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# CARDIFF UNIVERSITY POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS, HUMAN MATERIAL OR HUMAN DATA

# INTRODUCTION

# Cardiff University is committed to protecting the safety, rights and dignity of all those involved in research and to fostering an environment where research is conducted to the highest ethical standards.

# This Policy provides a framework for the ethical conduct of research involving human participants, human material or human data (referred to hereafter as ‘Human Research’) by confirming:

# the role and responsibilities of individuals, teams and committees in ensuring the ethical conduct of Human Research at Cardiff University;

# the guiding principles that underpin Human Research; and

# the University’s expectations and procedures for the ethical review of Human Research.

# For the avoidance of doubt, the University is committed to rigorous and objective inquiry and supports its staff and students to pursue research in an environment that affirms academic freedom. This Policy is not intended to limit academic freedom and does not require the avoidance of potentially high-risk research. Instead, this Policy aims to encourage staff and students to give proper consideration to the ethical issues and risks arising from their research and to manage such risks appropriately.

# This Policy must be read in conjunction with the University’s [Research Integrity and Governance Code of Practice](https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/research-integrity-and-governance) which comprises a framework for the responsible conduct of research at Cardiff University.

# SCOPE OF THIS POLICY

# This Policy applies to all members of staff and students at the University conducting Human Research, including those conducting Human Research outside the University (but as part of their University role), as well as any persons not employed by the University but with permission to carry out Human Research within, or on behalf of, the University (all referred to hereafter as ‘Researcher’ or ‘Researchers’).

# Research

For the purposes of this Policy, ‘Research’ means any project which attempts to derive generalisable new knowledge or apply existing knowledge, including studies that aim to generate hypotheses, as well as studies that aim to test them.

‘Service Evaluation’ and/or ‘Audit’ activities will not usually constitute ‘Research’ for the purposes of this Policy. However, Research Ethics Committees may exercise their discretion to require that such activities are subject to ethical review, where appropriate.

For the purposes of this Policy ‘Service Evaluation’ is an activity which seeks to assess how well an existing service is performing. The activity is designed and conducted with the sole purpose of defining or judging a current service. ‘Audit’ is an activity which usually involves a quality improvement cycle that measures performance against predetermined standards and recommends specific actions to improve performance.

# Human Material

# For the purposes of this Policy, ‘Human Material’ means material that comes from the human body including: (i) ‘Relevant Material’ for the purposes of the Human Tissue Act 2004 i.e. material that comes from the human body and contains or consists of human cells, including bodily fluids (e.g. saliva, blood and urine), waste products and solid sections of tissue; (ii) other material not considered ‘Relevant Material’ but which has (or is being) collected directly from a human (alive or deceased); and (iii) archaeological human remains[[1]](#footnote-2), including osteological material (whole or part skeletons, individuals bones or fragments of bone and teeth), soft tissue, including organs and skin, embryos and slide preparations of human tissue.

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# Human Data

# For the purposes of this Policy, ‘Human Data’ means:

# ‘Personal Data’ which comprises data relating to an identified or identifiable person i.e. a person who can be identified directly or indirectly by reference to an identifier such as a name, identification number, location data, online identifier or one or more factors specific to that person i.e. their physical, psychological, genetic, mental, economic, cultural or social identity; and/or

# Other information collected directly from, or relating to, a specific human regardless of whether the data is anonymised.

# Notwithstanding the above definition, Research involving the access and/or use of anonymised data only may be exempt from the University’s requirements for ethical review. Please see Section 5 for further detail. Even where ethical review is not required, Researchers proposing to conduct Research involving Human Data must still abide by the principles of this Policy.

# Researchers need to be mindful of situations where their perceived use of anonymised data may actually amount to processing of ‘Personal Data’. For example, data will be considered Personal Data where Researchers have, or will likely gain access to, a key, or other means, that would enable re-identification of the individual to which the data relates. Researchers will be deemed to have ‘access’ where the key to identify the individual(s) is held anywhere within Cardiff University. Further guidance on ‘Personal Data’ and ‘Anonymised’ data is contained in the University’s ‘Framework for the Ethical Review of Research using Secondary Data and/or Publicly Available information only’, contained at Appendix 2 of this Policy.

# ROLES AND RESPONSIBILITIES

# This section confirms the role and responsibilities of specific individuals, teams and committees in ensuring the ethical conduct of Human Research at the University. However, for the avoidance of doubt, everyone involved in conducting or supporting Human Research at Cardiff University is expected to abide by the highest ethical standards and to promote ethical and responsible practice in all research activity.

# Researchers (including Research Supervisors)

# Researchers are ultimately responsible for ensuring that their Research is conducted to the highest ethical standards. In respect of Human Research specifically, this includes taking personal responsibility for:

# identifying the ethical issues arising from their Research, giving particular attention to the matters stated in [Section 4](#_GUIDING_PRINCIPLES_IN);

# submitting an application for ethical review to the appropriate research ethics committee (where required), ensuring that all information provided within the application is complete and accurate (see [Section 5](#_ETHICAL_REVIEW_REQUIREMENTS));

# ensuring that the Research has obtained a favourable ethical opinion (where required), from an appropriate ethics committee, before the Research commences (see [Section 5](#_ETHICAL_REVIEW_REQUIREMENTS));

# undertaking appropriate training in research ethics and reflecting on whether such training and/or past experience enables them to evaluate the ethical implications of their Research;

# keeping the ethical issues arising from the Research under regular review, amending project documents and seeking ethical review of such amendments (where required);

# ensuring that all Research activity is within the scope of the favourable ethical opinion obtained, where applicable; and

# acting in accordance with all other relevant University, funder and professional body policies, procedures and guidance in relation to the ethical conduct of Research.

# Schools/Head of School

# Schools are responsible for either:

# establishing a School Research Ethics Committee (SREC) (or equivalent) and procedures for the handling of ethical issues arising in Human Research; or

# making alternative arrangements to ensure that all Human Research requiring review, in accordance with this Policy, is subject to appropriate ethical review.

# Where a School does not have a SREC, the Head of School is expected to provide a written declaration to the Open Research Integrity and Ethics Committee (ORIEC) to explain why such a committee is considered unnecessary. This declaration process is managed through an annual reporting cycle (from Schools to ORIEC).

