CONDUCTING ETHICAL RESEARCH

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1. Introduction

There are many processes involved in planning local evaluations. In addition to choosing a strategy and developing instruments to collect data (such as a questionnaire), in the earliest stages of planning your evaluation you will need to consider the ethical aspects of what is being proposed. The following guidance will outline some of the ethical issues which need to be considered when undertaking research, especially when it will involve families and children.

As you will be aware there are many long-standing and complex debates regarding research ethics. This document is less concerned with these philosophical issues than with the kind of questions which should be asked in order to ensure an ethical approach and procedures which will help to protect the welfare of all those involved in your Sure Start evaluation. The guidance therefore begins by considering briefly the question of what is meant by the term ‘ethical research’, before considering ethical issues relating to different elements of the research process, including access, informing parents and children about the research, the involvement of children, parents and staff in research, and confidentiality. This guidance is mainly directed to programme managers and partnerships and to those directly responsible for developing and implementing the local evaluation, but should be of interest and value to anyone who has an involvement in your programme’s evaluation.

2. What is ethical research?

The principle that underpins ethical research is the view that research is not just a matter of collecting information, but is concerned with the dignity, rights, safety and well-being of those who take part in research. Researchers and others involved in planning and undertaking research should therefore ensure that this principle is central to the different elements in the research process. Such concerns are not, of course, unique to research and there is considerable overlap between ethical research and ethical practice in health and social care relating to children and families more generally.

When considering the issue of research ethics, it should be acknowledged that research is far from being a neutral process. This is perhaps especially true of evaluation – many people in your programme, as well as the researchers and participants, will have a stake in the study that takes place. Questions also need to be asked, therefore, about why particular topics have been selected and how findings from the evaluation will be used. The question of how far the evaluation has the potential to improve practice and the well-being of service users needs to be considered if your research is to accord with the principle outlined above.

Assessment of whether or not it is ethical to research a particular issue will inevitably vary from programme to programme. What is appropriate to research for one programme at one point in time will not necessarily be appropriate for another. Ensuring that you have a clear rationale for the research that you propose to undertake, consideration of the resources and expertise available and the potential risks and benefits to participants as well as to the programme will all be important areas to consider. If you are unsure if what you are proposing to research is ethical
then you may also wish to consult with your regional support officer from NESS. It is also important that you discuss ethical issues with the evaluation sub-committee of your partnership board, and/or with members of the partnership as appropriate.

Research has not, unfortunately, always had the best of records when it comes to ethical practice. Many professional bodies and some organisations have therefore established codes of practice and committees which scrutinise research proposals to ensure that the research being suggested conforms to recognised standards of ethical practice. This approach is especially well-known in the health sector, where Local Research Ethics committees (LRECs) act as a clearing ground for research in health settings and involving patients. These will be discussed in further detail later in the guidance. Universities also frequently have ethics committees. Depending on who is conducting your evaluation and the issues you are researching, therefore, there may be another group of people who will consider the ethics of your proposed evaluation. However, even if you are using these formal processes, it is also important that you discuss ethical issues with programme staff, parents and other stakeholders. People are likely to hold different perceptions of what is ethical in relation to specific projects and it is important to have these discussions as early as possible.

3. Gaining access to families and young children

Gaining access is a major issue in any research project. You will need to think carefully about who should be asked to take part in your research and, following from this, the best way to collect information from them. There are a number of different ways in which you can ‘gain access’ to those groups of people you wish to include in your research, and these options are described below.

As the process of gaining access can be more time-consuming and difficult than is anticipated, it is worth discussing the issue thoroughly with members of the partnership at an early stage in the planning of your evaluation.

Accessing families directly
You will know of some families already such as those who use Sure Start services. These families may have ‘registered’ with your programme and have given their consent to be included on the Sure Start database. As part of the registration process many programmes are asking families to complete a form giving their details for monitoring purposes. You will need to ask them to sign a consent form (examples in the appendix and on the NESS website, selecting ‘Local Evaluation Methods’ and then ‘Registration and Monitoring’) so that you can hold this information. At this point you can also ask them to sign a consent form (examples in the appendix) which gives you permission to find out about them from other sources and also gives you permission to give their name and address to others within your programme who may find it relevant – either to offer a new service or to contact them for research purposes. Thus, with their written consent, you could give their name and address to your in-house evaluator who is conducting a survey about use of the toy library or another service for example.

Accessing families through gatekeepers
Gatekeepers are people who already have access to individuals or groups of people and who are attempting to safeguard the interests of others. They will therefore be
representing the interests of those others by assuming that, unless otherwise informed, the individuals do not want to be contacted. Most organisations that keep lists of their users will be reluctant to give you names and addresses, or telephone numbers. This may apply even if they are your partners in the Sure Start programme. You need to clarify with partners what kind of information they hold and what they are prepared to release, rather than planning a survey based on a non-accessible population! This issue may be a problem for your programme more generally, and one about which you are engaged in ongoing discussion.

An alternative approach may be to use the families to whom you have access as a base from which you can ‘snowball’ a sample. This refers to finding a small number of individuals and asking them to name people that they know who have similarities (e.g. a baby of one year old, English as a second language). The second round of people are again asked for names and so your sample grows!

**Gaining access to families not using Sure Start Services**

You may also want to collect information from families not using Sure Start services. There are a number of issues around sharing basic information about families living in the Sure Start area. These vary enormously between programmes. When entering into discussion with these agencies about information sharing generally, access for the purposes of evaluation should also be discussed. It may be possible for health visitors, for example, to give consent forms to families when undertaking visits. Schools in the area may also co-operate with you about this.

To reach families not using services you need to think about the places where families go, such as schools, GP practices, community centres, places of worship and recreation facilities. Some of these places will have lists of people using the service, and it may be possible to ask them to send letters out for you asking families to participate and giving them the opportunity to take part in your study. If the other organisation sends the letter to the families, then confidentiality is not breached because you do not receive the information. In addition, the principle of opt-in means that the families are not under any pressure to participate. However, asking families to contact you to say they want to take part in the research may lead to a low response rate and a small sample and the process can be time-consuming. In addition, your sample may be biased in that only those families who are interested in the research subject area and/or have strong feelings about it, are likely to respond to you (see NESS guidance on conducting user satisfaction surveys for more information [http://www.ness.bbk.ac.uk/documents/GuidanceReports/170.pdf](http://www.ness.bbk.ac.uk/documents/GuidanceReports/170.pdf)).

