National Design Academy

UNDERSTANDING ETHICS PROCEDURES

Framework for Identifying Low, Medium and High Ethical Risk for UG and PG Students

Undergraduate and Taught Post Graduate (UG/PG) research approved at a programme level should be low risk. In exceptional circumstances, medium risk research can be approved after consultation with the National Design Academy Course Director. The National Design Academy will not approve students to undertake high risk research.

Contents

Low Risk Guidance

Research Study Topic

Low risk studies for UG/PG should NOT involve sensitive topics such as sexual behaviour, illegal behaviour, experience of violence, abuse or exploitation, mental health, gender or ethnic status, or illness.

Interaction with Human Participants

UG/PG studies involving living adults who are 18 years and over without physical, cognitive or mental disability/issues, without pregnancy or breastfeeding, who can give a consent to the researcher by themselves are classed as low risk.

Low risk studies for UG/PG should NOT involve:

- Potentially vulnerable groups of people such as children, young people under 18 years old, pregnant women, breastfeeding mothers or people with a learning disability or cognitive impairment
- Participants who lack capacity physically, cognitively, and mentally
- Studies where permission of a gatekeeper is required (e.g. gatekeepers such as adult professionals working with children or the elderly)
- Deceased persons, body parts or other human tissues including bodily fluids

Involvement of Animals

Low risk UG/PG research must apply the principles of protecting and upholding high standards of animal welfare at all times and therefore should avoid or replace any involvement of animals.

Low risk studies for UG/PG should NOT involve:

- The involvement of animals for the purpose of teaching, testing, exhibition or performance
- The involvement of animals for biomedical or behavioural research
- Causing pain, suffering or distress to animals
- Breaking animal welfare legislation

Research Activity

Low risk UG/PG studies should involve straightforward, controlled procedures happening in the UK that are normally experienced in everyday life without causing any damage/ harm to the researcher, participants and/or environment

Low risk studies for UG/PG should NOT involve:

- Inducing any psychological stress, anxiety or humiliation
- Causing more than minimal pain
- Intrusive interventions such as administration of substances, vigorous physical exercise, or hypnosis
- Causing any health and safety issues for the researcher by, for example, international travel
- Causing any environmental damage or harm
- Deception
- Research happening outside of the UK
- Community-based participatory research (commonly led and undertaken by members of community groups/organisations themselves working alongside or in partnership with professional researchers)

Research Data

Low risk UG/PG studies should involve anonymised or pseudonymised data (non-sensitive and non-confidential information) on the research topic that do not identify both participants and non-participants that are used for the study only, without further data sharing (data deletion by the end of the project)

Low risk studies for UG/PG should NOT involve:

- Capturing visual or vocal data from which participants can be identified
- Utilising personal data, personal quotes, or personal visual images found on the internet (e.g. Facebook, Instagram)
- Access to records of personal or sensitive confidential information such as genetic or other biological information
- Any data sharing of confidential information beyond the initial consent given
- Administrative/secure data from which participants can be identified

Suggested Research Methods for Low Risk UG/PG Studies

Could involve

- Anonymous online questionnaire (no demographic questions on personal information from which respondents can be identified)
- Non-participant observation (taking photos of the place, products, etc. without people)
- Interviews/focus groups/workshops with the fellow students within the programme without involving external participants (taking notes only without audio/video recording)
- User testing with the fellow students within the programme without involving external participants (taking photos of the place/product/etc. and interaction between place/product and people without showing people's faces or identifiable body parts)

Identifying Medium and High Risk

The following is adapted from Research Ethics Code of Practice Appendix 2: Framework for Identifying Research Ethics Risk (De Montfort University, Research Services - November 2021) for partner staff and students at National Design Academy.

This framework should be used in conjunction with the National Design Academy Formal Ethics Assessment form and the Research Ethics Code of Practice. It sets out what is regarded as 'more than minimal risk' (low risk) in research ethics, which is further divided into medium and high risk. The relevant risk rating should be selected when submitting and reviewing an ethics application. Further guidance on the criteria can be sought from the National Design Academy Course Director, who may consult with university ethics advisors.

The list is not exhaustive nor prescriptive, and tutors/reviewers may recommend such ratings they feel appropriate based on the overall nature of the proposed research. For example, it may be appropriate to consider a project high risk if there are several medium risk issues. The relevant risk should be applied irrespective of mitigating measures put in place.

Undergraduate and Postgraduate (UG/PG) research approved by the National Design Academy should be low risk. In exceptional circumstances, medium risk research can be approved after consultation with the National Design Academy Course Director, who may consult with university ethics advisors. UG/PG students should not undertake high risk research, therefore research applications that are considered high risk will not be approved by the National Design Academy.

Note: Find guidance for Medium and High risk on the following pages

Medium Risk Guidance

Research Involving Potentially Vulnerable Groups

Question

Human Participation / Does your research involve participants who are in a potentially vulnerable situation?