# In accordance with the Cardiff University Template Procedures for School Research Ethics Committees, the Head of School is responsible for referring appeals and/or matters requiring advice and guidance (referrals) from the SREC to ORIEC.

# School Research Ethics Committee

# The SREC is responsible for reviewing applications for ethical review for all Human Research proposed by Researchers within the School unless ethical review falls within the remit of a mandatory external ethics committee or a specific exemption applies (see Section 5 and Appendix 1). The role of the SREC is to review the information provided by the Researcher, to consider the ethical implications of the Research proposal and to ensure that the Research complies with relevant ethical standards and protects participants from unnecessary harm. It is the responsibility of the SREC to provide Researchers with an ethical opinion on the Research.

# Each SREC operates in accordance with a procedural framework (entitled ‘Cardiff University Template Procedures for School Research Ethics Committees’) issued by ORIEC. The framework comprises a template procedure for adoption by the SREC and contains a set of minimum standards, alongside confirmation of the areas where the SREC has discretion to adopt bespoke/discipline-specific measures. As such, the SREC is responsible for publishing and managing its procedures for the ethical review of Human Research conducted within the School.

# School Ethics Officer

# Each School has appointed a School Ethics Officer (SEO) who is responsible for:

# ensuring there are effective mechanisms via the SREC or School Board (as appropriate) to bring any policy, guidelines or procedures developed with or through the ORIEC and the SREC to the attention of staff and students for whom the School is responsible. These mechanisms must make it clear that it is a University requirement that these policies, guidelines and procedures are followed;

# keeping School research ethics matters under review;

# managing and monitoring the School’s ethics procedures in practice;

# ensuring that appropriate records of applications, decisions and practices are made and retained by the School;

# reporting to the Head of School, as appropriate;

# reporting to the School through an appropriate forum, such as the School Board;

# reporting to ORIEC on an annual basis on behalf of the School; and

# conducting a three yearly review of School ethical procedures and reporting to ORIEC on behalf of the School.

# Open Research Integrity and Ethics Committee

# ORIEC is responsible for developing and sustaining a University-wide awareness of Research Integrity and this includes the ethical issues arising from Human Research. ORIEC is responsible for producing and monitoring guidelines on the responsible conduct of such Research and for ensuring that all Schools manage such Research appropriately. ORIEC’s function is, therefore, predominantly one of oversight and policy review/development.

# In exceptional cases, ORIEC will consider and give guidance on specific cases or other matters referred to it by the SREC, through the Head of School, including appeals against a decision of the SREC.

# ORIEC’s Terms of Reference and Membership are publicly available on the Cardiff University internet pages[[2]](#footnote-3).

# Research Integrity, Governance and Ethics Team

# The Research Integrity, Governance and Ethics Team (RIGE) (in Research and Innovation Services) is responsible for the provision of general advice and resources on research governance, research integrity and research ethics and for promoting the responsible conduct of Research and the responsible use of research assessment/metrics. RIGE has administrative responsibility for this Policy and for the University’s Research Integrity and Governance Code of Practice.

# The Head of RIGE is Secretary to ORIEC and prepares the agenda and minutes for each ORIEC meeting. RIGE works closely with ORIEC to provide assurance that the University has appropriate systems in place to ensure that Research is conducted to the highest ethical standards.

# In addition, RIGE has specific responsibility for helping Researchers to secure compliance with the rules that govern clinical research. This includes, but is not limited to, reviewing (and where appropriate, granting approval for) applications for Sponsorship in respect of all Research studies that fall within the scope of the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

3.7 Human Tissue Act Compliance Team

3.7.1 The Human Tissue Act (HTA) Compliance Team (based in the College of Biomedical and Life Sciences) is responsible for providing and maintaining a robust system of governance and ensuring Researchers have the framework to adhere to the HTA. The HTA Compliance Team has administrative responsibility for the University’s Code of Practice for Human Tissue Research and the associated SOPs.

3.7.2 In addition, the HTA Compliance Team has a specific responsibility to review all SREC applications that involve the collection or use of relevant material prior to submission to the SREC. This review is not limited to Schools within the College of Biomedical and Life Sciences; it includes any SREC application involving relevant material in the College of Arts, Humanities and Social Sciences and the College of Physical Sciences and Engineering.

# GUIDING PRINCIPLES IN HUMAN RESEARCH

# For all Human Research, the safety, rights and dignity of the participant must be the primary concern. This section contains the overriding principles that underpin Human Research, followed by guidance in specific areas.

# Overriding Principles

# The benefits of the Research must outweigh the risks; Research must be designed in a way that ensures the maximum benefit whilst minimising risk.

# Harm to those involved in, or affected by, Research must be avoided or minimised wherever possible. Researchers must conduct an appropriate risk assessment to identify and manage the risks posed to participants, and others involved in the Research.

# Participants must be treated as autonomous individuals and provided with an opportunity to give free and informed consent to participate in Research. As a general rule, participation in Research must be voluntary and participants must be free to withdraw from Research at any time without giving a reason, and without adverse consequences.

# Confidentiality of the information given by participants must be respected and Personal Data must be processed in accordance with data protection legislation and as notified to the participant. Whilst anonymisation of Personal Data is encouraged, this does not guarantee privacy and consequently all data must be stored securely and destroyed securely after the expiry of the relevant retention period set out in the University’s [Research Records Retention Schedules](https://www.cardiff.ac.uk/public-information/policies-and-procedures/record-management-policy-and-retention-schedules).

# The independence of Research must be maintained, and conflicts of interest must be declared and managed (please see guidance contained in our [Research Integrity and Governance Code of Practice](https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/research-integrity-and-governance)).

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# Recruitment of Participants

# Researchers must carefully consider and document (usually within a protocol/proposal) the recruitment procedures for their project, including:

# how potential participants will be identified;

# who will be responsible for determining whether a participant meets the eligibility criteria;

# who will make initial contact with the participant;

# whether any participants will be recruited publicly (using leaflets, posters or websites);

# the information to be provided to participants, before they are asked to give consent to participate (where applicable);

# who is responsible for obtaining informed consent (where applicable). See [Section 4.4](#_Informed_consent); and

# the number of participants required. This number should be sufficient to make the Research viable but should not be so high as to involve unnecessary recruitment and burden for participants.

