Research and Data Protection Legislation

Background and audience

The UK General Data Protection Regulation (UK GDPR) along with the Data Protection Act 2018 (DPA) sets out how personal data and privacy should be managed. The legislation applies to any research project which processes personal information,[1] and this also covers commercial research where you collaborate with, for example, industry. This also applies to research outside the UK that the University is involved in. Undertaking research in an ethical, fair and lawful manner complies with the requirements for data protection legislation and must start prior to project approval by incorporating data protection and privacy into the research planning process. This guidance is intended to assist researchers with this.

Participant Information Sheet

To comply with fairness and transparency, you will need to provide a Participant Information Sheet ('the PIS' – which for non-research data collection is called the 'privacy notice') for any research project which needs to include the following[2]:

- Who is the data controller (the organisation with the overall responsibility - this will be the University represented by the lead researcher)
- Enough information, in lay language, for the participant to understand what the project is about and what is required of them
- Any significant risks to the participants involved
- Safeguards put in place to limit risks
- Consent to participate in the research
- What the legal basis is that you rely on to make the research lawful (see below "*Legal bases for conducting research using personal data"*)
- Who participants can contact for more information (lead researcher's contact details), a complaints contact and the contact details of this organisation's Data Protection Officer (dpo@ed.ac.uk)
- Details of how people can exercise their rights (see below "Research Participants Rights")
- Assurances that their data will be held securely
- For special categories of personal data[3], compliance with the common law duty of confidentiality
- A note that if the research project changes in any way, the amended PIS will be shown on the project's, Research Centre's, Institute's or School's website.

Depending on your study and if you have a study website, some of the information in the PIS can be placed on the study website. If a website is not suitable, then all information needs to be in the PIS.

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[1] 'Personal data' means any information relating to an identified or identifiable natural person ('data subject')

[2] Templates for Participant Information Sheets can be found in the Appendices

[3] Special categories of personal data are physical and mental health data, data relating to race or ethnicity, to political opinions or religious beliefs, trade union membership, criminal convictions, sexual orientation, genetic data and biometric data.

The University has published the generic part of the PIS on a website. When you recruit participants, all you need to do is use the appropriate choice of the templates in the appendices to this guidance and link from that document to the generic PIS on the website. The website can be found here:

https://www.ed.ac.uk/records-management/privacy-notice-research

A template for a PIS for health and social care-related research in CMVM can be found on the ACCORD website: https://www.accord.scot/research-access/resources-researchers/sop

For all other research, a template can be found in Appendix B

If the purpose for which you have collected the data changes – if you decide to do follow-on research, or the research plan changes in any way, you will have to inform participants. If at all possible, you will need to issue a new information sheet pointing out the changes. If, however, that is not possible, then there will need to be another way to disseminate the information. Possibilities are posting the new information on the project's website, or, if no such website exists, on the website of the Research Centre, Institute, or School, or making use of social media. This does not apply if the data has been irrevocably anonymised.

Consent

Informed, voluntary and fair consent to participate in a study is the cornerstone of ethical research involving people. It is intended to ensure the rights of individual participants are respected and is closely linked with the participant information sheet. It is through this ethics consent process that research participants can understand what taking part in a specific study will mean for them, so they can make an informed choice to either take part or decline.

To summarise, you will need ethics consent to participate such as "I agree to participate in the ... study." linked to the participant information sheet. Note, however, that you will **not** need to obtain consent for processing, sharing or storing the research data. An example of this consent form can be found in Appendix A.

Legal bases for conducting research using personal data

Personal data

In most circumstances the legal basis for using personal data for research will be 'public task'. This is evidenced in the generic part of the PIS with a statement making reference to the University's public research purpose as established by the Universities (Scotland) Act 1966. By using 'public task' as the legal basis, we can ensure that as a publicly-funded organisation, it is always one of our official, public tasks when we use personal data from people who have agreed to take part in research, and that you are part of a reputable organisation that has a genuine reason to hold and use personal data. This is in addition to the control given to participants through the research ethics consent (to participate in research) process.

Special categories of personal data

If the research contains health data including genetic and biometric data, information about race or ethnicity or religious/philosophical beliefs, then you will need to have an additional legal basis for processing the data. In addition to the reference to the

research being a public task as stated in the generic PIS, the legal basis will be 'processing ... necessary for … scientific or historical research purposes in accordance with Article 89(1)'. This leads to the requirement for so-called safeguards in Article 89(1) for all research processing special categories of personal data and you will need to ensure that you comply.

