ensuring that potential study participants have a genuine choice about whether or not to take part. An individual should not be coerced to participate in any study, and interviewers need to be encouraging and persuasive to maintain response while avoiding being forceful.

There are various ways in which encouragement can be given, for example by providing information leaflets or project updates that show the respondent that the study is worthwhile, or by keeping in touch between waves to show that the respondent is valued by the study team. More specifically, though the Birth Cohort Studies and some other longitudinal projects purposefully reject this approach, it is now common for incentives to be given to respondents 'as a token of appreciation' (e.g. FACS, BHPS and ELSA). These are quite modest payments in the region of £10. Informal testing with respondents during pilot studies has made it clear that such payments are rarely perceived as coercive, but the ethical issues still need to be considered. In some studies such as the Health and Retirement Study (HRS), which is carried out in the United States, the incentive is pre-paid by cheque and is therefore unconditional on participation. The HRS also makes small payments as 'finders fees' to family members or neighbours who provide follow-up information, and it has occasionally increased incentives to study members who initially refuse to participate. ELSA has similarly tried using increased incentives for cases that, for a variety of reasons, have been returned by interviewers as unsuccessful. These have been issued for a second attempt to a different interviewer, while at the same time a letter is sent to the household offering a doubled incentive of £20.

Study teams also need to make sensitive choices about when to ask an interviewer to re-approach a respondent to see if they can be 'converted' into a productive interview.

When considering whether a study gives respondents a genuine choice about taking part, it is important to remember that longitudinal studies are unusual. Those who continue to take part month after month or year after year show a very personal commitment, and respondents may be too hesitant to refuse even if they feel that they are being asked for too great a commitment. As a result, it is a matter of trust that the investigators consider respondents' well being when making decisions about the content and frequency of future episodes of data collection. In the British Household Panel Study and the Family and Children Study the interview has been relatively short and self-contained, but even so the respondents give a lot of their time. In other cases a study may continue over many years, with relatively long and demanding interviews. Some involve several members of the household, as in the Millennium Cohort Study, and include physical or cognitive measurements (for example the Birth Cohort Studies and the English Longitudinal Study of Ageing). Fortunately, investigators have an opportunity to listen to the views of respondents through feedback from pilot studies and through other means such as specially arranged meetings of panel members. If there is no implicit understanding of what is and is not acceptable, a participant may feel that the only means of escape is to withdraw from the study. If a serious growth of the attrition rate follows, the validity of the entire study may be threatened.

Organisers of a longitudinal study are bound to place a great deal of emphasis on maintaining the number of participants in their sample over time. Success, from an analyst's viewpoint, must be measured at least as much by the overall, continuing response from the baseline sample as by response at any given wave. Once the first wave of the study is complete, there is a need to approach all participants again, unless they have explicitly asked to withdraw or have refused to allow any future approach. Clearly, a balance must be struck between inviting individuals who have opted-out because of a set of temporary circumstances and, on the other hand, persisting with an invitation which is unwelcome. Studies employ various approaches to manage this problem. The Family and Children Study, which involves an annual face to face interview, give respondents a 'study holiday' and then go back to check whether they might be persuaded to rejoin at a future wave.

The rate of attrition may rise when participants are lost because they have changed their address. This is less of an ethical issue in cross-sectional studies with named samples, but there have been concerns about what activities can be undertaken legitimately and ethically to trace such individuals. In all named samples it is common practice to make discrete enquiries with near neighbours without releasing information about the study or respondent, and also to search phone books or other local sources. In longitudinal studies, pre-emptive efforts are made to ensure respondents will tell the study team of any planned move or will contact the study when they have done so. Where these measures fail, those carrying out longitudinal studies may use a diverse range of techniques to trace people who move home. Increasingly, they collect and use telephone numbers (both landline and mobile) and e-mail addresses that may remain constant even when a household moves. A very effective method is to ask each respondent at any given wave to provide or update a stable contact address through which they could be approached in the event of a future move. The benefit of this kind of approach is that respondents have implicitly consented for this tracing activity to take place. Administrative sources may also be approached for information held by the Department for Work and Pensions or

through the avenue provided by the Office for National Statistics, to use information from the National Health Service Central Register. Through the good offices of the Health Authority and general practitioner, letters can then be sent to study members, asking them to renew their contact with the study organisers. While such efforts to trace individuals are both ethical and necessary – both for the study and to ensure that the participant is given proper opportunities to continue, there remains the risk of invading what has been the intended privacy of the respondent. For this reason, studies need to consider (as mentioned briefly above) whether consent to trace should be collected when the study is first introduced to the respondent.