# Researchers must ensure that the individual(s) responsible for identifying and/or approaching potential participants is appropriate in the circumstances. For example, in a clinical research context, only a member of the patient's clinical care team should have access to patient records without explicit consent, in order to identify potential participants and it is often more appropriate for a member of the clinical care team to make initial contact with potential participants. For Research involving prisoners, it is generally unacceptable for prison staff to be used as gatekeepers, as care must be taken to eliminate bias and to ensure that the decision by the prisoner to participate in Research is truly voluntary (see [Section 4.4.4](#_Freely_given)).

# If the Research involves the recruitment of staff or students within the University, consideration must be given to the method of recruitment to ensure the potential participants do not feel obliged to participate. Individuals should not be approached directly without having first given consent to be approached. A culture of routine participation as the expected norm should be avoided.

# Informed Consent

**The guidance contained in this Section 4.4 reflects the position for consent to participate in Research only; it does not address the requirements of the General Data Protection Regulation and the UK Data Protection Act 2018 if 'consent' is being used as the lawful basis to process Personal Data. Please see** [**Section 4.6**](#_Data_Protection_and) **for specific information about what participants must be told about the use of their Personal Data.**

# Informed consent is a key ethical requirement of Human Research and any departure from this requirement must be justified. Save for exceptional cases, Researchers must ensure that all participants have provided informed consent to participate in the Research.

# For consent to be valid, it must be fully informed, freely given and involve affirmative action from the participant. These principles are explored below:

# *Fully informed*

# Participants must be provided with clear and accurate information about the Research. This will usually be in the form of a Participant Information Sheet (PIS). However, it is important that Researchers do not place exclusive reliance on the PIS and actively discuss the Research with participants and provide them with an opportunity to ask questions.

# Any information provided to participants must be suitable for the participant group and must be written in lay language wherever possible. Where Research involves multiple participant groups, it may be necessary to prepare a separate PIS for each group. This will be particularly important when dealing with a wide-ranging participant age group (where the adult PIS may not be appropriate for, or understandable to, a child participant).

# Whilst not an exhaustive list, for consent to be 'fully informed', participants should generally receive information about all the matters contained within the University’s [template PIS](https://intranet.cardiff.ac.uk/staff/supporting-your-work/research-support/research-integrity-and-governance/research-ethics/ethical-review/school-research-ethics-committees-srecs)[[3]](#footnote-4).

# Participants must be given an appropriate length of time to consider the implications of participating in the Research, before being asked to give informed consent. There are no fixed guidelines for the time to be allowed to participants. In a clinical research context, it has been common practice to suggest a minimum of 24 hours, but this is not an absolute rule. Each project must be considered on its own merits.

# It is important that consent is managed as a process, rather than a one-off event, and Researchers must ensure that participants continue to be informed about the Research and provide their consent to participate throughout the Research process.

# *Freely given*

# Consent must be voluntary and participants must provide their consent free from pressure, coercion or inducement.

# Care must be taken where participants are in a dependent relationship with the Researcher/Research Team and may feel an onus to participate. Examples include:

* + Students/junior Researchers participating in Research conducted by their tutors/supervisors.
  + Members of staff participating in Research carried out, or formally supported by, the management of their organisation.
  + Residents of care homes.

# Similarly, where a 'gatekeeper' is required to enable a participant to consent, or to enable the Researcher to gain access to the participant, care must to be taken to ensure that participation is truly voluntary, and the participant did not feel pressured to take part. A ‘gatekeeper’ for the purposes of this section is any person that acts as an intermediary between the Researcher and the potential participant. Examples include health and social care professionals working with patients, children or the elderly or an employer (where Research is conducted with participants within an organisation).

# *Affirmative action*

# Informed consent must involve specific affirmative action by the participant, and cannot be inferred from silence or via an 'opt-out' process.

# Taking consent from participants

# Researchers proposing to take informed consent from participants are required to undergo appropriate training to ensure that the consent process is managed appropriately.

# Documenting consent

# It is important that consent is documented, and that evidence of consent is retained in accordance with the University's [Research Records Retention Schedules](https://www.cardiff.ac.uk/public-information/policies-and-procedures/record-management-policy-and-retention-schedules). Obtaining consent via a written and signed consent form is often regarded as the 'gold standard' for any Research project and any departures from this standard should be justified. The University has prepared a [template Consent Form](https://intranet.cardiff.ac.uk/staff/supporting-your-work/research-support/research-integrity-and-governance/research-ethics/ethical-review/school-research-ethics-committees-srecs)[[4]](#footnote-5) for Researchers to consider and utilise as appropriate.

# However, written consent may not always be the most appropriate form of recording consent, particularly if a participant is illiterate or is visually impaired. In such cases, Researchers must ensure that the consent process is otherwise documented or verified, which may involve the use of a witness or the use of audio/video equipment to capture oral consent. Whatever consent process is adopted, this must be documented (usually within a protocol/proposal).

* Consent taken via an app should be no less robust and informed as that taken in a face-to-face environment. An electronic copy of the information sheet and consent should be made available to the participant and an informed consent quiz should be considered in order to demonstrate the participant understands key elements of the project.

# It may not be feasible or appropriate (e.g. during a pandemic) to seek written consent from a participant. Electronic or remote methods may be used for seeking, confirming and documenting informed consent in research studies.

Attention should be paid to the needs of specific participant populations and individual participants and the nature of the information that needs to be provided to them. The method of recording consent that should be used depends on whether the recruitment and consent procedures taken as a whole (and considered as part of a proportionate approach) mean that you:

* can trust that the person who consented is who they say they are
* can trust that the consent form hasn’t been altered
* can trust when the consent was given
* can demonstrate that trust if required.

If your research is taking place within the NHS refer to the [HRA/MHRA Joint statement on seeking consent by electronic methods](https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/) (September 2018) for definitive guidance.

# Exceptions to Obtaining Informed Consent

# There are forms of Research where obtaining informed consent from the participant prior to participation may not be possible or practical. The Researcher must be able to justify this to the ethics committee reviewing the Research and ensure that appropriate safeguards are in place to protect participants (e.g. to obtain consent at a later stage; to obtain prior consent from an appropriate representative).

