University of Sussex

GUIDANCE ON DATA PROTECTION, CONFIDENTIALITY, AND RECORDS MANAGEMENT

The legal framework for processing personal data in the UK is set out in the Data Protection Act 1998 (DPA).

Personal data is defined as information that relates to and identifies a living individual. Properly anonymised information is not personal because it does not identify anybody individually. Processing is defined as obtaining, using, maintaining or holding personal information.

Under the DPA data subjects have certain guaranteed rights in relation to their information. This includes a right of access and in certain situations the right to prevent further data processing. All research with human participants will process personal data at some stage and all researchers are required to comply with the DPA. Researchers should be fully aware of the requirements of the DPA.

Data Protection Act - Key points to consider:

- Participants should be fully informed about the use of their personal information and researchers must respect participants' expectations of confidence and privacy.

- Personal data cannot be used freely for further research if this research is not covered by the participants' original consent (usually detailed in your participant Information Sheet and consent form).

- You cannot collect **sensitive personal data** without *explicit consent*. Having this statement on your consent form or questionnaire ensures that you are complying with the Act. Sensitive personal data is:

    - the racial or ethnic origin of the data participant;
    - his or her political opinions;
    - his or her religious beliefs or other beliefs of a similar nature;
    - whether he or she is a member of a trade union;
    - his or her physical or mental health or condition;
    - his or her sexual life;
    - the commission or alleged commission by him or her of any offence;
    - any proceedings for any offence committed or alleged to have been committed by him or her, the disposal of such proceedings or the sentence of any court in such proceedings.

- Data must be kept securely. You need to discuss the arrangement with your School about arrangements to ensure personal information provided by participants is handled properly. **STUDENTS PLEASE NOTE:** You must ensure that your supervisor knows exactly what you are doing with the research data. *Your supervisor has overall responsibility for ensuring that personal information supplied by participants is handled appropriately.*

- Data should not be transferred outside the European Economic Area (EEA) without formal arrangements to ensure that participants' rights are protected. Formal arrangements include contracts that are drawn up between the University of Sussex and any third parties who are transferring the data.

- The ethical approval that you are applying for is specific to the research project that you have outlined in this application, and the consent given by participants is only for the purposes outlined in the consent form that they sign. If at any future date you wish to use the research data for any other purpose, you will need to apply for further approvals, and get consent from participants for this.

i. Data Collection for Screening Purposes

In some studies data is collected from people for screening purposes (to ascertain whether they are eligible to participate in the study) but it does not contribute to the study if they are excluded as a result of the screening. Please ensure that you either obtain consent for the collection and use of data for the purposes of screening (using the standard sentence relating to the Data Protection Act 1998 in the consent form) or ensure that data provided is destroyed immediately once a participant leaves the study (and that you inform participants that you will be doing this in the information provided prior to screening).

ii. Confidentiality

Confidential participant information is restricted and should not be disclosed beyond the study team. Confidence is a binding legal duty, which arises when a direct assurance of confidentiality is given by a researcher to a participant. A duty of confidence may also arise naturally when material of a sensitive or private nature is exchanged in a confidential context. Here a participant will have every right to expect that their information will remain confidential even if no direct assurance has been given. **NOTE: Researchers should generally assume that the personal information of participants is confidential especially if it touches on private or sensitive matters.**

iii. Security of Data

Researchers have a legal duty to make sure that confidential information stays secure. Anonymisation is often the best technique. Proper anonymisation ensures that privacy is protected and that sensitive data cannot be directly associated with any specific individual. Sometimes it may be appropriate for a participant to remain personally associated with their contribution. It might be right in terms of the data and of the study that information is not anonymised. In these cases the consent of participants should be secured. If confidential information needs to be disclosed to translators, transcribers, auditors or anyone else then this should be made clear to participants at the outset.

For **staff research** the person responsible for all research data and records management is the lead researcher (as named on the form). For **student research** arrangements for the management of research data and records must be discussed and agreed between the student and the supervisor, and the student is expected to abide by the agreements reached; the responsibility for managing confidential personal information provided by participants always rests with the supervisor as the University is legally responsible for this data.