A balance needs to be reached between not coercing respondents and operating unethically by failing to provide equality of access. This is an equally important, but perhaps contradictory driver. Survey research practice shows that there are alternative routes to maintaining a participant's involvement in a study, for example by allowing them to complete their interview using an alternative medium such as telephone or web, and/or to carry out a shorter interview. This may be appropriate if they are reluctant or if they are sick (in which case a proxy informant may be able to answer on their behalf if they cannot do so in person). If this possibility is anticipated then the most ethical approach may involve seeking the respondent's permission in advance to allow a nominated informant to carry out a proxy interview. Other, administrative ways of tracking eligible individuals may also be theoretically available which could allow some data from the sample population (or even the whole population) to be documented - without consent and regardless of their agreement to any future participation. Concerns about the ethical aspects of an approach of this kind have yet to be resolved.

In longitudinal research the corollary of ensuring that respondents have a genuine choice about whether or not to take part is that individuals should have a genuine ability to withdraw from a study. From time to time, a respondent may ask to do this. Though this happens only occasionally, and for a variety of reasons, it is a circumstance that is challenging for many investigators. This is because longitudinal research projects are usually a composite of data collection and analytical activities, and it is not immediately obvious what the implications of such a withdrawal should be, and what set of decisions is both practical and ethical.

It is clear that an individual who has asked to withdraw from a study should not be invited to take part in any primary data collection activity in the future, and systems need to be established to put this into effect reliably. However, though few studies would deliberately risk irritating a study member in this way, it is less obvious whether that person would choose to receive correspondence from the study team, for example telling them about the latest findings.

It also seems likely that someone who asks to withdraw from a project would not want to be included in the next stage of any on-going administrative data collection exercise. One example of this is the biennial downloads of National Insurance Contributions, benefits and tax credit data that roughly three-quarters of ELSA respondents agree to. However, our assumptions may be wrong, and it might be the case that they would not object to future downloads of administrative data, so long as it did not involve them personally.

The appropriate response is even less clear with another administrative data linkage. This is the agreement to be flagged on the National Health Service Central Register which, at some time in the future, will result in information from the person's death certificate being passed to the study team so that their age and cause of death can be identified. At the point that an individual withdraws from a study, it is again unclear

whether the 'one-off' consent that they gave for this flag, perhaps many years earlier, is necessarily void.

As well as these concerns about collecting data, an individual withdrawing from a study also raises difficult questions about what analysis can be done in the future and how their past data should be treated. It seems relatively clear that any data that has been collected about an individual, but has not yet been made available for analysis, should not be released. It is also possible, though some would say undesirable, that analysts who request data for the study for the very first time should be offered new versions of all past data sets with that case removed. Some would argue, further, that any analysts holding past data sets should be notified of any withdrawals and that the relevant data records should be deleted or the whole data set should be recalled. If this approach is to be implemented effectively then very strict controls are needed when new data is released so that updated versions can be provided and monitored. It should be acknowledged that those studies that never release general data sets are in a much better position to manage this issue than others.

The contrary position is that analysts who already hold specific data sets should be allowed to complete their current work and even carry out any new analyses with that case under the confidentiality restrictions that they had already agreed. Furthermore, that past data sets should be kept in tact so that analyses are consistent. The resistance to deleting data from past data sets is both a practical and principled one. Deleting past data might mean the analyst would need to re-run their current analyses; it would mean that published findings could not be perfectly replicated; it would make one analysis project slightly incompatible with another and it would have a marginal effect on any weighting variable that had been constructed. In principle, it can be argued that the respondent gave their data at a specific time, it was carefully anonymised so that it contained no personal details about them, and on that basis it was analysed in good faith. With that in mind, some analysts would argue that a withdrawal from a study represents a clean break for future data collection, but not for the analysis of records of past activities.