# There are some cases where informed consent from participants may not legally be required. Examples include:

# Research involving Personal Data where an application has been approved by the Health Research Authority (HRA) following an application to the HRA’s Confidentiality Advisory Group (CAG), for access to/processing of the data without consent under Section 251 of the Health and Social Care Act 2001[[5]](#footnote-6).

# ‘Existing holdings’ of tissue under the Human Tissue Act 2004, i.e. ‘relevant material’ which was already held prior to 01 September 2006. Note: a favourable ethical opinion for the use of existing holdings is required.

# The Human Tissue Act also details an exemption to obtaining consent for the use of anonymised ‘relevant material’ from living donors for Research purposes, providing the justification for not obtaining consent has been reviewed and received a favourable ethical opinion from an NHS research ethics committee. SRECs are not recognised under the Act and cannot facilitate this exemption.

# The secondary use of human tissue, where the tissue was originally collected with consent and where its use can be demonstrated to be within the terms of the favourable ethical opinion provided for the original project.

# Research Involving Children and/or ‘at risk’[[6]](#footnote-7) (vulnerable) Adults

# Ethical issues are especially important where Research involves people who need additional protection. Care must be taken when dealing with children and/or adults at risk (sometimes referred to as ‘vulnerable adults’), particularly those who lack mental capacity. Obtaining informed consent in such circumstances can be complex and requires careful consideration.

# Research with children and/or adults at risk must be undertaken with care and in accordance with the University’s [Safeguarding Policy](https://www.cardiff.ac.uk/public-information/policies-and-procedures/safeguarding) and [Activity Specific Guidance](https://www.cardiff.ac.uk/public-information/policies-and-procedures/safeguarding/activity-specific-guidance).

# Where Research involves participants who lack mental capacity, or may lose mental capacity during the project, Researchers must comply with the Mental Capacity Act 2005 (MCA). The MCA applies to any intrusive research, wherever it takes place, except for Clinical Trials of Investigational Medicinal Products (which are covered by the Medicines for Human Use (Clinical Trials) Regulations 2004 and its subsequent amendments). It is not limited to Research undertaken within public bodies or NHS organisations. Intrusive research means Research that would require consent if it involved people with capacity. Intrusive research is not limited to trials of interventions. All Research coming under the MCA requires approval from a 'recognised' Ethics Committee. Each NHS Research Ethics Committee (REC) in England and Wales, and the national Social Care Research Ethics Committee, are 'recognised'. University ethics committees are not recognised and are, therefore, unable to review projects which come under the MCA.

# For Research involving children (i.e. those under the age of 18), it is usual practice to obtain informed consent from a parent/legal guardian, alongside the consent or assent of the child. Whether the child is competent to give 'consent' will depend on a number of factors, including age, experience and the subject matter of the Research. It may not always be appropriate to obtain parental consent and this will depend on the particular circumstances. Ethics Committees will expect Researchers to justify any departure from usual practice. However, in all cases, informed consent must be obtained from the appropriate person.

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# Data Protection and Research

# Data Protection legislation requires a lawful basis for collecting and processing Personal Data. Whilst valid and informed consent is one lawful basis, this is unlikely to be the most appropriate legal basis for Research following implementation of the General Data Protection Regulation and the UK Data Protection Act 2018. Instead, Researchers should rely on public task/interest as the legal basis to process data for Research purposes. Further information is available from the University’s [Guide to GDPR and Research](https://intranet.cardiff.ac.uk/staff/services/managing-information/data-protection) and [the University’s Privacy Information Guide for Researchers](https://intranet.cardiff.ac.uk/staff/services/managing-information/data-protection).

# Researchers must note that, even where consent to process Personal Data is not necessary (because another lawful basis applies), this does not affect any ethical consent requirements and the need to ensure that the processing of the Personal Data is fair and complies with the data protection principles[[7]](#footnote-8).

# Confidentiality

# Confidentiality is a guiding principle in all Human Research. A duty of confidentiality will exist between a Researcher and a participant and confidential information revealed by a participant to a Researcher may only be disclosed to others if the party providing the information has given specific authorisation or the Researcher is under a legal or professional obligation to disclose it. Whether information is confidential will depend on the circumstances; the two key questions are: would the provider of the information consider it as confidential and would the provider expect it to be treated as such. If the answer to both questions is “yes”, the duty of confidentiality will arise. Furthermore, the duty arises when the Researcher has volunteered to keep confidential the information and/or the identity of the provider.

# As a result of this duty, Researchers must be aware of any circumstances, such as professional codes of practice or legal requirements, that preclude them from being able to give absolute assurances of confidentiality. For example, a Researcher may be required to override confidentiality where:

# there are serious concerns about the safety and well-being of a participant or a significant risk to the safety of others. Note: there are specific legal duties in respect of disclosing concerns about children who may be at risk of abuse;

# there is a requirement to give evidence or disclose documents, as part of a legal claim;

# information is disclosed which indicates that a criminal act has been (or will be) committed.

# In light of the above, it is important that Researchers:

# do not convey personally identifiable information obtained in the course of Research to others, except with the express permission of the participant unless either alternative arrangements have been agreed by a participant (see (b) below) or where the Researcher is subject to a legal or professional obligation to disclose that information;

# do not give unrealistic guarantees of confidentiality and anonymity, and alert participants to the risk that professional and/or legal obligations may require them to override confidentiality;

# where possible, anticipate threats to the confidentiality and anonymity of research data;

# take appropriate measures to store research data and records in a secure manner and in accordance with the University's data protection and information security policies and [Research Records Retention Schedules](https://www.cardiff.ac.uk/public-information/policies-and-procedures/record-management-policy-and-retention-schedules); and

# take care to prevent data being published or released in a form which would permit the actual or potential identification of participants.