As part of your evaluation you may also want to talk to children who do not use Sure Start services. If this is the case then you will need the explicit consent of each child’s parent – it will not be enough to have the agreement of those running the service e.g. the manager of a nursery. Again, however, it may be possible for the service to send out letters asking for this consent and explaining what the research will involve.

In conclusion, it is essential that your research protects the rights of all families who participate in Sure Start evaluations. This includes both adults and children.
Although the process of gaining access to families may prove challenging, it must be a priority to ensure that consent is sought from all those who might take part.

4. **Informed Consent - Explaining research to parents and children**

As noted above, you may already have sought general permission from Sure Start families to access information about them from other sources, and also to share such information for research purposes. The principle of informed consent takes this further and refers to the individual’s right to decide whether they wish to participate in a specific research project. Any research you undertake will need to ensure that procedures are in place which allow potential participants to make this decision.

All research projects should, as far as practicable, be based on the freely given and informed (usually written) consent of those taking part i.e. they should understand that they are being asked to take part in research, what will be involved and their participation, based on that knowledge, should be completely voluntary. Equally, they should be aware that they can withdraw from the study at any point and without fear of retribution. They can also choose to withdraw data even after they have provided the information. However, the principle of informed consent does not remove from the researcher the duty to minimise the effects of the study – for example, through undue intrusion in the lives of participants.

In order to ensure that individuals are freely consenting to participate, they need to be given an explicit choice about whether or not to participate in the study. As the researcher/evaluator you must therefore tell them all about the study that you plan to conduct, and what it will mean for them if they do (and if they don’t) take part, prior to their agreement being given on an informed consent form. You will also need to explain why the research is being done, what it will be used for and which groups of people are being asked for information. It is important not to assume that people understand what is involved in a research project and that individuals have the opportunity to ask questions or to have explanations repeated.

**Involving children**

The 1989 United Nations Convention on the Rights of the Child, ratified by the UK in 1991, states that children should be informed about decisions that affect them. Children should also have the right to express their views, though this will of course vary according to the age and maturity of the child concerned. Similarly, the 1989 Children Act states that children, according to their age and understanding, should be consulted about plans affecting them. The qualification that age and developmental state is significant when consulting with children is important in relation to Sure Start evaluations, where children will of course be very young.

However, this does not mean they cannot or should not be included in any research you are undertaking. Within social research there has been a growing recognition non only that children should actively participate in research, but that their welfare needs to be protected within the research project. The key issue must be that children are not exposed to distress, anxiety or embarrassment as a result of the research. You may wish build on existing activities, for example story telling sessions or art/craft and drama activities.
If you are involving children then, as noted above, you will require the consent of a parent or guardian. If the latter is the case then it is especially important that the adults involved are alert to any signs of discomfort with the process.

A range of methods have been used with young children, including observation, group discussion and short one-to-one interviews, often using pictures as aids. It is important that children are in an environment that is familiar and comfortable to them and that adults known to them, whether staff or parents or carers, are available. Those undertaking such evaluation should also possess appropriate skills and experience of working with young children.

**Information for participants**

It is good practice to ensure that you have an ‘Information sheet’ that tells potential participants all about who you are, why you are doing the research, and what it will involve. If your research falls within one of the categories that require scrutiny by a Local Research Ethics Committees (see Section 8), then they will also expect to see this (and may want to change it!).

However, you may wish to consider how you present information about the evaluation. For example, you may want to approach families without the label of ‘coming from Sure Start’ so that they are completely honest about how they feel about a service. This may also be important in relation to investigations of the ‘added value’ of Sure Start to existing services – for example, an evaluation looking at changes in the health visiting service which have stemmed from Sure Start. Working with external evaluators can be useful in this respect in that they can approach families from a university base, or representing a commercial organisation, and can then produce a different kind of information sheet which does not mention Sure Start and gives a telephone contact and address not connected with the service.

The information sheet for participants should include a description of the study; what it means for the participant; how long participants will spend answering questions/filling in a questionnaire; information on confidentiality; whether taking part is compulsory and details of those to contact to ask more questions. The information sheet will need to describe all of this in very simple language, and translated into other languages spoken in the community (if applicable). You will also need to consider parents who have low literacy levels and that they only agree to take part after fully understanding what is involved. How this is managed will depend on the way in which you are accessing the sample and the methodology of the project. You may wish to give a verbal presentation to potential participants with time for questions at the end. It is also worth thinking about different ways of presenting information about the evaluation - question and answer formats and cartoons to back up written information are often useful.

**Risk or Harm**

The concept of risk or harm also needs to be carefully considered before you begin any research. In this context harm is difficult to define, as the issues will vary depending on the nature of the research. However, it is important to recognise that harm can be psychological as well as physical. Whilst physical harm needs little in the way of explanation, psychological harm can be more complex. Examples of psychological harm might be if participants are embarrassed or humiliated or placed
under undue stress during the course of a study. Less obviously, questionnaires that
ask people to reveal their attitudes or beliefs, or personal information about income,
religious or political affiliations can cause anxiety for some respondents. You need to
be sensitive to the fact that some topics can have unexpected consequences (e.g.
talking about a stressful pregnancy, or about reasons for not being able to access a
service, may lead respondents to re-live upsetting events in their lives).

While it is not always possible to anticipate all the possible consequences of
participating in a research project, specific issue – both risks and benefits – should be
identified. In this respect external scrutiny of consent forms and information sheets is
useful in terms of ensuring that your proposed research accords with accepted
principles of good practice as far as this is possible. Depending on who is
undertaking the evaluation and the nature of the research topic, this may be
undertaken by a university committee or the local LREC. If these structures are not
available to you, then it is worth consulting with other evaluators or researchers with
the necessary expertise or your NESS regional support officer.