Personal data should be managed with special care. It should:

- Be kept securely
- Remain retrievable
- Be accessible only to identified individuals according to clear access rules

For **research overseas** the application should include information concerning any risks to the safety of research records arising from the local research setting. Normally, records should be transferred to the University as soon as possible – other arrangements will need to justified and thoroughly detailed.

iv. Copyright Information

The handling of copyright information is also a concern. Copyright is a legal right to control the use and exploitation of original creative material. Copyright in a work is usually owned by its creator. For some of the information gathered during a research study, copyright will rest with contributing participants and not with researchers. This includes:

- Written responses to open ended questions (but not standardised multiple choice answers)
- Recorded interviews
- Transcripts of interviews

With this type of information participants are the copyright owners of their own contributions. This means that they will need to be asked for their permission every time that material is substantially copied, reformatted or reused. For advice on copyright matters contact the University's Contracts and IP team.

In addition to research data, consent forms and administrative records also need to be properly managed throughout the study. Signed consent forms are especially important and are an essential source of evidence in claims of harm resulting from participation. They must remain secure and accessible at all times. It is recommended that the study consent form and information sheet be printed back to back on the same sheet of paper. Participants should always be given their own copy of the information sheet to keep.

v. Data and Records Management Responsibilities

It is essential to retain an adequate record of the study's progress for audit and review and to manage ongoing liabilities. At the end of the study the following records should be collected together and stored securely for an appropriate period:

- A copy of the research protocol;
- A copy of the application for ethical approval along with related correspondence;
- Details of research participants including names and, as appropriate, addresses, dates of birth and other relevant details;
- A copy of the code which links participants' names to research data/results as appropriate;
- All records relating to unexpected events that arose during the research;
- Copies of research data/results;
- Copies of research publications.

The Principal Investigator is formally responsible for making proper arrangements for the ongoing storage of all study information. Storage of both physical and electronic information must be secure. The appropriate period for which study information should be retained may vary. It will depend on the nature of the study and on funder or sponsor requirements.

For original research, **anonymised data** in a useful form should be archived and made available for reuse by other researchers whenever possible. Funders are increasingly making data archiving a condition of their support.

Unanonymised personal data can be legitimately retained and reused for further research under the terms of the DPA. However, its use must remain within the scope of the participant's original expectations and any published results must be

anonymised. **If unanonymised data is to be used widely and freely then participant consent must be secured at the outset.**

vi. What About Potential Obligation to Disclose Information?

Occasionally research brings to light information about a participant which could affect the welfare of others, or the participant. For instance, an interviewee might reveal professional misconduct or a risk to public health. In these cases the need for a researcher to disclose information to an appropriate authority might override concerns about confidentiality.

Researchers are expected to identify all reasonable likelihoods concerning potential disclosure within the Participant Information Sheet and ensure that the participant is aware of situations where confidentiality may be an issue.

Potential obligations to disclose include:

- public interest (where there is a real or serious risk that another individual, or the public at large, may be put in danger by the participant);
- statutory provisions (including the Children Acts 1989 and 2004, the Public Health (Control of Diseases) Act 1984, Proceeds of Crime Act 2002 and the Terrorism Act 2006); and
- disclosures (e.g. evidence of professional misconduct) which the researcher is obliged to report in accordance with their own professional obligations.
- Researchers have a professional obligation to inform the appropriate authorities if it comes to light during a study that a child is under serious threat of abuse.
- Balance is necessary with issues of confidentiality. It is vital to respect the interests of participants but it is unnecessary to place excessive restrictions on data. Anonymisation and proper consent to disclosure will help ensure that data is protected but that it can remain useful throughout the study and beyond.

Ethical Considerations Relating to Gaining Consent

i. Informed Consent

Research participants must have the right to choose whether or not they will participate in research, and obtaining INFORMED consent is central to the ethical conduct of all research involving human participants. Fully informed consent in this context means consent freely given with proper understanding of the nature and consequences of what is proposed. The following process is recommended to ensure that this is in place:

- Each participant should be given an oral explanation.
- Each participant should then normally be given an **Information Sheet** explaining in simple, non-technical terms, what participating in the research will entail, any potential risks and hoped-for benefits.

- The participant should be given reasonable time to consider this information and to consult others as necessary.