Article 89(1) safeguards

The new legislation has been written with research in mind, and most of the safeguards needed will already be familiar to you and are likely to be present in most scientific research already. These safeguards consist of technical and organisational measures and provide research participants with assurance that their personal data is:

- Necessary to support research,
- Will only be used to support legitimate research activities that are considered to be in the public interest,
- Their interests are safeguarded/protected, and
- Not be likely to cause substantial damage or distress to an individual.

Technical and organisational measures are:

- The minimisation principle – use only the absolute minimum of personal data required for your purpose
- Anonymise personal data if you can
- If you cannot anonymise, wherever possible, pseudonymise all personal data
- Store the data securely

Besides having these technical and organisational measures in place, you must be able to prove that your research is in the public interest. Similar to the technical and organisational measures, the types of evidence for proving that research is in the public interest will be familiar to research and very likely already in place.

Public interest test – examples of evidence:

- Your research must be proportionate
- Your research is subject to a governance framework
- REC review (does not have to be a European REC)
- Peer review from a funder
- Confidentiality Advisory Group (CAG) recommendation for support in England and Wales or support by the Public Benefit and Privacy Panel (PBPP) for Health and Social Care in Scotland

Specifics for using medical or other confidential data

For some kinds of medical research, you must still comply with other relevant statutes and requirements such as the Human Tissue (Scotland) Act 2006.

Please also note that the common law duty of confidence is **not** affected by the implementation of the UK GDPR and DPA. While personal data and confidential information will frequently overlap, they are not identical. Information is considered confidential under common law if:

- It is not in the public domain, and it can be related to an identifiable individual who can be living or deceased, and

- It has a degree of sensitivity associated with it, and
- It is given with the expectation that it will be kept confidential, such as due to the relationship between a patient and their doctor, nurse, researcher, etc.

Research initiated before 25 May 2018

If a study has started before 25 May 2018, i.e. before the new data protection legislation came into force, you do not have to do anything as you can rely on the consent that you have originally obtained from the research participants. If the study started before 25 May 2018 and is still recruiting, the same consent form can still be used. If you want to conduct any follow-on studies, you will not have to re-consent the participants, instead, the original consent will be considered 'broad consent' which includes future studies.

If, however, the data you want to use for your research was originally collected for non-research purposes and the legal basis was consent, then that consent does NOT cover your research.

Research Participants' Rights

You can restrict the rights of research participants if you believe that granting them would prevent or seriously impair the achievement of the research purpose, however, only where 'appropriate safeguards' are in place. The lead researcher will make the final decision.
In these circumstances, you can restrict the following rights:

- The right to rectification
- The right to restrict processing
- The right to object to processing
- The right to erasure (right to be forgotten)

To evaluate whether granting these rights would prevent or impair research, you will need to consider timing: The decision is always context dependent and may change during the course of a study. For example, the request to erasure by a single individual from a research project may be easier to facilitate and therefore would have little impact on the study. The same request from ¾ of the participants of that project would have a serious impact on the study. At the same time, the possibility of the participants in, for example, a clinical trial suffering distress is exponentially greater than participants in a paper-based survey.

At a reasonably early stage of a study it could be possible to meet a research participant's request for erasure without significantly impairing the quality or validity of research in a way that might not be possible at a later stage.
<u>Take into consideration:</u>

- resource implications
- available technology

<u>In addition, you will not have to comply with subject access requests, where:</u>

- the results of the research or any resulting statistics will not be published in an identifiable form, or
- in the opinion of an appropriate health professional, disclosure to the data subject is likely to cause serious harm.

You should seek the advice of your local Data Protection Champion first before responding to any exercise of a data subject's rights.
You can find out who your local Data Protection Champion is on this website: https://www.wiki.ed.ac.uk/pages/viewpage.action?spaceKey=FoIP&title=Data+Protection+Champions
You can also ask the University's Data Protection Officer for advice, who can be reached at dpo@ed.ac.uk**.**

Data Protection Impact Assessments (DPIA)

A DPIA is an assessment to help you identify any potential risks a project might have as regards intruding into participants' privacy. The DPIA then assists with implementing appropriate measures and controls to minimise and manage those risks. The legislation has made DPIAs mandatory to ensure that privacy and data protection are key considerations from the start of any project and then taken into account throughout the project's lifecycle.