Human Participation / If applicable, describe any existing relationship between the investigator(s) and participant(s) (e.g. teacher-student or employer-employee).

Further Guidance:

For example, children and/or young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Dependent or unequal relationships can be defined as pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other.

Medium risk examples may include relationships between:

- Health care professionals and their patients or clients;
- Teachers and their students;
- Governmental authorities and refugees;
- Employers or supervisors and their employees;

Service-providers (government or private) and especially vulnerable communities to whom the service is provided (e.g. homeless, rough sleeping).

Research Using Administrative Data or Secure Data

Question

Scope / Does your research involve only secondary data?

Data Management / Is there an access control process or a gatekeeper for access to data e.g secondary data?

Data Management / Will participant data be anonymous?

Data Management / Will participant data be pseudonymised or link-anonymised?

Further Guidance:

Researchers using these data sets will need to be approved by the body supplying the data and keep data in secure areas. In most cases a review confirming that researchers have met these requirements will be sufficient. Issues however may arise when data are linked and where it may be possible to identify participants.

Research Involving Groups Where Permission of a Gatekeeper is Normally Required for Initial Access to Members

Further Guidance:

This includes research involving gatekeepers such as adult professionals (e.g. those working with children or the elderly), or research in communities (in the UK or overseas) where access to research participants is not possible without the permission of another adult, such as another family member (e.g. the parent or husband of the participant) or a community leader.

Research Involving Deception, Covert Research of Which is Conducted Without Participants' Full and Informed Consent at the Time the Study is Carried out

Question

Human participation / Will informed consent be obtained from the research participants?

Human participation / Will the research involve actively deceiving participants?

Further Guidance:

Includes research using opt-out consent. It is recognised that there are occasions when the use of covert research methods is necessary and justifiable and consent may need to be managed at a point beyond the completion of research fieldwork.

Such research may be considered high risk depending on a case-by-case basis.

Research Involving Members of the Public in a Research Capacity in Research Data Collection (e.g. community-based participatory research)

Further Guidance:

Further guidance can be found in the "Supporting Templates & Documents" section and on the National Co-ordinating Centre for Public Engagement web page regarding ethics in community-based participatory research.

Community-based participatory research: A guide to ethical principles and practice

Research Involving Access to Records of Personal or Sensitive Confidential Information

Question

Scope / Does your project require external ethical review?

Human Participation / Will the research involve discussion or collection of information on potentially sensitive, embarrassing or distressing topics?

Further Guidance:

Including genetic or other biological information, concerning identifiable individuals. Such projects may require external approvals and advice should be sought from the National Design Academy Course Director before proceeding.

Research Undertaken Outside of the UK Where There may be Issues of Local Practice and Political Sensitivities

Question

Scope / Does your project require external ethical review?

Scope / Where will the project be undertaken?

Human Participation / Please describe how and where the participants will first be approached and by whom.

Further Guidance:

In some cases, partnership with a research organisation in the area involved may prove helpful. It is also necessary to check the requirements for ethics review in the countries included in the research.

Research Involving Respondents Through the Internet, in Particular Where Visual Images are used, and Where Sensitive Issues are Discussed

Question

Scope / Where will the project be undertaken?

Human Participation / Identifying participants / How will participants be identified? / Will human participants be recruited or identified through the internet?

Human Participation / Does the project involve study or participation in social media activity?

Further Guidance:

The British Psychological Society's Ethics Guidelines for Internet-mediated Research should be consulted prior to the commencement of research along with DMU's Guidelines for Internet Mediated Research. The term 'internet-mediated research' (IMR), as used in this document' covers a wide range of quantitative and qualitative approaches to research involving human participants. IMR can be broadly defined as any research involving the remote acquisition of data from or about human participants using the internet and its associated technologies.

Participants recruited or identified through the internet, in particular when the understanding of privacy in these settings is contentious or where sensitive issues are discussed - for example in 'closed' discussion groups where there is potential for quotes and visual images to be identifiable.

Other Research Involving Visual/Vocal Methods Particularly Where Participants or Other Individuals may be Identifiable in the Visual Images Used or Generated

Question

Data management / Does the research involve photographs, videos or audio recordings of research participants?

Further Guidance:

Including visual photo diaries in which the participant may be identified.

Research Involving Procedures Beyond Those Normally Experienced in Everyday Life

Question

Human Participation / Does the research involve invasive or potentially intrusive procedures?

Human Participation / Does the research involve the administration of substances?

Further Guidance:

Including, but not limited to:

- Administration of substances.
- Administration of medicinal products (including placebos).
- Investigations of medical devices and studies that use a device on the participant that is not yet CE marked or licensed for its intended use.
- Ingesting food or drink or other products (including vitamin supplements, nutritional studies etc.) which exceed normal recommended consumption levels, are outside any market authorisation, or where there is product warning and the participants are likely to be covered by that product warning.
- Inhalation of gases.

There may be regulatory requirements for all of the above examples for which further advice should be sought from the National Design Academy Course Director.