Benefits of research are easier to mention than risks since much of your research will
be designed to improve services for families. However it must also be clear that this
usually means improvement in a general sense – for all families – not that participants
personally will receive better treatment if they complete your questionnaire.
Assurance should also be given that participation is voluntary, that research activity is
quite separate from service provision and their use of services is not related to
whether or not they take part, and that confidentiality will be upheld.

Confidentiality
The issue of confidentiality, or what happens to the information provided in the
course of a research study, can be a complex one. For example, if you are evaluating
a specific service such as home visiting, parents will want to be assured that they will
not lose the service if they do not take part in the research, or if they say something
negative about the service. Participants should be assured that no one will reveal any
names or know that they have taken part. Ensuring confidentiality is maintained will
involve making sure that information collected during a research study is kept secret
and is not used for other purposes (unless agreement has been obtained from
participants and in cases where, for example, child protection concerns have
emerged). Only researchers should be able to access the information, which should
be held in a secure place.

Involving members of the community as researchers
This issue can be especially sensitive if project staff or other service users are
undertaking the research. If this is happening then it is essential that training is
provided which includes consideration of ethical issues. You will need to be explicit
about the boundaries of the research and that information collected should not be
discussed outside the research team (and even then should not be attributed to named
individuals).

The way in which confidentiality is dealt with will also vary according to the
methodology being used, and you will need to consider this issue carefully when
selecting the methods for your study. Sometimes the issues are more straightforward –
for example, in face-to-face interviews participants can be assured that the
information will only be seen/analysed by the researcher(s) involved. In relation to focus groups, where people are being asked to express their opinions in a group of people they may or may not know, it will be important to undertake some discussion with the group about what confidentiality means in such circumstances. You may choose to develop a charter or agreement in the group about how information is to be treated, respect for individuals’ viewpoints and so on. This is a good example of the way in which an ethical approach to research should inform the entire research process.

Anonymity
A related, but separate, issue is that of anonymity. Again, participants in a research project will often be concerned about whether their names will be written down. It is usual to provide individuals with the assurance that their names will not be used in anything written as a result of the research. If you wish to undertake a follow-up study with the same individuals, you need to explain this at the point of access. Numerical codes can be attached to addresses and names (again with numerical codes attached) stored separately. However, individuals might feel they can be identified in terms of their occupation or where they live. Consideration should also be given to the use of names of, for example, schools or health centres. While again these are often disguised in research reports, when evaluating a specific service or services in a small geographical area this may be less important.

Payment to research participants
It is generally thought acceptable to offer some recompense to research participants but payment must not be used as to induce people to risk harm beyond that which they risk without payment in their normal day-to-day lives. However, payment can also lead to problems, particularly for families who are receiving benefits. A gift voucher is therefore often a better option. Other ideas for creative ways to offer some recompense while at the same time not jeopardising their benefits are given in our guidance booklet on involving parents and carers in Sure Start local evaluations (http://www.ness.bbk.ac.uk/documents/GuidanceReports/171.pdf).

Summary
To recap- the information sheet that you show to an ethics committee (if appropriate) and in due course to research participants (giving them a copy to keep) will include the following:

- The title of your evaluation – explain what it involves, how participants are being recruited, the purpose of the research, who the investigators are and their affiliations (e.g. the local health authority, Sure Start staff, local evaluator).
- Procedures – describe what the participant will be required to do e.g. where interviews are to be conducted, the length of the interview and the topics to be addressed, if any repeat questionnaires or interview or other kind of follow-up is required
- Potential risks and benefits (both to participants and to society) – discuss any psychological, social and economic harms and benefits
- Voluntary participation – give assurance that taking part is voluntary – the potential participant should be informed that he or she can withdraw from the study at any time and that doing so will not result in any penalty.
• Be clear about what the research will and will not do. Potential participants might agree to take part in a study because they feel that refusing to do so might incur negative effects e.g. their social security benefits or services might be cut. On the other hand, they might anticipate positive effects e.g. their services might increase.

• Provide assurance of the confidentiality of responses and the non-identification of participants. Explain where and how data will be stores and who will see and use the data.

• Give the name and telephone number of a researcher the family can contact with enquiries

**Consent form**
Written consent forms are usually employed to document that the process of informed consent has taken place. They will say that the individual has been given an information sheet, that it has been explained to them and that they were given a chance to ask questions about the study. It usually mentions again the idea that they are free to stop their involvement at any time, even after agreeing, and that the services they receive will not be affected in any way. Care should be taken when devising a consent form to use clear and simple language i.e. avoid jargon, technical terms and complicated sentences. There is normally a space for the respondent to sign and one for the researcher to sign. Then they will be given a copy to keep and the researcher will take the second. This form is likely to have the individual’s name and address and particular care must be taken that this is stored in a locked file in a separate location from the actual information that will be collected later (see below on data confidentiality). There are examples of consent forms which you can use as models at the back of this guidance (see Examples 3, 4 and 5).

*Research with children*
If your projects involve talking to children under the age of 16 years directly, or asking them to complete questionnaires or take part in a discussion group, then informed consent should be obtained first of all from parents or guardians. However it is common practice to also ask for children’s agreement to take part (sometimes called assent). This makes it clear to children that they can decide for themselves about their role and gives them more of a sense of participation in research.

At the beginning of your evaluation projects you will make it plain to the families that they have a right to withdraw from the investigation at any time, whether or not payment or inducement has been offered and this must also be made plain to children. Children may find it difficult to refuse an adult, so researchers should be alert to any signs of reluctance or unwillingness to take part. If this is apparent then the child should be allowed to withdraw and appropriate reassurance provided.

5. Promising and Maintaining Confidentiality
The information sheet should normally contain a promise to research participants that confidentiality will be maintained. From the outset you will be collecting information about children and families, including their name and address, possibly age, occupation, education and a variety of other characteristics. You may ask them for their views about a particular professional, about a service, or their opinions on how to discipline children, or their opinions regarding weaning. They need to be assured that you will keep that information safe, will not reveal any opinions (or even characteristics such as age) to others. At the same time you also need to state clearly that where there are concerns that a child is at risk of being harmed, then this will be reported to appropriate professionals.