# Research involving the use of Social Media Data (or similar internet-based data)

# The University recognises that Human Data obtained through social media or similar platforms can lawfully be used for research purposes without explicit consent, provided certain conditions are met. However, there are still important ethical matters to consider whenever a researcher is proposing to use such data for research purposes. As such, any research project involving access to information and/or the collection of data from social media sites must be subject to ethical review

# The Legal position

Subject to the Terms and Conditions/Terms of Use of the social media platform, Personal Data obtained through social media or similar platforms can lawfully be used for research purposes without explicit consent, where:

* + - the data has been ‘manifestly made public by the data subject’, as opposed to being made public by someone else;
    - the data is not being used to make decisions about individuals;
    - the use of the data would not impinge on the rights and freedoms of the individuals;
    - the use of the data would not cause substantial damage/distress to the individuals;
    - data minimisation techniques are employed so that only relevant information necessary for the research is captured and anonymisation takes place prior to publication; and
    - the Researcher complies with the general data protection principles contained within the General Data Protection Regulation. See Cardiff University’s [GDPR Guidance for Researchers](https://intranet.cardiff.ac.uk/staff/services/data-protection/research)[[8]](#footnote-9) for further details.

Anonymised data obtained through social media or similar platforms (i.e. where the data being accessed or collected contains no identifying information) is not subject to data protection legislation, and therefore can be used lawfully for research purposes.

* + 1. The Ethical Position

In addition to ensuring the relevant conditions for lawful use are satisfied (as set out above), researchers must consider (and the SREC will consider) the ethical implications of using the data for research purposes. Some relevant ethical questions to consider are:

* + - * + whether the information is truly ‘public’. For example, if a researcher obtains information from a closed social media group/page or from a forum only available to certain users, the individual to which the data relates is unlikely to expect that the information will be used for another purpose. The terms and conditions of the internet provider may provide a useful starting point in terms of what content is considered ‘public’;
        + the extent to which anonymity can truly be achieved. For example, if a researcher is proposing to use direct quotations in a research publication, the individual from which the quote was obtained may be easily ascertainable; and
        + whether the information being accessed/used for research purposes is sensitive (which may increase the changes of harm/distress).

There are various frameworks available that address the ethical considerations of using social media/internet data in further detail. Whilst many of these were drafted prior to the introduction of the General Data Protection Regulation, they still provide a useful starting point for researchers and SRECs. Examples include:

* + - * + ‘[Social Media Research: A Guide to Ethics’](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=2ahUKEwjGwvOd_q_mAhU2VRUIHdlqCUIQFjABegQIAhAC&url=https%3A%2F%2Fwww.gla.ac.uk%2Fmedia%2FMedia_487729_smxx.pdf&usg=AOvVaw1h472SF5SSWJLg6hIcxomw), ESRC and the University of Aberdeen
        + ‘[Internet-mediated research’](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=6&ved=2ahUKEwizqcq5_q_mAhX0ShUIHVM9BV4QFjAFegQIBRAC&url=https%3A%2F%2Fukrio.org%2Fwp-content%2Fuploads%2FUKRIO-Guidance-Note-Internet-Mediated-Research-v1.0.pdf&usg=AOvVaw2FiCfIv-gHQfOQIE0QpZ9H), UK Research Integrity Office
        + ‘[Internet-Based Research’](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwiIgfDK_q_mAhUfSRUIHdQCCOsQFjAAegQIAxAC&url=http%3A%2F%2Fwww.admin.ox.ac.uk%2Fmedia%2Fglobal%2Fwwwadminoxacuk%2Flocalsites%2Fcurec%2Fdocuments%2FBPG_06_Internet-Based_Research.pdf&usg=AOvVaw3H_Zu37pnbf3NSy13xEV5K), University of Oxford

# Sensitivity of Research

# Researchers must reflect on whether the Research they are conducting is particularly sensitive and whether this will present specific risks to those involved. Potentially sensitive topics include:

* Race or ethnicity
* Political beliefs
* Religious, spiritual or cultural beliefs
* Health conditions (physical and mental)
* Sexuality and/or gender identity
* Sex, pornography and nudity
* Criminal or illegal activities (including drug use, violence, abuse, terrorism or extremism)
* Asylum
* Personal finances

# Where the subject matter of the Research presents risks to those involved (emotional distress, for example), Researchers must consider whether any action can be taken to minimise such risks. Participants must be informed of any potential risks of taking part in the Research before they are asked to consent to participate.

# Payment to Participants

# In order to ensure that participants agree to take part in Research freely, and without inducement, care must be taken whenever it is proposed that participants receive payment for taking part in Research. As a general rule, participants must not be paid for taking risks and any payment must be set at a level that would not unduly influence participation. Where payment to participants is proposed, this must be ethically justified, and non-cash payments should be considered, wherever possible. Information about payment to participants must be provided to the ethics committee reviewing the Research and must be contained within the PIS (or equivalent).

# Notwithstanding the above, participants should not be financially burdened as a result of participating in Research and should not be substantially out of pocket. The reimbursement of reasonable expenses (travel, meals etc) is, therefore, generally acceptable. As above, any arrangements regarding the reimbursement of expenses must be explained to participants.

# Publishing the Research

# Where the Researcher intends to use verbatim quotes from a participant within a publication, this must be addressed in the consent form provided to the participant. In the majority of cases, it will not be necessary to publish identifying information about participants (and it is often inappropriate to do so). However, if identifying information is intended to be published, participants must be informed of this. Preferably these issues should be addressed in the PIS and consent form that are issued before the Research commences.

# Informing Participants of the Results of the Research

# Researchers are encouraged to consider informing participants of the results of the Research, or where they may be able to access this information, if appropriate. Taking part in Research is a voluntary matter, requiring good-will on the part of participants. It may, therefore, be appropriate for participants to receive feedback on the Research in which they have been involved.

# Where Researchers wish to inform participants of the results of the Research, they must consider the mechanism by which this is achieved and the manner in which the information is presented. Researchers undertaking clinical research should refer to the Health Research Authority's [guidance](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/publishing-your-research-findings/) on information for participants at the end of the project.

4.12. Risks to the Researchers

4.12.1 Researchers must consider the risks to their own safety and well-being, alongside risks to participants. Researchers are expected to assess the risks involved in any planned research project (usually via a documented risk assessment) and to ensure that appropriate provision is made if there are specific risks from the participant cohort or project location. Researchers must avoid using personal contact details in Research materials wherever possible.