For most studies, the DPIA is included in the internal Research Ethics Committee approval process, however, some funders will require a separate DPIA. If this is the case, seek the advice of your local Data Protection Champion who will be able to direct you to the template and guidance. You can also ask the University's Data Protection Officer for advice, who can be reached at dpo@ed.ac.uk**.**

Student research

The University is not the data controller for personal data processed by students to pursue a course of study with the University. Students undertake a course of study with a University for their own personal purposes, most obviously to obtain a qualification. They make decisions about what work they will do, the way in which they will do it and what to include in the final write up themselves in order to prove that they are capable of degree-level work. They work on behalf of themselves and not the University. The domestic purposes exemption applies with the result that students are not subject to data protection laws, however, students will still be bound by the University's policy and procedures – to ensure that their work complies with the data protection principles, that they complete a DPIA and follow the guidelines provided in this document. See also here:
Personal data processed by students

APPENDIX A
PARTICIPANT CONSENT FORM

Study Title: ……

Please initial box

1. I confirm that I have read and understood the Participant Information Sheet for the above study. ☐

2. I have been given the opportunity to consider the information provided, ask questions and have had these questions answered to my satisfaction. ☐

3. I understand that my participation is voluntary and that I can ask to withdraw at any time without giving a reason and without my medical care or legal rights being affected. ☐

4. I understand that my anonymised data will be stored for a minimum of 5 years and may be used in future ethically approved research. ☐

5. I agree to take part in this study. ☐

Name of person giving consent	Date	Signature
_____	_____	_____

Name of person taking consent	Date	Signature

APPENDIX B – NON-MEDICAL RESEARCH

PARTICIPANT INFORMATION SHEET

You are being invited to take part in research on [research topic]. [Name and position] at the University of Edinburgh is leading this research. Before you decide to take part it is important you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to [summarise research focus and aims.]

WHY HAVE I BEEN INVITED TO TAKE PART?

You are invited to participate in this study because you [give reasons for contacting the individual].

DO I HAVE TO TAKE PART?

No – it is entirely up to you. If you do decide to take part, please keep this Information Sheet and complete the Informed Consent Form to show that you understand your rights in relation to the research, and that you are happy to participate. If you do decide to take part you are still free to withdraw at any time and without giving a reason. Please note down your participant number (which is on the Consent Form) and provide this to the lead researcher if you seek to withdraw from the study at a later date. Deciding not to take part or withdrawing from the study will not affect your xxx (e.g. healthcare, employment etc.)

WHAT WILL HAPPEN IF I DECIDE TO TAKE PART?

You will be asked a number of questions regarding [briefly describe the kinds of data you will require]. The questionnaire/interview/focus group [delete as appropriate] will take place in a safe environment at a time that is convenient to you. Ideally, we would like to audio record your responses (and will require your consent for this), so the location should be in a fairly quiet area. The questionnaire/interview/focus group [delete as appropriate] should take around [specify likely time duration] to complete.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

By sharing your experiences with us, you will be helping [name] and the University to better understand … [key research focus].

ARE THERE ANY RISKS ASSOCIATED WITH TAKING PART?

There are no significant risks associated with participation. [if there are any significant risks, these must be specified].

WHAT IF I WANT TO WITHDRAW FROM THE STUDY?

Agreeing to participate in this project does not oblige you to remain in the study nor have any further obligation to this study. If, at any stage, you no longer want to be part of the study, please inform the project administrator [name, contact details]. You should note that your data may be used in the production of formal research outputs (e.g. journal articles, conference papers, theses and reports) prior to your withdrawal and so you are advised to contact the research team at the earliest opportunity should you wish to withdraw from the study. On specific request we will destroy all your identifiable answers, but we will need to use the data collected prior to your withdrawal, and to maintain our records of your consenting participation.

DATA PROTECTION AND CONFIDENTIALITY

Your data will be processed in accordance with Data Protection Law. All information collected about you will be kept strictly confidential. Unless they are anonymised in our records, your data will be referred to by a unique participant number rather than by name [amend as appropriate]. If you consent to being audio recorded, all recordings will be destroyed once they have been transcribed. Your data will only be viewed by the researcher/research team. [if the data are to be shared with 3rd parties, you must declare this here and name the parties concerned.] All electronic data will be stored on a password-protected computer file and all paper records will be stored in a locked filing cabinet. Your consent information will be kept separately from your responses in order to minimise risk.