Confidentiality should include the following considerations:

- Data storage and handling
- Reporting of findings
- Passing on details of participants to other agencies

At its most basic, maintaining confidentiality means that the names and addresses of participants should be stored away from all other information, linked only by an ID number, with that linkage between name and ID stored in yet another place and restricted to a small, named group. If information is moved on to other databases, this should also be made explicit and proper security checks carried out to ensure confidentiality.

**Strategies for protecting confidentiality** might include

- Coding response sheets or questionnaires prior to their administration, including only an ID number, to ensure participants cannot be identified
- Allowing only the essential members of staff to have access to the original list of participants
- Keeping research data secure (locked filing cabinets or password-protected computer files) so that only those who have a legitimate reason for accessing the data are able to do so
- Care must be taken in handling, transporting and storing the data
- Making plans for the ultimate disposal of the data, or if it is to be retained, for continued security (e.g. audio-tapes can be wiped).

**The legislative framework**

There is legislation and other protocols which aim to ensure that individuals are protected and these regulations merit careful attention. The Data Protection Act 1998 is often the subject of much confusion and is briefly outlined below. However, the Act does contain a lot of complex information and to read further, you may wish to access the website at [www.hmso.gov.uk](http://www.hmso.gov.uk). Alternatively, your partner agencies may have produced protocols or guidance concerning data protection which are worth consulting. External evaluators may also have access to advice on data protection as it relates to research.

**Data Protection Act 1998**
The processing of data is subject to the Data Protection Act 1998, which sets down eight principles governing the processing of data. Some of these apply to research information – thus data obtained for research purposes should, for example be processed fairly and lawfully and should be accurate and, where necessary, kept up-to-date. Data should not be processed to support measures or decisions relating to particular individuals, nor should it be processed in a way that would cause damage or distress to an individual.

However, information that is obtained or held for research purposes is also subject to a number of exemptions under the Act. For example, if information has been obtained for a particular purpose, then it is possible under the terms of the Act for this to be processed further if this is only for research purposes. Also, personal data which are processed only for research purposes can be held indefinitely.

There are also special rules relating to the processing of data which is considered sensitive, that is data relating to the racial or ethnic origin of the subject, their political opinions, religious beliefs, membership of a trade union, physical or mental condition, sexual life, criminal record and so on.

Other organisations have also produced guidelines that are more practical. For example, the General Medical Council regarding the electronic processing of data has issued the following advice:

- You must be satisfied that there are appropriate arrangements for the security of personal information when it is stored, sent or received by fax, computer, e-mail or other electronic means.
- If necessary, you should take appropriate authoritative professional advice on how to keep information secure before connecting to a network. You should record the fact that you have taken such advice.
- You must make sure your own fax machine and computer are in secure areas. If you send data by fax you should satisfy yourself as far as is practicable, that the data cannot be interrupted or seen by anyone other than the intended recipient.
- When deciding whether, and in what form to transmit personal information, you should note that information sent by e-mail through the Internet might be intercepted.

**Dissemination and reporting**

It is important that a participant’s individual opinions are not attributed to identifiable individuals. You can however use a false name, perhaps using only a first name or a description of the respondent e.g. mother of one, aged 27. If you wish to use case studies, it may be appropriate to change some of the details such as age, if the case study is being used to illustrate a wider point applicable to several members of the sample. Anyone handling information should be careful not to discuss individual cases with professionals or members of the public other than in exceptional circumstances, for example where there are child protection concerns. Care should be taken when reporting and reviewing your research report in partnership meetings, for example, that individual cases and participants are not discussed. Individuals should never be discussed in this way.
6. Involving members of the community in research

The Sure Start guidance on evaluation highlights the importance of involving parents, carers and grandparents in research and more detailed guidance can be found in the NESS document "The Involvement Parents and Carers in Sure Start local evaluations" (http://www.ness.bbk.ac.uk/documents/GuidanceReports/171.pdf). Often this will be as research participants, but there is also scope for parents and other members of the community to become involved as researchers, and this has already happened in a number of programmes. but it is necessary to highlight the ethical issues which should be considered if you are involving parents or other members of the community in this way.

All the same principles and issues as discussed in the rest of this guidance will be relevant and the key principle remains that of safeguarding the welfare of participants. It is also important, however, that attention is also given to the welfare of those undertaking the research, who are unlikely to have experience of this type of work and should not be exploited. Programmes should not, therefore, underestimate the need to invest time and resources in enabling parents or others to undertake research work.

Arrangements will need to be made for payment to the researchers, and some means of evidencing of their work on the evaluation – for example, you may wish to contact local colleges to find out if there are ways people could receive some form of accreditation. This can be complicated to arrange but is worth exploring. You will need to consider how people are to be recruited – for example, will literacy be a requirement for being a researcher on the evaluation? It is also recommended that those recruited to undertake the research are police-checked. Crucial to the process will be the provision of training that is of a high quality. Local universities may be willing to provide this; alternatively there are some organisations that offer evaluation training to communities. In addition to this, however, it is also important that anyone undertaking research as part of your evaluation has access to an appropriate level of support – for example, someone they can phone if they are out doing interviews as well as opportunities for debriefing.

7. Other ethical dilemmas

Giving advice
Sometimes a researcher is seen as an expert and during the course of an evaluation project participants might ask for advice about educational, health, behavioural or other such issues. If you are not qualified to offer assistance the appropriate source of professional advice should be recommended. You may be able to anticipate many requests for information or questions participants may have. It may be a good idea to have this information to hand when engaging participants for the first time. Staff should ensure that such requests are followed up to the best of their ability.

Child Protection Protocols
In the course of visiting a family or asking questions researchers sometimes discover situations that give rise to child protection concerns. Interviewers need to be trained to recognise and deal with this kind of situation. It can be unclear what action to take when one has approached a family as a researcher as this is not the same as visiting
for service provision. The researcher's job is to pass on any concerns to appropriate professionals, though they should also explain to the family that this is going to happen. It is therefore very important that at the start of any research encounter it is made clear that this will happen. Such concerns should be referred as quickly as possible, and it is essential that all those involved in research know whom to contact in such situations. This is also true for professionals who may be undertaking the research. Although they should be aware of child protection procedures, if they are carrying out research work then it is important that the same procedures are followed and that roles do not become confused. This is another important area for research training.