In practice, it is highly unlikely that a particular respondent understands the choices that are available to them or the principal investigator, or the implications these choices will have. It is conceivable that a study member who is withdrawing, however disgruntled they may be, will feel more positive about a study that has disappointed them, if they are able to express these preferences. They may, in fact, be happy to know that the data they have contributed in the past continues to help analysts. On the other hand, if they genuinely want to withdraw without reservation, then it is important they understand what can and will be done, and if necessary what cannot.

This issue has several implications. Study teams may be nervous about approaching sample members who have asked to withdraw, but there is almost certainly a lot to learn in terms of understanding why they no longer want to be part of the study. Furthermore, to act ethically, longitudinal studies should ideally correspond with individuals who wish to withdraw in order to establish what their wishes are in relation to these issues and to clarify what is and is not possible. All longitudinal studies may need to be more explicit in the future (as some already are) about the actions they will take in this situation.

4. Avoiding harm

"Harm to research participants must be avoided." (ESRC, p)

All medical and social researchers have an ethical obligation to avoid causing harm. Social surveys, which form our main focus here, rarely do this, but there are four possible ways in which this might happen.

- In studies that involve a nurse visit, there may be specific instances where direct harm could result. For example, taking a blood sample could cause bruising, a measurement of walking-speed could lead to a fall, or an assessment of grip-strength could cause pain to a respondent with arthritis. Though problems of this kind are rare, measurements like these are only carried out where safety precautions are in place, genuine benefit is anticipated, and protocols are closely followed.

- Even in a standard face-to-face interview where there is minimal likelihood of physical harm, some questions may cause distress or embarrassment. Asking about depression, life-satisfaction or incontinence are examples, and even apparently mundane questions can occasionally upset respondents with particular sensitivities. One of the objectives of pilot studies is to identify problem questions which can be then be removed, asked more sensitively, or included in a paper or computer based self-completion instrument to provide additional privacy.

- There may also be a risk of 'social harm', for example in terms of exposing to neighbours the fact that an individual is involved in a study of lone parents, or making carers aware that their client is answering questions designed to identify abuse of the elderly. Risks of this kind are managed in various ways, for example by training interviewers not to release information to non-participants, or by framing a research project to take account of possible sensitivities. This may, in certain circumstances, partially conceal the genuine purpose of the study and so reduce the possibility of fully informed consent.

- Finally, there may be indirect effects that could be construed as harmful to respondents, for example, if the findings of a study inform a national change in pension policy that has a negative effect on an individual. Few would argue that consequences of this kind would make a project unethical.

In these examples, the nature of harm in social surveys is generally much less dramatic than in medical research and on the whole, these risks do not prevent research from progressing, either in cross-sectional or longitudinal studies. In longitudinal studies, however, there may be one consequence for the study itself that arises from its ongoing nature and the possible effects of either intentional or accidental feedback.

There is inevitably an ethical obligation to feed back results to avoid harming the respondent[3], for example, if blood samples are taken and analysis in a laboratory reveals an abnormality such as leukaemia. Less extreme findings of anaemia or high blood levels of cholesterol are more common, and feedback of this kind can have an effect on a longitudinal project if respondents change their behaviour during the

[3] There are some exceptions. For example, providing feedback from genetic analysis could inappropriately influence a respondent's assessment of health risks or of heritable disease. Part of the consent for this kind of test is therefore to ensure that respondents understand they will not receive any results. A study team may also resist feeding back measures that are not considered reliable at the individual level – for example where assessments of cognitive function in a research setting might mistakenly be assumed to be of diagnostic value.

course of a study. It can only be left to investigators to consider whether individual changes of this kind can affect the reliability of data provided in a particular study.

The concern, whenever feedback is given, is that care must be taken to ensure that details provided by the research should not be misconceived or influence a participant to take actions which are inappropriate or based on limited or poor information. Consistent with this, interviewers are trained to refer respondents to other agencies rather than to provide specific feedback, for example, if financial questions reveal that a respondent is not claiming a benefit to which they might be entitled. In such circumstances, investigators are encouraged to give help line numbers as appropriate.