INTERNATIONAL DATA TRANSFERS [only required if applicable]

Your data may/will [delete as required] be stored and processed in [state location]. Please note countries outside of the European Economic Area may not offer the same level of data privacy protection as in the UK. [NB: contact the Data Protection Officer before you share any personal data outside the EEA].

WHAT WILL HAPPEN WITH THE RESULTS OF THIS STUDY?

The results of this study may be summarised in published articles, reports and presentations. Quotes or key findings will always be made anonymous in any formal outputs unless we have your prior and explicit written permission to attribute them to you by name. Information may also be kept for future research [delete if not applicable]

WHO CAN I CONTACT?

If you have any further questions about the study, please contact the lead researcher, [name, contact details].

If you wish to make a complaint about the study, please contact:

[insert names and contact details of supervisor, line manager or Associate Dean for Research]:

In your communication, please provide the study title and detail the nature of your complaint.

You can get this document on tape, in Braille, large print and various computer formats if you ask us. Please contact us on [insert contact details] and quote reference number [.....].

For general information about how we use your data go to:

Privacy notice for research participants (continued)

APPENDIX C – MEDICAL RESEARCH – see also guidance from ACCORD at https://www.accord.scot/research-access/resources-researchers/sop

PARTICIPANT INFORMATION SHEET
[Study Title]

You are receiving this as you are currently a participant on this clinical research study. The information below details what data is held about you and who holds or stores this.

[[University of Edinburgh] [NHS Lothian] is the sponsor] OR [University of Edinburgh and NHS Lothian are the co-sponsors] for this study based in [the United Kingdom/ country]. We will use information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. [The sponsor] OR [The co-sponsors] will keep identifiable information about you [for x years after the study has finished] OR [until x].

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

OPTIONAL TEXT – select appropriate sections and delete other options. Delete all grey highlighted text and sections of text that are not relevant to your study.

A: Where participants are providing personal data directly i.e. personal data is obtained for the primary purpose of research either verbally or in writing from participants e.g. questionnaires or interviews, or documented by care staff e.g. diagnosis, or obtained from care interventions e.g. lab results

Providing personal data directly e.g. verbally, in a questionnaire or from your care provider

EITHER:

1. If a code system is used and the key is kept confidential and not disclosed to the sponsor, except where the sponsor is also the site

[NHS/ other site] will keep your name, [NHS/ Community Health Index (CHI) number] and contact details [add other identifiers] confidential and will not pass this information to [sponsor organisation]. [NHS/ other site] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from [sponsor organisation] and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [Sponsor organisation] will only receive information without any identifying information. The

people who analyse the information will not be able to identify you and will not be able to find out your name, [NHS/ CHI number] or contact details.

[NHS/ other site] will keep identifiable information about you from this study [for x years after the study has finished/ until x].

OR

2 [If the sponsor will receive personal data, or where the sponsor is also the site]

[NHS/ other site] will use your name, [NHS/ Community Health Index (CHI) number] and contact details [add other identifiers] to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from [sponsor organisation] and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [NHS site] will pass these details to [sponsor organisation] along with the information collected from [you and/ or your medical records]. The only people in [sponsor organisation] who will have access to information that identifies you will be people who need to contact you to [insert reason] or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, [NHS/ CHI number] or contact details.

[NHS/ other site] will keep identifiable information about you from this study [for x years after the study has finished/ until x].

B: Where participants are providing information indirectly e.g. being obtained from previously collected medical records or database.

Providing personal data indirectly e.g. from your medical records

EITHER

1. If a code system is used and the key is kept confidential and not disclosed to the sponsor

[Sponsor organisation] will collect information about you for [research/ this research study] from [source]. [Source] will not provide any identifying information about you to [sponsor organisation]. We will use this information to [purpose].

OR

2. If the sponsor will receive personal data

[Sponsor organisation] will collect information about you for [research/ this research study] from [source]. This information will include [your name/ NHS/ Community Health Index (CHI) number/ contact details/ add other identifiers] and health information, which is regarded as a special category of information. We will use this information to [purpose].

C. Where data is intended to or likely to be used for future research

Use of data for future research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this

organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

EITHER:

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

OR:

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of healthcare research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee and/ or the sponsor.

Contact for further information

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at www.accord.scot.

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; https://www.hra.nhs.uk/information-about-patients/.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Data Protection Officer contact information:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
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Tel: 0131 465 5444
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