There may also be instances where it may be felt that the situation does not warrant action in respect to child protection but that some form of professional intervention is desirable. There is inevitably a measure of individual judgement here. It is helpful if there is a ‘debriefing’ procedure in place for researchers so that any potential concerns can be discussed with another person. In general, however, if researchers witness what they consider to be unacceptable behaviour likely to harm a child, or perhaps a child indicates abuse has taken place/is taking place, they must report to a designated person such as the programme manager who will take whatever action necessary to protect the child or children. Your programme will have a Child Protection protocol and it will be necessary to refer to this when planning how you would respond to such situations in the research context.

Information about professionals
Sometimes research participants reveal information, which may alert the evaluator to the fact that a professional has acted inappropriately or negligently. This could range from complaints about programme staff being late or unsympathetic to serious professional negligence such as lying, having sexual relations with service users or criminal activities such as fraud. Programmes should have a protocol, which allows them to raise such issues with the programme manager or another senior manager, and for keeping the participant informed of the progress of the complaint.

8. NHS Research Ethics Committees (RECs)

In order to provide research participants with complete protection and to ensure that research is ethically sound and protects confidentiality, all health-related research is overseen by NHS Research Ethics Committees (RECs). The Central Office for Research Ethics Committees (COREC) co-ordinates the establishment and management of regional Offices of Research Ethics Committees (ORECs) which in turn oversee the activities of local Research Ethics Committees (LRECs) in England.

In the majority of cases involving health related research, programmes would need to apply to an NHS local Research Ethics Committee for approval. Whether the evaluation project is being undertaken in one Sure Start programme or across several (for example a city-wide project investigating a specific theme) the procedure for application remains the same providing the programmes are located within an area covered by a single Strategic Health Authority (SHA) or domain. This procedure involves direct application to your NHS local REC (whose phone number may be found on the COREC website at www.corec.org.uk - more details given below in the section ‘New procedures for applying to LRECs’). In the unlikely event that more
than one SHA is involved, application should be made via the Central Allocation System (tel. 0845 270 4400).

8.1 When do you need to seek LREC ethical approval?

By no means all Sure Start local programme evaluations will have to go through an LREC but you will probably need approval from an LREC in the following circumstances:

- If your research involves accessing information or records held by health professionals about potential participants (e.g. their name and address)
- If your research involves NHS staff recruited as participants by virtue of their professional role
- If the researcher(s) are employed by the NHS
- If your research involves recruiting research participants in their capacity as NHS patients – for example, via a practice nurse in a GP’s surgery.

Health-related research therefore implies a broader context than simply research about a single health-related topic. Improving children’s health is a Sure Start priority and local Health Trusts/PCTs are expected to feature heavily in the majority of Sure Start local programme partnerships. With the current focus on impact evaluations you are likely to undertake some health–related evaluation.

For example, home visiting by health visitors is a key delivery mechanism for local programmes (being identified as an important intervention for tackling health inequalities – for more information on this visit www.hda.nhs.uk/evidence). Therefore you may want to conduct specific evaluation focusing on the impact of the services provided by your health visitors. LREC approval would need to be sought by your evaluator prior to the study. If you are not sure that it is necessary to seek LREC approval for a specific piece of evaluation you are planning, you can outline the study in brief (perhaps on one side of A4 paper) and submit this to the chairperson of your LREC (information on who to contact given below in the section ‘How to Apply – which REC?’). You will then be advised as to whether you will need to undertake the full approval procedure (outlined below).

An interim step might be to approach the Research and Development (R & D) department of your local Health Authority and discuss your evaluation project with them. It may well be the case that they could advise you on methodology and also peer review your study design before you submit an LREC application. If you are not sure whether your evaluation could be described as ‘research’ and thus perhaps would not require LREC approval you can go to http://www.rdforum.nhs.uk/docs/categorising_projects_guidance.doc (note: there are underscores in the gap between ‘categorising’ and ‘projects’ and between ‘projects’ and ‘guidance’). This website relates to a working guidance document produced by the NHS R & D forum and is entitled “Guidance on categorising and managing research and related projects”. There are activities (e.g. clinical audit, patient and staff surveys, quality assurance programmes, service evaluations) that may use similar methodologies to those in research but would not necessarily require assessment by a research ethics committee. The NHS R&D forum has developed the guidance to help NHS organisations to adapt a systematic approach to deciding how borderline
activities should be dealt with. This said, it is stated very clearly towards the end of the guidance document (Section 3.1 g) that any research involving NHS staff recruited as research participants by virtue of their professional role should be subject to ethical review by an NHS Ethics Committee. Therefore, given that Sure Start evaluation relating to child health will probably involve NHS staff (perhaps health visitors/midwives) it is likely that ethical approval will need to be sought.

8.2 New procedures for applying to LRECs

This is only a brief overview; for a full explanation of the new procedures refer to the Central Office for Research Ethics Committees (COREC) website www.corec.org.uk. Contained within the COREC website is a searchable database of REC contact details and meeting dates. Research Ethics Committees are listed (both geographically and alphabetically) and telephone numbers and email addresses of who you need to contact in your area are also given.

Prior to 1st March 2004, application for ethical approval via an LREC could be a lengthy process, however new operational procedures have been introduced intended to streamline and improve the system. Under the new system it is intended that all applications will be dealt with within 60 days. Ethics committees now meet on a monthly basis. (Previously under the old system it was not unheard of for approval to take between 6 – 9 months.)

Before applying you will need:

• A plan of your study, clearly outlining how you intend to go about your research. The plan will include your research question(s), sampling strategy, method(s) of data collection, data analysis and storage. You can if you wish approach the Research and Development (R & D) team of your local health authority for advice on your plan.
• An information sheet giving details of the study and a consent form for your participants (reminders on writing these can be found at the end of this section)
• You also need to make application for Peer Review of your proposed study at a local college or university (or in some cases this may be possible at your local health authority R & D department). This is to ensure that there has been prior critique of your research plan by experts in the relevant research methodology before LREC submission.

Having taken these steps you are now ready to apply for ethical approval.

