UCT GUIDELINE FOR RISK-BASED ETHICAL REVIEW OF RESEARCH (HUMAN PARTICIPANTS)

Title	UCT Guideline for Risk-Based Ethical Review of Research (Human Participants)
Valid from	February 2021
Person(s) responsible for drafting, review and revision	Lyn Horn (Director, ORI) Paula Saner (RIC, ORI)
Next review date	February 2024
Status	Guideline

Contents

Preamble

Authored by Lyn Horn, Director Office of Research Integrity UCT, with research and technical assistance from Phiroza Kamish, Lisa Williams and Paula Saner, and input from members of the Ethics Governance Review Committee, a short-term committee convened under the auspices of the eRA Project Implementation Committee in 2020 with the task of reviewing and providing recommendations for strengthening, and harmonising where appropriate, ethics review processes at UCT.

ORI Website: http://www.researchsupport.uct.ac.za/office-research-integrity

Comments on the document, including suggestions for improvement are welcome and can be sent to research.integrity@uct.ac.za

Introduction

This document has the status of a **GUIDELINE** aimed both at faculty REC members and researchers. It has two Sections:

Section A: A risk-based approach to the ethics review and approval of research

This section discusses the ethical risk evaluation of research involving human participants by both researchers and ethics committees prior to the ethics review of the project. Risk level assessment will determine the process and level of ethics review (i.e. can the project be reviewed at department level? Can it be reviewed as an expedited review by only one or two persons? Or does it require full committee review? Should it be referred to another committee for review?).

Section B: Risk-Benefit Assessment and Risk Mitigation

This Section briefly discusses the Risk-Benefit Assessment of a research project by the research ethics committee as part of the ethics review process, as well as risk mitigation steps.

Section A: A risk-based approach to the ethics review and approval of research

Why a risk-based approach to the ethics review and approval of research?

A risk-based approach to review and approval of research means that research projects assessed as being of low ethical risk can be reviewed in an expedited manner, whereas projects assessed to be of higher ethical risk are reviewed and discussed in more detail, usually at a convened research ethics committee (REC) meeting. Discussion and debate of the ethical aspects of projects at convened meetings is a critical skills development factor, in the context of research ethics. When most projects are reviewed in an expedited manner without discussion it is almost inevitable that ethical risk will at times be inadequately appraised and mitigated. This can lead to a variety of problems during the course of the research, including allegations of misconduct or breach of ethical norms by participants and communities, project delays as unanticipated issues have to be resolved, risks to researchers especially students, withdrawal of funding and challenges to published research on ethical grounds, by reviewers or others.

However, it must be acknowledged and recognised by both researchers and REC members that ethics review and approval processes are 'front-ended' processes and that ethics risk can evolve and change during the course of a project in both directions. Changes to context or research environments may both reduce risk or increase it. Hence it is essential that an awareness is created around the notion of ethical risk and evolving risk. The fact that risk can and does evolve during the course of a project does not imply that an adequate risk assessment, accompanied by identification of risk mitigation measures at the beginning of a project, if done thoughtfully by adequately trained REC members, cannot be valuable.

This document is primarily aimed as a guideline for ethics risk assessment outside of a biomedical or clinical research context.

How should ethical risk of a research project be evaluated?

When RECs evaluate the risk of a project their main concern is evaluating risks to participants. However, the following categories of risk all need to be carefully considered in an overall project risk assessment.

- Risk to participants (discussed in more detail below)
- Risk to researchers, especially inexperienced student researchers or projects taking place in unsafe environments
- Risk to stakeholders other than participants, including communities from which participants are drawn - this includes risk of stigmatisation or legal risks
- Risk to the institution, which may include risks to reputation

Evolving Risk

As mentioned above it may be impossible to anticipate all the ethical risks at the beginning of a project. Hence continuous reflection and re-evaluation of risk should occur throughout the project. If necessary, evolving, or unanticipated risks should be documented and discussed with the project team and supervisor, other stakeholders, and the ethics committee, so that additional risk-mitigation actions can be incorporated into the project.