Could be medium or high risk based on the nature of the study.

High Risk Guidance

Research Involving Potentially Vulnerable Groups

Question

Scope / Does your project require external ethical review?

Human Participation / Does your research involve participants who are in a potentially vulnerable situation?

Further Guidance:

For example, children and/or young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Dependent or unequal relationships can be defined as pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other.

High risk examples may include relationships between: Carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients or people in residential care or supported accommodation; Prison authorities and prisoners.

Research Involving Those who Lack Capacity

Question

Human Participation / Will informed consent be obtained from the research participants?

Human Participation / Does your research involve participants who are in a potentially vulnerable situation?

Further Guidance:

All research involving those who lack capacity (as defined under the Mental Capacity Act 2005 Part 1 Section 2), or who during the research project come to lack capacity, must be approved by an 'appropriate body' operating under the Mental Capacity Act 2005.

It is illegal to conduct such research without approval of illegal to conduct such research without approval of an 'appropriate body'. An 'appropriate body' is a Research Ethics Committee (REC) recognised by the Secretary of State or Welsh Ministers. All NHS Research Ethics Committees (RECs) in England and Wales are recognised. RECs in Scotland and Northern Ireland are not recognised for the purposes of the Mental Capacity Act In addition, there is a national Social Care REC (SCREC) established in 2009 under the aegis of the Social Care Institute of Excellence (SCIE), which is recognised as an 'appropriate body' under the Mental Capacity Act.

Warning: You must contact the National Design Academy Course Director before submitting any application for research involving people who lack capacity.

Research Involving Sensitive Topics

Question

Scope / Does this project involve the use of sensitive or restricted materials?

Human Participation / Does the research involve investigation or possible disclosure of illegal activities or behaviours?

Human Participation / Is it possible that this research will lead to awareness or the disclosure of actual or intended harm to a participant or other individual?

Further Guidance:

Including, for example, but not exclusively, participants' sexual behaviour, their illegal behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status and certain illnesses and/or including bereavement.

Such research may fall under the Policy on Conducting Sensitive Research
DMU's Conducting Sensitive Research Page
DMU's Conducting Sensitive Research Policy

Research Which may Induce Psychological Stress, Anxiety or Humiliation, or Cause more than Minimal Pain

Question

Human Participation / Is there a risk of physical harm, psychological harm or discomfort for participants, or prolonged or repetitive testing which may be a burden to participants?

Further Guidance:

Minimal can be defined as negligible or of a minimum amount, quantity or degree. Examples include:

1. Induce physical discomfort and/or pain beyond which that they may routinely encounter in their everyday life.

2. Expose the participants to visual, auditory or other stimuli beyond that which would normally be experienced in everyday life.

3. Alter the participants' normal patterns of sleeping, eating or drinking. Such research could be considered medium risk on a case-by-case basis.

Such research could be considered medium risk on a case-by-case basis.

Research Involving Intrusive Interventions or Data Collection Methods

Question

Human Participation / Does the research involve invasive or potentially intrusive procedures?

Human Participation / Does your research involve participants who are in a potentially vulnerable situation?

Further Guidance:

This may include, for example, the administration of substances, vigorous physical exercise or techniques such as hypnosis. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life.

Could be considered medium risk on a case-by-case basis.

Research Where the Safety of the Researcher may be in Question

Question

Methodology / Does the research have potential to cause distress or discomfort to any member of the research team?

Methodology / Does the research involve lone working?

Methodology / Will the research involve international travel and/or travel to a potentially risky environment?

Further Guidance:

In particular those conducting field research and where research assistants are recruited locally working outside the UK.

May include visiting areas of potential or actual known violence or conflict, as defined by the Foreign and Commonwealth Office. May also include travel within the UK to environments that are potentially risky.

Could be considered medium risk on a case-by-case basis.

Research Which may Involve Data Sharing of Confidential Information Beyond the Initial Consent Given

Question

Human participation / Will informed consent be obtained from the research participants?

Further Guidance:

For example, where the research topic or data gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

Research that has the Potential to Cause Environmental Damage or Harm

Question

Scope / Does the project have the potential to cause environmental damage or harm?

Further Guidance:

Further guidance should be sought from the National Design Academy Course Director before proceeding with research that may cause environmental damage or harm.

Research with Pregnant or Breastfeeding Mothers

Further Guidance:

For example, where the research topic or data gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

Research Involving Deceased Persons, Body Parts or Other Human Tissues Including Bodily Fluids (e.g. blood, saliva)

Question

Human Participation / Will your research involve collecting, storing or processing human tissue samples?

Human Participation / Does the research involve invasive or potentially intrusive procedures?

Further Guidance:

Warning: Neither De Montfort University nor the National Design Academy hold a Human Tissue Authority licence and so human tissue falling under the remit of that Act cannot be stored. Research involving collecting, storing or processing human tissue samples should not be undertaken. Please seek further advice from the National Design Academy Course Director.