8.3 How to apply

The COREC (Central Office for Research Ethics Committees) website www.corec.org.uk, was re-launched on the 14th June 2004 and is now clearly signposted with regard to user requirements. On accessing the homepage first click on Applicants then on Apply and you will be presented with a step-by-step guide on how to apply for ethical approval for your project. Information is listed under the following headings:

• Guidance for applicants – COREC has published a leaflet (New Operational Procedures for NHS RECs – Guidance for applicants to Research Ethics
Committees) to help applicants with the new operational procedures which is available on line or in hard copy. A full glossary of terms is available on the last page of this leaflet and is essential for understanding and negotiating the application procedure. A shortened glossary of terms relevant to the type of study likely to be undertaken by Sure Start programmes and Children’s Centres can be found at the end of this section.

- **Application form** - the application form can be completed on-line at [www.corecform.org.uk](http://www.corecform.org.uk). Although it is submitted electronically it also needs to be downloaded so that a paper copy containing the relevant signatures can be sent by post (this may change when the software for electronic signatures has been fully developed/implemented)

- **Applicants checklist** – any supporting documents that are required to accompany your application form are listed here

- **Which REC** (research ethics committee) – under this heading scroll down to the last paragraph which reads ‘If your proposed project is not a clinical trial of a medicinal product, does not involve prisoners and will take place within a single domain apply direct to any REC in that domain’ click here for a geographical list of all RECs in the area, arranged by domain. ‘Domain’ refers to the area covered by a Statutory Health Authority.

- **When to apply** - telephone your LREC to find out when the next meeting is to take place and the submission deadline for application (see the following section for more explanation)

- **Application fee** – there is no longer a fee for application

- **I’ve applied, what happens next?** – you will receive a validation letter acknowledging receipt of your application and accompanying documents

- **After approval** - you will be advised by letter if your project has been approved

### 8.4 Points to note when applying for ethical approval

Although the form appears lengthy at first sight you do not have to complete all the sections as these relate mostly to clinical trials, especially to trials of drugs and other medical procedures and you will not be undertaking this type of research. However, ensure you complete the form as fully as possible and watch out for questions that require more than a ‘yes’ or ‘no’ answer. Some questions ask for more information depending on whether you answer ‘yes’ or ‘no’. If questions are not answered the form may be rejected by the administrator as being not ‘valid’ and this will delay your application.

Once you have completed the form:

- Telephone your local ethics committee (the telephone number can be found on the COREC website – see above) and book in your application in advance. An agenda slot will be allocated and a reference number given (if your local ethics committee has a full agenda for their next meeting you will then be offered a space on the agenda of a different ethics committee but still within your local area (domain) in order to expedite your application. Or if you prefer you can book your application in to be heard at the next available meeting of your nearest committee.)
• The reference number must be entered onto the application form. You can send the form electronically but a paper copy with the relevant signatures and any supporting documentation should also be sent to the LREC within 4 days of booking. The 60 day clock starts on the day your LREC receives a valid application.
• You will receive a letter confirming validation within 5 days. You will be invited to attend the meeting at which your proposal will be heard. If the committee requires further information from you the clock will be stopped whilst you supply it. You will be advised of the opinion of the committee within 60 days and if the study is approved a confirmatory letter will be issued to you.

8.5 Glossary of terms
(taken from Guidance for Applicants to Research Ethics Committees)

Administrative Amendment – amendments that can be acknowledged by the REC administrator (e.g. change of contact details) and do not require review
Amendment – a change to the study after it has started
Appeal – a rejected application submitted in essentially its original form to a second committee
Booking in application – applicants book in applications by telephone via the Central Allocation system or direct to the REC (applications for single site research that is not a clinical trial of a medicinal product must be made direct to your local REC, the phone number for your local REC may be found on the COREC web-site)
Chief Investigator – the person with overall responsibility for the research; all applications must be submitted by the chief investigator
Clock – the 60 day clock for delivering a decision on a valid application
35 day clock – for amendments (no stopping)
Clock starts – on the day a valid application is received. If the clock has been stopped it starts again on the date a complete response to a request for written clarification is received
Clock stops – on the date of letter seeking written clarification or further information from applicant
Domain – the area covered by a Strategic Health Authority
LREC – Local Research Ethics Committee
Main REC – an operational term to describe the ethics committee that is undertaking ethical review for a multi-site study
MREC – Multi Centre Research Ethics Committee
Non-EU Directive studies – all studies that are not clinical trials of medicinal products
Principal Investigator (PI) – the person who is responsible for the research at a site, one PI per site
Provisional Opinion – decision reached subject to seeking further information or clarification from applicant on specific issues, the clock stops whilst waiting for a response
REC – Research Ethics Committee
REC reference number – assigned by the REC accepting the application for review
Research Site – the single organisation responsible for hosting the research at a particular locality
Revisions – changes made prior to the start of the study (and processed in the same way as Amendments)

SHA – Strategic Health Authority

Validation – an administrative check to confirm application is complete (including supporting documentation)

8.6 Research governance for Health and Social Care

At present there are no parallel arrangements such as the ones just described for research in the area of social care, however an implementation plan has been drafted by the Department of Health entitled ‘Research Governance Framework for Health and Social Care’ which aims to address this issue. This document is available at www.dh.gov.uk/assetRoot/04/08/41/83/04084183.pdf

In July 2004 the Department of Health published a consultative document setting out options for a system of ethics review in social care research. Following the consultation period, by June 2005 an implementation plan for a national system of social care ethics review will be published. It is anticipated that a national system of review will be in place by Summer 2006.

The Research Governance Framework (RGF) sets out five core principles of good practice which apply equally to research undertaken in the NHS and social care contexts. These are as follows:

ethics: ensuring the dignity, rights, safety and well-being of research participants;

science: ensuring that the design and methods of research are subject to independent review by relevant experts;

information: ensuring full and free public access to information on the research and its findings;

health and safety: ensuring at all times the safety of research participants, researchers and other staff;

finance: ensuring financial probity and compliance with the law in the conduct of research

It is recognised that there are important differences in health and social care contexts relating to the nature and volume of research, to local service structures and to the mix of stakeholders and academic disciplines. Social care research can involve some of the most vulnerable and marginalised members of society and take place in difficult and demanding social circumstances. Whilst it may not present physical risks it can be experienced as intrusive or distressing, therefore affecting participants’ well-being.