Risks to research participants and communities

RECs are accustomed to considering risks especially to vulnerable participants and groups.

Minimal Risk

'Minimal risk' is defined as the risk a participant would experience within the context of an average day, measured against the average day of an average person with access to an acceptable level of resources, living in a mostly safe environment.

Research Vulnerability

Vulnerable research participants are those that may not fully or partially be able to look after their own interests in a research context. Two particular issues are relevant:

- Consent: they may not be able to provide a valid consent for whatever reason (adequate understanding of all relevant information transparently disclosed; and the ability to consent legally; and voluntarily, with no undue influence)
- They may be vulnerable to being easily exploited (treated unfairly)

Identifying potentially vulnerable participants is context dependent, in some contexts, participants belonging to particular groups may not consider themselves vulnerable and even take exception to the 'label'. Some examples of potentially vulnerable participants include (but are not limited to):

- Children
- People with mental disabilities
- People with physical disabilities
- Pregnant women and foetuses
- Participants with low literacy levels
- Participants with low social economic status
- Rural women
- Prisoners
- Students
- Those working in very hierarchical environments such as the military, hospitals etc
- Persons in dependent relationships
- Persons highly dependent on medical care, the elderly, terminally ill, parents of chronically ill children etc
- Stigmatized groups such as 'persons living with HIV/AIDS' (PLWH), members of the LGBTQ+ community, sex workers, and illegal immigrants

Types of harm in social and behavioural research

The following risks should be considered in the context of Social Science, Behavioural and Education Research.[1]

Psychological Risks: Psychological risks may be experienced during participation in the research and/or afterwards as a result of participating in the research. These risks include anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, and/or altered behaviour (*SBE Standard Operating Procedures*, 2019, version 1.5 pg. 52).

Social/Economic Risks: Economic risks include alterations in relationships with others that are to the disadvantage of the subject, and may involve embarrassment, loss of respect of others, labelling with negative consequences or diminishing the subject's opportunities and status in relation to others. These risks include payment by participants for procedures, loss of wages or income, and/or damage to employability or insurability.

Legal Risks: Legal risks include risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally liable.

Loss of privacy and/or confidentiality: Confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks from breach of confidentiality include invasion of privacy, as well as the social, economic, and legal risks outlined above. Loss of confidentiality is the most common type of risk encountered in social and behavioural science research (University of Chicago, *Social & Behavioural Sciences IRB & Investigator Manual*, 2009:12).

In certain types of non-biomedical research physical risks to both researchers and participants must also be considered.

Assessing risks to communities and other stakeholders

Assessing the risk that a project might bring to a community may be challenging. Projects taking place in communities should ideally include a community engagement plan that indicates community engagement timelines and scope and that incorporates a discussion of risk as well as steps that can be taken to mitigate risk. Issues that need to be considered are whether or not the involved community will be identified in published reports or papers. For example, several communities in the Western Cape have been significantly stigmatized by research into Foetal Alcohol Syndrome.

Stakeholders other than community members (using the term in a conventional sense) may also be placed at risk of harm or recipients of the negative consequences of research. In some instances, researchers and RECs may feel that this is justified for example research that involves harmful apartheid-era practices or similar. Researchers should consider these potential aspects of their projects and provide adequate explanation and justification in their research proposals.

[1] This section comes directly from the Stellenbosch University *Social, Behavioural and Education Research Ethics Committee SOP*, 2020, V1,6 Stellenbosch University. Section 4.9.1 pgs 51-52 which cites the University of Chicago, *Social & Behavioural Sciences IRB & Investigator Manual*, 2009:12.

How can risk-based screening of projects be implemented?