Some participants may also be influenced by feedback that is not an intended part of longitudinal research. For example:

- Interviews can throw a spotlight, whether healthy or unhealthy, on a participant's life. In longitudinal studies some harm may come from being made more aware of one's own decline - in walking speed or in cognitive function – though this effect can be minimised by the customary precaution that the assessments are carried out in private. It is also possible that feeding back study findings can encourage comparisons between cohort members which shows some people's lives in an unfavourable light. However, it must be accepted that influences of this kind arise in the course of everyday living and can never be totally avoided.

- In very rare instances, individual data from a study can have a more powerful influence on a respondent's life. A child, for example, who was involved in a study but subsequently separated from her birth parents, can seek information about her childhood from the study. The ethical position is that all participants have a right to the information held about them.

The best means of avoiding harm in a social survey is to use the time-honoured approach to participants by maintaining the best possible relationship between respondent and interviewer. This involves communicating effectively, and providing explanations of the study's objectives and findings so that the participant has a positive response to being both a participant and a member of a cohort.

- Providing information and updates about the progress of the project is not only desirable in longitudinal studies (though as stated above it may occasionally encourage comparisons that could be unhelpful) but is also very possible. Apart from the need for a good relationship, investigators will hope that by encouraging participants to keep in contact (or discover that respondents have moved more promptly) and so will minimise the rate of attrition that is the cause of anxiety in all ongoing studies.

- The reverse to this positive approach is reflected in the harm which can arise when study managers fail to respond appropriately to specific enquiries or fail to feed back to respondents promptly. Participants may feel that the commitment that they give over time in a longitudinal survey should command respect, so bureaucratic errors or a failure to respond might be seen as a serious betrayal.

On the other hand, participants in longitudinal qualitative research studies can at times have a very positive feeling that they themselves are the beneficiaries. Investigators sometimes comment about participants who perceive themselves to be members of a team that is special and irreplaceable and, for them, the experience seems to be excellent. There is a reciprocal relationship between respondent and

interviewer that grows over time, so there are benefits in sending the same interviewer to a household wherever possible. Interviewers in quantitative surveys give the same feedback, though there is little research that systematically substantiates this. That said, respondents will sometimes drop out if faced with an interviewer they do not like, so it is possible that a respondent will need to be given the choice to have an alternative interviewer from time to time. In practice, this is done for quantitative surveys through standard practice of 'reissuing' unsuccessful cases to different interviewers.

5. Participant confidentiality and data protection

> "The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected." (ESRC, p)

The final principle underlying any ethical study that we consider here is that of participant confidentiality and the protection of a respondent's data. There are two main areas where this needs to be considered in relation to longitudinal research. The first is within the interview itself and relates to confidentiality issues that arise as a result of dependent interviewing. The other is the treatment of research data – an issue that also preoccupies cross-sectional research studies. In this section we look at these two areas in turn.

Dependent interviewing

In recent years, longitudinal studies have incorporated a technique called dependent interviewing. This is where data collected during an earlier interview is pre-loaded into the current one and used in one of three main ways. These are:

- to avoid asking questions that were answered previously, for example the cause of death of a parent that is already known
- to read out, check and update information given previously, for example to find out whether someone still lives in the respondent's household, or whether their job has stayed the same or has changed (this is known as proactive dependent interviewing)
- to check potentially inconsistent responses as they are given, for example if a respondent says he does not smoke but this conflicts with a response given at a previous interview (this is known as reactive dependent interviewing).

Dependent interviewing anchors responses and reduces reports of change that may be artificial. In doing so it reduces 'seam effects' which are an acknowledged problem in longitudinal studies. This is a benefit where the circumstances in question are factual, unlikely to be contested, and where only limited change is expected. It is ideal, for example, when updating household or other rosters. However dependent interviewing is problematic where any anchoring effect is likely to distort the respondent's answers which can be expected to change more fluidly from wave to wave, for example when accounting for the level of income and assets in a household.

Dependent interviewing introduces great complexity into any questionnaire and massively increases the resources needed to prepare each stage of a longitudinal study. Nevertheless, it is generally perceived positively by respondents and reduces the burden placed on them. Though it does no harm, the technique can occasionally cause frustration or a loss of confidence if a previous response has been miscoded or if several errors occur. Issues of this kind are, however, rare. Arguably, reactive dependent interviewing is more likely to cause offence since it might be construed as

checking up on, or contradicting a respondent. On the whole, this does not appear to create problems in practice. But there are two more significant issues that are introduced by dependent interviewing which need to be addressed when considering the ethical balance of a study.