4.12.2 Researchers must follow all applicable Health and/or Safety policies, procedures and guidance issued by the University, including external guidance endorsed by the University (such as guidance on [Lone Working](https://intranet.cardiff.ac.uk/staff/supporting-your-work/health-safety-and-environment/procedures-guidance/general-safety)[[9]](#footnote-10)).

# ETHICAL REVIEW REQUIREMENTS

# The University requires that all Human Research conducted by its Researchers be subject to ethical review by an independent, competent, and properly constituted ethics committee, unless a specific exemption applies. The requirements of ethics review at the University are designed to demonstrate that Researchers have given consideration to ethical issues surrounding the design and conduct of their Research.

# For all Human Research projects conducted by Researchers at Cardiff University, the University requires that the project is subject to ethical review by the relevant SREC unless the Research:

# is being reviewed by an external ethics committee e.g. an NHS REC (see Appendix 1 for examples of Research requiring review by an external ethics committee). Where an external ethics committee is responsible for conducting ethical review, neither the SREC nor ORIEC is empowered to provide a favourable ethical opinion for the Research.

# is exempt from ethical review under the University’s framework for the ‘Ethical Review of research using Secondary Data and/or Publicly Available information only’ (see Appendix 2). This framework allows certain research projects using secondary data and/or publicly available information only to proceed without ethical review by a SREC provided certain conditions are met.

# only involves the use of Human Data and/or human tissue that has already been collected with appropriate consent and that has been given a favourable ethical opinion (from either a UK ethics committee or an ethics committee based in a country with similar standards of research ethics) and will only be used within the terms of the original consent.

# is being led by another university or institution that has undertaken ethical review of the Research in accordance with its own procedures (provided such procedures are of an equivalent or higher standard to those adopted by Cardiff University). If this paragraph applies, Researchers are required to submit evidence of the ethical review conducted to the SREC. This evidence must include the outcome letter/communication and a copy of the ethical review policy of the institution.

# Research projects involving more than one Academic School should normally be reviewed by the SREC of the School where the lead/principal investigator is based. It may occasionally be more appropriate for the SREC of the School where a co-investigator is based to review the project (if that SREC has expertise in the subject area/methodology of the Research). If a Researcher is unsure if ethical review is required, or if a Researcher is unsure to which ethics committee they must apply, they should contact their School Ethics Officer. A list of School Ethics Officers is available [here](https://intranet.cardiff.ac.uk/staff/research-support/integrity-and-governance/research-ethics/ethical-review/school-research-ethics-committees-srecs)[[10]](#footnote-11).

# Ethics Committee Decisions

# Whilst the exact decision-making framework (and terminology) differs across ethics committees, there are four kinds of decision that can be made by an ethics committee:

# Favourable opinion (no conditions)

# Favourable opinion with conditions (changes must be made but resubmission to the committee is generally not required)

# Provisional opinion (resubmission of changes to the committee is required to obtain a favourable opinion)

# Unfavourable opinion (proposal rejected)

# The decision of the ethics committee will be confirmed to the Researcher in writing and, where applicable, will be accompanied by feedback. The Researcher must retain a copy of the decision of the ethics committee with the Research records.

# A Researcher is not permitted to commence Research activity until they have received a favourable ethical opinion from the relevant ethics committee. Commencing Research activity without a favourable ethical opinion (where ethical review of the research was required), may amount to research misconduct, or academic misconduct in a student context. If a proposal is granted a favourable ethical opinion with conditions, the Researcher must not commence the Research until all relevant conditions have been met. Under no circumstances should participants be recruited before a favourable ethical opinion has been obtained or before the conditions of a favourable opinion have been met.

# Granting a favourable ethical opinion retrospectively is not permitted at Cardiff University and any instances of a Researcher failing to obtain a favourable ethical opinion before commencing Research must be notified to the Head of School and School Ethics Officer within which the Researcher is based. The Head of School and School Ethics Officer are responsible for reporting all such cases, including any action taken to remedy the failure by the Researcher to obtain ethical review, to ORIEC.

# Researchers must note that a decision by an ethics committee to give a favourable opinion should not be taken to imply an expert assessment of all possible dangers or risks involved with the Research. All ethics committees address themselves to ethical matters and are dependent upon information supplied by the Researcher. It is, therefore, the responsibility of Researchers to ensure that the information provided to ethics committees is complete and accurate.

# Action following a Favourable Ethical Opinion

# Once a favourable ethical opinion is obtained, Researchers must act in accordance with the opinion provided and comply with any conditions or reporting/monitoring requirements of the relevant ethics committee.

# Any proposed changes to the Research must be actioned in accordance with the procedures of the relevant committee.

# Other Review, Approval and/or Registration Processes

# Researchers must carefully consider whether other forms of review, approval and/or registration of the Research may be required, in addition to ethical review, before the Research commences. For example:

# Research involving the collection or use of human tissue (including saliva and other bodily fluids) must initially be reviewed by the University’s Human Tissue Act Compliance Team prior to submission to an ethics committee. This is still the case where the material will be rendered acellular immediately.

# Research falling within the scope of the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)/Research involving the NHS will usually require:

# Sponsorship from the University’s Research Governance Team (further details are available [here](https://intranet.cardiff.ac.uk/staff/research-support/research-projects/conducting-research-in-the-nhs/applying-for-sponsorship)[[11]](#footnote-12));

# Approval from the Health Research Authority/Health and Care Research Wales; and

# Local NHS site approval (capability and capacity review, previously known as ‘R&D approval’).

# Research involving prisoners may require approval from the National Offenders Management Service, the Scottish Prison Service or the Northern Ireland Prison Service.

# Health-related research involving access to Personal Data without consent will require approval from the Confidentiality Advisory Group.

# Research involving investigational medicinal products or medical devices will require Sponsorship from the University’s Research Governance Team and approval from the Medicines and Healthcare products Regulatory Agency.

* Research in the areas of terrorism, extremism and/or radicalisation (or research involving access to materials of such a nature) must be registered with the University in accordance with the [Security-sensitive Research Policy](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/security-sensitive-research" \t "_blank).