The main purpose of the RGF is to protect participants by ensuring there is a system to identify and manage any risk associated with a study. The standards and principles of the RGF will relate to any research undertaken by academic or independent bodies, individuals in or with social care agencies, and research undertaken by those agencies themselves.
8.7 Participant information sheet: points to remember

Print on institution **headed paper** – all these points need to be covered.

**Study Title** – Is the title self-explanatory and easy to understand?

**Invitation Paragraph**
This should explain that the participant is being asked to take part in a research study/evaluation. e.g.
‘You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.’

**What is the purpose of the study?**
The background and aim of the study should be given here. Also mention how long it will last.

**Why have I been chosen?**
You should explain how the participant was chosen and how many other participants will be taking part in the study.

**Do I have to take part?**
You should explain that taking part in the research/evaluation is entirely voluntary. e.g. ‘It is up to you to decide whether or not to take part. If you do decide to take part you will be given this Information Sheet to keep and be asked to sign a Consent Form. If you decide to take part, you are still free to withdraw at any time and without giving a reason’

**What will happen to me if I take part?**
You should say how long the participant will be involved in the research, how long the research will last (if this is different), how often they will be interviewed. You should set out simply the research methods you intend to use.

**What are the possible disadvantages and risks of taking part?**
You should clearly state any disadvantages or risks. Remember that there could be risks to participants when talking about sensitive issues, and it must be demonstrated that you will have the capacity to cope with any distress.

**What are the possible benefits of taking part?**
Where there is no intended benefit to the participant from taking part in the study this should be stated clearly. It would be reasonable to say something similar to:
‘The information we get from this study/evaluation may help us to improve services to families and children in this area.’
Will my taking part in this study be kept confidential?
You should explain that all information collected about them will be kept strictly confidential. e.g. ‘All information which is collected about you during the course of the research will be kept strictly confidential.’

What will happen to the results of the research study?
You should be able to tell the participant what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? You might add that they would not be identified in any report/publication.

Contact for further information
You should give the patient a contact point for further information. This can be your name, or that of another researcher involved in the study.

Remember to thank your participant for considering whether to take part in this study!

9. Resources and further information

A number of other professional groups have also established their own ethical codes and guidelines which aim to regulate research by specific professionals who may well be part of your research team (e.g. British Psychological Society, 1991; National Children’s Bureau, 1993) so it is important to read up on the ways in which these professional groups are expected to approach participants and to obtain their agreement to be part of a research study – see the list of references below.

10. Final points

Reflecting on the points outlined above may help you towards ensuring good practice in your research. Perhaps your main duty as evaluators/researchers is to respect confidentiality, and ensure data security. The Sure Start initiative is designed to improve the lives of young children and their families and research can highlight ways to modify or improve services so that children and families will benefit. However, despite this, not all families will have the time or inclination to be part of a research project and this must be respected and balanced against your efforts to make your research as useful as possible. It is also your responsibility to be honest and accurate as possible in presenting your research findings, so that all Sure Start Programmes can benefit.
References and contact information


Children and Society, volume 10, 1996 – whole volume on the ethics of research with children.

General Medical Council (website www.gmc-uk.org) Confidentiality: Protecting and Providing Information


Royal College of Paediatrics and Child Health: Ethics Advisory Committee (2000) Guidelines for the ethical conduct of medical research involving children. Archives of Disease in Childhood, 82, 177-182


Useful organisations

Consumers in NHS Research
The Help for Health Trust
Highcroft
Romsey Road
Winchester
Hampshire SO22 5DH

Tel: 01962-872247
Fax: 01962-849079
Email: conres@hfht.org

The National Children’s Bureau
8 Wakley Street
London EC1V 7QE
Tel: 0207 843 6000
www.neb.org.uk
The Neighbourhood Initiatives Foundation (provides training on evaluation)
The Poplars
Lightmoor
Telford TF4 3QN

Tel: 0870 7700339
Fax: 01592 591771
Email: training@nif.co.uk
Website: www.nif.co.uk
Appendix. Examples of written materials

1. Registration form
2. Initial research contact letter
3. Information sheet
4. Initial consent form
5. Consent form
6. Consent form
Example 1. Sure Start registration form that allows research contact

Sure Start Children’s Information Collection Sheet
Private & Confidential

Please inform parents/carers that all information will used for monitoring and referral purposes only

Date Seen: _____________________

How did you hear about Sure Start?:

________________________________________

Child’s Details

Child’s First Name: _______________________

Family/Surname Name: ___________________

Date of Birth: _________________________

Family Information

Mum’s Name: __________________________

Date of Birth __________________________

Address:

_____________________________________________________________________

Post Code: ______________________________

Dad’s Name __________________________

Telephone: ____________________________

Carer’s Name: _________________________

Mobile Tel: ____________________________

Carer’s Tel. ____________________________

Brothers’ / Sisters’ Names Date of Birth

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________
What is the main language spoken in the home?
_______________________________________

**Health Information**

G.P. Name _____________________________
Tel: _________________________________

Address: _______________________________________

Information Requested by Parent:
_________________________________________________

Further Action (please specify):
_________________________________________________

---

**Monitoring information.**

Is mum pregnant?
Yes/no*

Are you a single parents
Yes/no

Is mum or dad Smoker:
Mum Yes/no
Dad Yes/no

Are you or your partner employed
You Yes/no
Partner Yes/no

Are you planning to return to work
Yes/no

Do you have any Special Needs?
Yes/no

Does your child have any Special Needs?
Yes/no
If yes please give details:

*Delete as necessary

Ethnic Background: White: British - Irish - Other.  
Black: British - Caribbean - African - Other  
Mixed: White/Black Caribbean - White/Black African -  
White/Asian - Other  
Asian: Indian - Pakistani - Bangladeshi - Other Asian  
Background  
Chinese  
Other (please specify): ____________________________________

‘I the undersigned understand that the information on this sheet will be used for monitoring and research purposes, I also understand that this information may also be used for referral purposes, to gain appropriate additional services. This information will not be shared without my prior consent.’