The first issue that we need to be careful about when we carry out dependent interviewing is whether we are revealing confidential data inappropriately. For example, it seems reasonable that we should only feed back information to the individual who originally gave the information so as to avoid providing other individuals with information given in confidence. This rule is not strictly adhered to if the interviewer is trying to ascertain something as straightforward as who lives in the household and is eligible for interview. But it is particularly important if, for example, a proxy informant completes all or part of an interview on behalf of someone who has previously responded to the survey in person. In that event it would not be appropriate to repeat back to the proxy informant any information that the sample member had previously reported in private. Similarly, in studies such as ELSA, where concurrent interviewing is allowed, it would not be appropriate to feed information given at one wave, back to a respondent in the presence of a new partner.

Another scenario that presents difficulties is when the interviewer changes. It is questionable whether information that is given in confidence to one interviewer, should be reported back to the respondent by another. This is one of several arguments against feeding back the most sensitive information, for example about income and assets. A possible solution is to avoid complex situations such as concurrent interviewing at least where household composition has changed. Another solution is to provide respondents with a consent question which would 'switch off' dependent interviewing if the respondent was not comfortable with past information being introduced into the current interview. However this would affect the consistency and quality of data collected. Furthermore, feedback from piloting and in-depth discussions suggests that respondents expect us to remember what they have told us in the past and appreciate the fact that we acknowledge and update this information. That said, in some instances this is less clear cut, for example where the initial interview was carried out for one study and the follow-up interview (which may not have been anticipated at that time) was carried out for another. This was the situation when ELSA drew its sample from HSE respondents. In theoretical terms at least, this situation needs to be explicitly considered and defended.

The treatment of research data

All those involved in collecting primary data have an obligation to safeguard the information that is provided by study participants and to ensure that their identities remain confidential. This obligation is equally great whether the study is cross-sectional or longitudinal. Arguably, however, the criteria for judging the potential disclosivity of a longitudinal study should be more demanding, and the control measures that must be put in place to minimise this risk should be higher.

The main criterion used for assessing the potential risks that a data set has for disclosure is recommended by ONS. This is that an analyst who has no knowledge about who has or has not taken part in a study should not be able to identify an individual [check against ONS documents]. In a longitudinal study, observations of change across several waves might be used to generate unique combinations that would provide clues to an individual's identity. For example, the movement of an individual from one area of the country to another, or from one occupational classification to another, may create virtually unique scenarios that could lead to their identification. This is an example of the way that even based on this quite limited understanding of risk of disclosure, longitudinal studies may be associated with more

risk than those with only one stage of data collection, which may in turn suggest that tighter controls are needed.

This is the primary way that analysts think about risks of disclosure and follows the recommended approach to judging whether or not a data set is disclosive. The advice rules out concerns about disclosure that might take place when a rogue analyst knows that an individual has taken part in a study or knows something about an individual which might lead them to search for information about them. But the examples below show that excluding this type of abuse may not be appropriate for longitudinal studies (and perhaps some cross-sectional studies as well).

- First, a number of longitudinal studies have recruited their samples using selection criteria that are unusually transparent to the outside world. For example, three of the four British birth cohort studies selected all births in a given week of a given year, in 1946, 1958 and 1970. Similarly, the Avon Longitudinal Study of Parents and Children (ALSPAC) sampled a slightly broader birth cohort, but within a tight geographical location. This means that if one knew that an individual fitted these criteria it would be possible to search for them.

- Secondly, even without these tell tale criteria, participation in a longitudinal study, almost by definition, means that there will be repeated contacts between the study team and the study members which may increase the likelihood that attention will be drawn to an individual's participation. For example, ALSPAC invites children to visit clinics where measurements are taken, and the density of study children in local schools means that discussion about participation at the school-gate is almost inevitable (and indeed is welcomed). In these, and other similar cases, an outside observer might relatively easily identify a study member if very strict controls were not imposed.