# BREACH OF THIS POLICY

# A failure to comply with the requirements of this Policy, including a failure to obtain a favourable ethical opinion for Human Research where required, may be grounds for disciplinary action and/or may amount to research misconduct or academic misconduct, depending on the nature and severity of the breach.

# APPROVAL AND REVIEW OF THIS POLICY

* 1. This Policy will be kept under regular review by ORIEC.
  2. Approval History[[12]](#footnote-13)

|  |  |
| --- | --- |
| Version 1 | |
| Reviewed and Approved by the University Research Integrity and Ethics Committee (now the Open Research Integrity and Ethics Committee) | 09 October 2018 |
| Version 2 | |
| Reviewed and Approved by the Open Research Integrity and Ethics Committee | 20 May 2021 |

# CARDIFF UNIVERSITY POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS, HUMAN MATERIAL OR HUMAN DATA

**Appendix 1**

**Research requiring review by an external ethics committee**

1. The following types of Research must be referred to **an NHS Research Ethics Committee** (NHS REC) for review and approval:

Research involving:

* 1. patients and users of the NHS i.e. individuals identified as potential participants from, or because of their past or present use of, NHS services (including services provided under contract with the private or voluntary sector);
  2. individuals identified as potential participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
  3. collection of, or access to, data, tissue or other bodily material from patients or users of the NHS, as defined above;
  4. the storage of ‘Relevant Material’ from the living or deceased on premises in the UK (excluding Scotland) without an appropriate licence from the Human Tissue Authority;
  5. The storage or use of Relevant Material from the living, collected on or after 01 September 2006, where the research is not within the terms of consent from the donors, and the research does not come under another NHS REC approval;
  6. the analysis of DNA from bodily material, collected on or after 01 September 2006, where such analysis is not within the terms of consent for research from the donor;
  7. A clinical trial of an investigational medicinal product;
  8. A clinical trial involving the participation of practising midwives;
  9. A non-CE marked medical device, or a device which has been modified or is being used outside of its CE mark intended purpose. A definition of a ‘medical device’ can be found at the www. gov.uk[[13]](#footnote-14);
  10. Exposure to ionising radiation;
  11. The processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent;
  12. Intrusive procedures (refer to section 4.5.3 for definition of intrusive) with adults who lack capacity to consent for themselves, including participants retained in a project following the loss of capacity;
  13. Prisoners in the custody of the National Offenders Management Service, the Scottish Prison Service or the Northern Ireland Prison Service, where the research is health-related; and
  14. Xenotransplantation (putting living cells, organs, or tissue from animals into humans).

1. Social care research funded by the Department of Health must be referred to **the Social Care Research Ethics Committee** (now managed through the Health Research Authority, alongside the NHS RECs).
2. Any Human Research funded or sponsored by the Ministry of Defence (MOD) must be referred to **the MOD Research Ethics Committee**.

# CARDIFF UNIVERSITY POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS, HUMAN MATERIAL OR HUMAN DATA

**Appendix 2**

**ETHICAL REVIEW OF RESEARCH USING SECONDARY DATA AND/OR PUBLICLY AVAILABLE INFORMATION ONLY**

1. **INTRODUCTION AND SCOPE**

This framework has been developed to assist Researchers in determining whether ethical review is required for research projects involving access/use of Secondary Data and/or Publicly Available information only.

**Please see Appendix for definitions of ‘Secondary Data’ and ‘Publicly Available’.**

This framework does **not** apply if:

1. the research project involves human participants or human material (including human tissue or ancient human remains) - all research projects involving human participants or human material must be subject to ethical review; **and/or**
2. the responsibility for conducting ethical review falls to an external ethics committee i.e. not Cardiff University (as the terms/scope of the external ethics committee is relevant in such cases). For further information on research requiring review by an external ethics committee, please refer to Appendix 1 of the [*University’s Ethics Policy for Human Research*](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics)*.*

**If (1) or (2) apply, this framework does not apply to your research. Please refer to your School Research Ethics Committee (SREC) or external ethics committee, as required.**

Please note that a failure to obtain ethical review, where it is required, may be grounds for disciplinary action and/or amount to research misconduct.

1. **ACCESS/USE OF ANONYMISED DATA ONLY**

**Please see Appendix for definition of ‘Anonymised’.**

If your research project only involves accessing/using Anonymised data that is Publicly Available, ethical review is **not** required.

If your research project only involves accessing/using Anonymised data that is not Publicly Available, ethical review is **not** required unless:

1. there is a risk that the proposed use of the data and/or the research outcomes may impact negatively on, or cause harm to, a specific group or class of individuals; **or**
2. you believe there is another valid reason why ethical review is required and you have discussed this with the SREC.

Due to the diverse nature of research, it is not possible to provide an exhaustive list of the scenarios where (1) or (2) above might apply. **Researchers must evaluate their specific research proposal and seek advice from their SREC if in doubt**. However, the following examples are provided for reference purposes:

* Research on genealogy of war criminals or research estimating genetic potential for disease in an identifiable class of living people may fall within (1); and
* Research which requires ethical review as a result of funder or (proposed) journal terms and conditions, or research which is likely to be perceived by the public as highly controversial, including research on a ‘taboo’ subjects, may fall within (2).

Regardless of whether ethical review is required, Researchers are ultimately responsible for ensuring adherence to all relevant legal, ethical or professional standards that apply to their research and/or the proposed use of the Secondary Data and/or Publicly Available information.

Researchers are responsible for ensuring that their proposed use of the data is compatible with any terms and conditions and/or restrictions that relate to the data.

1. **ACCESS/USE OF PERSONAL DATA (IDENTIFIABLE DATA) OR DATA NOT OTHERWISE MEETING THE DEFINITION OF ‘ANONYMISED’**

**Please see Appendix for definitions of ‘Personal Data’ and ‘Anonymised’.**

If your research project involves accessing/using Personal Data (identifiable data), or data that does not otherwise meet the definition of ‘Anonymised’, ethical review **is** required unless:

1. the data was obtained from one of the following five Publicly Available sources: a) Published Biographies; b) Newspaper accounts of an individual’s activities; c) Published minutes of a meeting; d) Interviews broadcast on radio/tv/online; e) Diaries/Letters in the public domain; **and**
2. you are satisfied that the proposed use of the data/the research outcomes will not impact negatively on, or cause harm to, the individuals to which the data relates or to a specified group or class of individuals. Please note that the more ‘Sensitive’ the data, the more likely that harm or detriment could arise from the use of such data; **and**
3. you are not aware of any other valid reason why ethical review may be required.