Signature____________________________  
Date____________________

Print Name________________________________

For office use only:  
Sure Start Contact_________________________________ Child  
ID__________________

Referral/letters_____________________________ Mothers  
ID__________________

Sent_____________________________ date & sign

Entered_____________________________ date & Sign
Example 2. Initial research contact letter

Dear Parent

We are carrying out some research in your area into the community, children and parents.

The research relies entirely on you, as a parent, to help us to discover what it is about your community that helps you and that which does not.

The research is looking at all aspects of the community and we are particularly keen to involve you and get your views and opinions.

We need you to fill out a questionnaire with one of our researchers. It will take about 45 minutes of your time, in your own home. I know that most questionnaires can be a bit boring but I am sure that you will find this one interesting and well worth the time from your point of view as well as mine. We will be happy to fit in with your day and call on you at any time that is convenient to you.

All of the information given is strictly confidential. The information is made anonymous so that it is impossible to link your information to you.

The research is of national importance and we hope will be to the benefit of all parents. We would very much like you to be part of the future of parenting.

This letter has been sent to you via your Health Visitor. To enable us to contact you directly we need your permission.

I would be very grateful if you would allow us to meet you by signing this letter below and returning it to the school.

Thank you for reading this letter.

Name of Researcher

To the Health Visitor

I would like to be part of the research. Please give my name and address to ------------
-------------

Signed………………………………………

Name………………………………………..

Telephone number…………………………
INFORMATION SHEET

EVALUATION PROJECT

THE STUDY
You are being invited to take part in a research study. Before you decide it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with friends and relatives. Take time to decide whether or not you wish to take part.

We have recently set up a project that will look at how the community you live in and the area may have an impact on you as a parent. We hope that what we find out will help local policy makers as they plan services for children and families. In order to find out what difference the local community makes to parents, and which features of the community help parents, we need to compare several communities and one of those chosen is your area in [town]. We are asking mothers and fathers who live in your area to help with this important research.

WHAT IT WILL MEAN FOR YOU
Your health visitor has agreed to us contacting mothers of babies born in 2000. We would like to invite you to talk with a member of the research team to discuss whether you are willing to take part. If you agree we would like to keep in touch on a regular basis to find out how you, your child and other family members are getting on. This will involve in the first instance a visit by a member of our research team to your home, to talk to you for about one hour and complete some questionnaires. We may ask some mothers and fathers to take part in small group discussions with other local parents, but you can take part in the study without any group discussion.

The questions in the interview will cover some background information about your family, information about contact with relatives and friends, your views on you local neighbourhood, questions about parenting and your baby, how you are feeling, and some background about the community you lived in as a child. If you agree to take part, the first visit will be in the next few months, before your baby is one year old, with a visit or a postal questionnaire once a year for the next three years after that.

IS THIS CONFIDENTIAL?
Yes. Everything you tell us will be treated as confidential. When the information is put together, families can only be recognised by a code number. The information will not be seen by anyone outside of the research team. With your permission we will also obtain some information on your child’s progress from your child’s health record.
IS TAKING PART COMPULSORY?
No. We would like to stress that you are under no obligation to take part in the study, it is up to you to decide whether to take part or not. If you agree to take part, you will be given this information sheet to keep and be asked to sign a consent form, which you will also have a copy of to keep.

WHAT IF I HAVE QUESTIONS?
If you have any questions about the project please contact me on………………….. If you do decide to take part you are free to withdraw at any time and without giving a reason. Your decision regarding the study will have no effect on your on-going medical care or any other services in the community in any way.

Thank you for reading this.

Signature of Researcher
Example 4. Initial approach consent form

I have read the information sheet which explains the [name of study] project and I am interested in finding out more about the study.

I am happy for you to contact me in the near future to discuss the project further.

My baby’s date of birth……………………... Name of baby……………………...

Place of birth………………………………

My name …………………………………

Address …………………………………… Tel ………………………………

…………………………………………

…………………………………………

Post Code ………………………………

Signed …………………………………... Date………………………………

Investigator’s
Signature…………………………….
Example 5. CONSENT FORM

Title of research proposal:

Name of Volunteer (Block Capitals):

Address:

- The study organisers have invited me to take part in this research.
- I understand what is in the leaflet about the research. I have a copy of the leaflet to keep
- I have had the chance to talk and ask questions about the study.
- I know what my part will be in the study and I know how long it will take.
- I know that the local Research Ethics Committee has seen and agreed to this study
- I understand that personal information is strictly confidential: I know the only people who may see information about my part in the study are the research team or an official representative of the organisation which funded the research
- I know that the researchers will/might tell my general practitioner (GP) about my part in the study
- I freely consent to be a subject in the study. No-one has put pressure on me.
- I know that I can stop taking part in the study at any time.
- I know that if there are any problems, I can contact: (Researcher’s name and contact number)

Volunteer’s: Signature ........................................................
Witness’s Name ..............................................................
Witness’s Signature: ..........................................................
Date ..........................................................

The following should be signed by the Investigator responsible for obtaining consent

As the Investigator responsible for this research or a designated deputy, I confirm that I have explained to the volunteer named above the nature and purpose of the research to be undertaken.

Investigator’s Name: ..............................................
Investigator’s Signature: ............................................. Date: .............................................
Example 6. Consent Form

<table>
<thead>
<tr>
<th>Address for Correspondence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE OF PROJECT:</strong></td>
</tr>
<tr>
<td><strong>NAMES of INVESTIGATORS:</strong></td>
</tr>
</tbody>
</table>

### Section

<table>
<thead>
<tr>
<th>Please</th>
<th>Initial</th>
<th>Each</th>
</tr>
</thead>
<tbody>
<tr>
<td>I confirm that I have read and understand the information sheet.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I confirm that I have had the opportunity to ask questions and discuss the study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have received satisfactory answers to all my questions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am willing to allow access to my medical records but understand that strict confidentiality will be maintained.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I agree to take part in the study.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Participant</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Person taking Consent (if not researcher)</td>
<td>Date</td>
<td>Signature</td>
</tr>
<tr>
<td>Name of Researcher</td>
<td>Date</td>
<td>Signature</td>
</tr>
</tbody>
</table>