- Finally, many longitudinal studies have several study members or respondents within each household (for example, MCS and BHPS). In some examples, these individuals may even give some of their responses in each other's presence (for example in ELSA). An individual is most likely to be able to find their own record on a data set, and by association is quite likely to find that of their partner or child. It may be extraordinarily unlikely that someone would wish to do this and have the wherewithal to do so, but it is not inconceivable, particularly when we remember that households split and that some longitudinal studies (such as BHPS and ELSA) will continue to follow several parties.

To some extent, the greater difficulty that carrying out longitudinal analysis involves may provide a natural barrier to any casual or accidental abuse. Nevertheless, the arguments above suggest that our approach to the protection of confidentiality and data security could, perhaps, be based on stricter criteria. This is something that is implicitly or explicitly acknowledged by many longitudinal study teams. The various levels of controls exercised by some of the main longitudinal studies are illustrated below.

Box 2: Examples of controls on access to longitudinal data

- As with cross-sectional studies, it is important that there is controlled access to data that is governed by accepted standards. Signed agreement is needed before data for studies such as NCDS and BCS70 can be released from the social science data archive, the Economic and Social Data Service (ESDS).
- The ESDS has recently introduced 'special licenses' to provide additional controls for more sensitive datasets (e.g. xxx).
- Despite this provision, a number of longitudinal studies will only allow analysis to

take place in a data enclave, or by using special tools that facilitate remote analysis. This is true of the ONS Longitudinal Study and the Scottish Longitudinal Study, which do not allow any data to be released externally.

- Similarly, ALSPAC and NSHD provide analysts with special data sets for each analytical project, each of which is kept separate and must be destroyed after the analysis project is completed.
- Other studies use a combination of approaches depending on the sensitivity of the data being used. For example, ELSA provides access to core data through ESDS, imposes more stringent controls on analysis which involves geography (producing special reduced data sets for that purpose), and insists on analysts working in a recognised safe setting when using administrative or genetic data.

It is also important that longitudinal studies think carefully about in-house security measures. These tend not to be the main focus of attention in these discussions but since some part of the study team is likely to hold personal details the risks of disclosure are actually greatest in this hub of activity. The ALSPAC study provides an excellent example of carefully prescribed arrangements.

6. Independent ethical overview and participant involvement

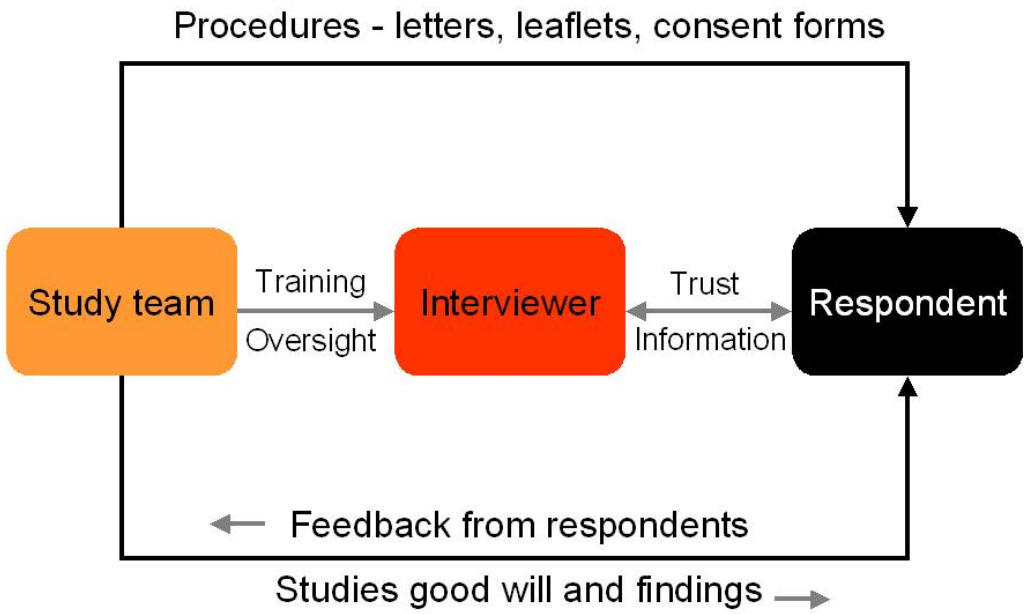
After World War II, public concern was aroused when a number of clearly unethical medical research projects came to light. This led to the establishment and continuing development of new codes of practice and to the establishment of Ethics Committees, concerned initially with clinical research but subsequently with cross-sectional and longitudinal surveys of individuals. All types of survey share some similar problems, but the time scale of longitudinal surveys adds to these, especially if there are changes in the nature of a study or when, with time, children become adults or adults age both physically and mentally. What is considered to be best practice in ethical research can also change as the years pass.