- Except in the case of self-completion questionnaire based studies, the participant should usually be asked to sign a **consent form** (this should normally be witnessed in the case of vulnerable participants to ensure that the participant has understood the explanation and freely consents to enter the study).

- For research taking place in non-literate situations, or under other exceptional circumstances where obtaining written consent is either impossible or inappropriate, the research should clearly state the reasons why written consent is not being sought, and outline how consent will be obtained in another way.

To ensure compliance with the Data Protection Act, participants must be informed of what information will be held about them and who will have access to it (this relates to personal, identifiable information). In the case of sensitive data, explicit consent must be given, including for questionnaire based studies. It is recommended that researchers use the following sentence with a tick box option on the Consent Form:

'I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be treated in accordance with the terms of the Data Protection Act 1998.'

Important special considerations relate to research projects involving **children**: please refer to the guidance for researchers produced by the National Children's Bureau, which can be found in the 'research' section of the NCB website: www.ncb.org.uk

If it is proposed that research be conducted on persons who are not able to give fully informed consent on their own behalf justification for this must be clearly stated. Although consent cannot be given on behalf of another, it may sometimes be important to inform and/or enlist the support of those involved in the care of vulnerable individuals. Where appropriate, letters to parents, teachers and medical staff should be provided. Research involving adults (aged 16 or over) lacking the capacity to consent is governed by sections 30-34 of the **Mental Capacity Act 2005** which came into force on the 1st of October 2007. If you wish to carry out research involving individuals who lack capacity you must apply to an NHS REC http://www.nres.npsa.nhs.uk/. You should note that research projects can be approved under the Mental Capacity Act *only* if the research cannot be carried out without the participation of individuals with the 'impairing condition' *and* the research is specifically connected to that impairing condition. Where a participant loses capacity during a research project, researchers may use the data which has been collected before the onset of incapacity, but must exclude that participant from that point until they regain capacity. Alternatively they should contact an NHS REC and submit a new application which, if approved, would then permit them to use this group of participants.

ii. Right of Withdrawal

Participants have the right to withdraw at any time. This must be explained and respected throughout the research process. Researchers must not pressure any participants to re-engage with the research. It must also be made clear on all Information Sheets that the right to withdrawal extends beyond actual participation (to cover research data) and that researchers should make it clear at what point withdrawal of data is no longer possible (give a cut off date). Please give an account of the circumstances in which participants might discontinue the study, and under

what circumstances the study as a whole would be stopped. Please note that, while it acceptable for researchers to set a cut-off point for the withdrawal of data being used within the project, this cut-off point should not be at the convenience of the researcher but rather what is reasonable given the constraints of the project.

iii. Consideration of Relationship between Researcher and Potential Participant

Where the **relationship between recruiter and potential participant might be influential**, i.e. if prospective participants are colleagues or students of the researcher, this must be acknowledged. Please also provide an explanation of how you will deal with predictable problems resulting from the prior relationship (i.e. how will the researcher counteract a perceived pressure to participate on the part of the volunteer, how will the risk of potential confidentiality/anonymity breaches be minimised and what level of anonymity can realistically be guaranteed, what will happen if the researcher comes upon data suggesting professional misconduct, etc). If there are any **conflicts of interes**t in undertaking the research, this should be drawn attention to and you should indicate how these will be managed or mitigated

In **action research/research into your own workplace**, you must evaluate the extent to which your own role impinges on the research process. It is recognised that students often have dual roles, and may be studying and carrying out research whilst continuing an additional professional role. Students for whom this applies often choose to conduct their research project in their place of work. If this is relevant to your research, you may find it useful to read a King's College London guidance paper: *Research in the Workplace.* This guide includes some of the common conflicts which arise from this type of research and how to address these in a research ethics application.

iv. Deception or subterfuge

Normally deception is to be avoided unless the research topic explicitly demands this to ensure that the appropriate data are collected. In this case, you will need to clearly justify using this type of research in your ethics application. In this type of research, it is particularly important to safeguard the anonymity of participants, and where ever possible, informed consent should be sought post-hoc (British Sociological Association). See also the relevant sections of the British Psychological Society Code of Ethics and Conduct.

Acknowledgements: King's College London