**Please see Appendix for definition of ‘Sensitive’.**

For the avoidance of doubt, any research project involving access to information and/or the collection of data from social media sites **must** be subject to ethical review.

Regardless of whether ethical review is required, Researchers are ultimately responsible for ensuring adherence to all relevant legal, ethical or professional standards that apply to their research and/or the proposed use of the Secondary Data and/or Publicly Available information.

Researchers are responsible for ensuring that their proposed use of the data is compatible with data protection legislation and any terms and conditions and/or restrictions that relate to the data.

**APPENDIX**

**DEFINITIONS AND GUIDANCE**

**‘Personal Data’**

Personal Data is defined in Data Protection legislation as:

*Any information relating to an identified or identifiable natural person (data subject); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or one or more factors specific to that person i.e. their physical, psychological, genetic, mental, economic, cultural or social identity.*

Online identifiers include IP addresses and social media or internet usernames.

Further guidance on what constitutes ‘Personal Data’ is available on the Information Commissioner’s Office (ICO) [website](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/key-definitions/what-is-personal-data/#1).

**‘Anonymised’**

Data will only be considered ‘anonymised’ if:

(1) all identifying features have been removed (or were not originally collected) prior to the data being received and/or accessed by the Researchers, so that the data does not relate to identifiable individuals; **and**

(2) there is no feasible way for the Researchers to trace the information back to an individual (including through data linkage).

If the data relates to a small group with a specific characteristic, or if a data subject has a distinctive characteristic, the data will not be considered ‘anonymised’.

Further guidance:

- Identifying features are those which enable a specific individual to be identified i.e. enables them to be distinguished from other individuals. Some examples of ‘identifiers’ are contained in the legal definition of ‘Personal Data’ above but it is important to note that whether information enables someone to be ‘identifiable’ will depend on context.

- Even where direct and obvious identifiers are not present in the data (such as name, ID number or online identifier), it is possible that a combination of other data points may enable someone to be identified. It is also possible that the access or use of one anonymised medical image or scan may enable an individual to be identified based on further medical images/scans.

- Researchers will be considered as having a feasible way of tracing the information back to an individual if they have, or could likely gain, access to a key or other means of identifying the individual(s) to which the data relates. Researchers will be deemed to have ‘access’ where the key to identify the individual(s) is held anywhere within Cardiff University.

- Secondary Data obtained from another Researcher at Cardiff University (member of staff and/or student researcher) will not be considered ‘anonymised’ if that member of staff/student was involved in the primary data collection or otherwise has, or had, access to the Personal (identifiable) Data.

- There are many other useful resources on anonymisation more broadly, including what researchers should consider when anonymising their own research data for publication. Researchers may wish to review the ‘[Safe-Harbour’](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html) guidance on anonymisation or [ICO guidance on anonymisation](https://ico.org.uk/media/fororganisations/documents/1061/anonymisation-code.pdf).

**‘Secondary Data’**

Data that was collected and recorded by someone other than the researcher now proposing to access/use it, or data collected for a purpose other than the one now being considered (or a combination of the two).

**‘Publicly Available’**

Data and information will only be considered ‘publicly available’ if:

(1) it is freely available; **and**

(2) realistically accessible to a member of the general public.

Further guidance:

- The fact that registration and/or payment is required to access the data does not prevent it from being ‘freely available’ provided a member of the general public would realistically be able to access that data if they registered/made the required payment.

- ‘a member of the general public’ is a hypothetical average member of the general public who is interested enough to conduct some searches, but does not possess specialised knowledge or research skills.

- Data disclosed to a limited audience or data that is only available to people/groups who meet certain criteria (bone fide researchers; higher education institutions) will not be considered ‘realistically accessible to a member of the general public’

**‘Sensitive’**

Researchers should consider whether the data/information would reasonably be perceived as ‘sensitive’ by a member of the public. Whilst what is regarded as ‘sensitive’ will likely be case-specific and may be informed by disciplinary norms, Section 4.9 of the [CU Ethics Policy for Human Research](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics) provides some examples, including:

- Race or ethnicity

- Political, religious, spiritual or cultural beliefs

- Health conditions (physical/mental)

- Sexuality and/or gender identity

- Sex, pornography and nudity

- Criminal or illegal activities

- Asylum

- Personal finance

1. For further information refer to <https://www.britishmuseum.org/pdf/DCMS%20Guide.pdf> [↑](#footnote-ref-2)
2. Terms of Reference link - <https://www.cardiff.ac.uk/about/organisation/governance/charter-statutes-ordinances>

   Membership link - <https://www.cardiff.ac.uk/public-information/corporate-information/committees> [↑](#footnote-ref-3)
3. Student webpage link: <https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics> [↑](#footnote-ref-4)
4. Student webpage link: <https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics> [↑](#footnote-ref-5)
5. Further information is available at <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/> [↑](#footnote-ref-6)
6. As defined in the University’s Safeguarding Policy [↑](#footnote-ref-7)
7. https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/principles/ [↑](#footnote-ref-8)
8. Student link: <https://intranet.cardiff.ac.uk/intranet/students/documents/Guide-to-GDPR-and-Research.pdf> [↑](#footnote-ref-9)
9. Student webpage link: <https://intranet.cardiff.ac.uk/students/study/your-rights-and-responsibilities/procedures-and-guidance/general-safety> [↑](#footnote-ref-10)
10. Student link: <https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics/ethical-review/school-research-ethics-committees-srecs> [↑](#footnote-ref-11)
11. Student link: <https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/conducting-research-in-the-nhs/applying-for-sponsorship> [↑](#footnote-ref-12)
12. The table below indicates the date this Policy received approval from the Committee with primary responsibility for maintaining this Policy. Other University groups and committees may have also reviewed, noted, endorsed and/or approved this Policy prior to its publication. [↑](#footnote-ref-13)
13. https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device [↑](#footnote-ref-14)