In this chapter we have considered four fundamental principles that underlie ethical research practice (informed consent, voluntary participation, avoidance of harm and confidentiality) and seen how they might be applied in longitudinal studies. In addition, the ESRC identify two general principles that must be adhered to. These are that the “research should be designed, reviewed and undertaken to ensure integrity and quality” and that “the independence of research must be clear, and any conflicts of interest or partiality must be explicit”.

On the whole, ethical committees have demanded formal arrangements to ensure these principles be applied. Scientific teams scrutinise content and oversight committees increasingly ensure that there are appropriate controls in place to steer major studies of this kind. But the informal dimensions of ethical research also need to be given consideration. To take one small example, in securing informed consent, ethical committees place significant emphasis on the content of the advance letter and (increasingly) on the content of any study information leaflet or consent form. But in practice, the act of giving consent requires trust, a concept that may sometimes be neglected or dismissed. And in addition to the formal documentation that is designed to elicit informed consent, activities such as the training and support given to interviewers so that they explain and reinforce the key information may be as or more important in providing assurance to the respondent. The box overleaf shows one representation of how both the formal and informal procedures necessary for an ethical study might be conceptualised.

Of course, study participants also rely on the study team to ask what is reasonable and to make good use of their contribution. As a result, investigators have a particular responsibility to identify and respond to any concerns that a committed participant might have, and to consider issues that a vulnerable participant may not identify for himself or herself. And investigators have an obligation to consider the more detailed ethical dilemmas that their own studies are likely to raise, which may not be noticed by an ethics committee viewing the study from a distance. They should also be encouraged to consult with independent experts and representatives of their participant group as the ALSPAC study has done so effectively.

Box 3: Formal and informal dimensions to ethical issues (trust)



Important though all of these ethical considerations are, it has been suggested that the actual conduct of social scientists must depend largely on the scientist's own set of values rather than the imposition of formal or legal controls (Douglas, 1979; Pool, 1979; Beauchamp et al, 1982). In practice, the ethical attitude of the investigator remains as vital as any formal or legal requirements.

Attitudes change, and the meticulous standards we now require would have seemed excessive a generation ago. In applying the ethical values we now adopt, there is nevertheless a need to avoid unnecessary bureaucratic requirements that have nothing to do with ethical values. The question that needs to be asked – both by investigators and by ethics committees – is: can the use of this data in the way that is proposed possibly harm the interests or the confidentiality of those who gave permission for its use. If the answer to that is no, the conscientious investigator – and the members of ethics committees - can have less to fear over the ethical validity of longitudinal surveys.

References (more to be added)

Beauchamp, TL, Faden, RR, Wallace, R, et al. (1982) Eds. Ethical Issues in social science research. Johns Hopkins University Press, Baltimore

Canada Council consultative group on ethics (1977). . Ethics: report of a consultative group on ethics, pages 6-8.

Douglas, JD (1979). Living morality versus bureaucratic fiat. In: Klockars and O'Connor 13-33 [Need full reference to Klockars' book]

GSS-Government Statistical service (1984) Code of practice on the handling of data obtained from statistical enquiries. HMSO, London

Jowell, R. (1986). The codification of statistical ethics. Journal of Official Statistics, 2, 217-253.

Medical Research Society (2005) Code of conduct [Check reference]

International Statistical Review (1986) 54, 2, 227-242

Papworth, MH (1962). Human Guinea-Pigs: A Warning, Twentieth Century Magazine, Autumn.

Papworth, MH (1969). Human guinea-Pigs. Rutledge & Kegan Paul