The first step in implementing this approach is to ensure that researchers, including students and their supervisors, are encouraged to think systematically about ethical risk. All project proposals should include a section on 'Ethics' that discusses potential ethical risk. Below are some of the questions that researchers should be asked to consider:

- WHO do you want to recruit as participants? Are they a vulnerable group?
- HOW are you going to find and approach them?
- HOW will you protect their identity? Do you need names or other identifiers?
- WHAT are you going to ask them, or of them?
- Could your research expose them to risk? For example, research that recruits and investigates illegal immigrants.
- Could your research result in stigmatisation? For example, research that recruits vulnerable groups such as sex workers or members of the LGBTQ+ community.

It is important to note that a project risk assessment must be made independently of steps taken to mitigate risk, such as compensation of participants time, or payment of travel costs. These actions do not alter the assessment of level of risk but may favourably alter the overall risk-benefit evaluation of the project.

What will this mean for ethics review committees and processes?

UCT RECs are encouraged to consider revising their ethics review and approval processes to incorporate a risk-based approach. This means that an effective screening process for all projects needs to be implemented to ensure that low risk projects can be expedited and approved in a devolved manner and higher risk projects are reviewed and discussed in more detail, ideally at convened and minuted meetings.

REC application forms should be revised to include appropriate risk-based screening that incorporates the issues discussed here (see example of screening questions below). Applicants should be primarily responsible for the risk screening of their own projects and be held accountable if risk allocation is assessed incorrectly. Research ethics offices must be adequately resourced to assist with questions around risk assessment.

However, risk assessment exclusively by ethics applicants is unlikely to be sufficient in many cases (although this will improve over time), hence faculties will need to implement systems that can monitor risk assessments and ensure that projects are allocated appropriately for review (expedited = one or two reviewers, signed off by Chairperson; or full committee review = one or two reviewers who present the project to the REC for discussion).

A record of all applications, risk assignment and mode of review should be maintained.

Examples of risk-based categorization in a non-biomedical research context

NB! Examples may not be applicable to all research contexts. Different faculties and domains should adjust categories and examples to their own requirements but ensuring that these adjustments are appropriate and reasonable and in keeping with the standards and spirit of this document. See discussion of risk in HREC Manual of SOPs for biomedical research pgs. 54- 57.

No/Minimal/Low Risk

- The following types of research are generally considered low risk and are suitable for expedited review and approval processes:
- Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys, and participant observation. For example, anonymous market research surveys may be considered to be 'no risk' if an anonymous survey was paper based and participants deposited surveys into a box, or an online platform was used with no risk of identification of individuals.
- The participants are adults and not considered to be a vulnerable research population. Children are generally considered to be a vulnerable research population.
- Information will be collected that would generally not be regarded as sensitive, such as opinions rather than personal information.
- There is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than an inconvenience to participants. Examples of inconvenience in human research may include filling in a form, participating in a de-identified survey or giving up time to participate in a research activity (playing a video game, completing a puzzle, reviewing pictures)
- The only foreseeable risk is one of discomfort. Discomforts include, for example, discomforts related to measuring blood pressure and limited anxiety induced by an interview.
- No specifically identifiable community is involved in the research or no specific community will be identified when the study is reported; there is no anticipated need for any form of community or stakeholder engagement activities in relation to the study and study results will not need to be fed back to a community.

Medium Risk

The following types of research may be considered medium risk and may not be suitable for expedited review i.e. judgement required based on the context of each proposed project:

- The research topic is considered 'sensitive'.
- Information gathered is personal, rather than opinion or attitudes, or is a combination of these.
- The information needs to be collected with personal identifiers (name, student number, etc).
- The research participants may come from a vulnerable or marginalised group, such as those with disabilities, people living with HIV or other chronic diseases, the economically or educationally disadvantaged, etc.
- The research participants may come from an identifiable community which could potentially be at risk of stigmatisation; it is possible that the community will be identified in project outputs. This could either be a geographic community or participants from a particular institution or group; it is anticipated that some kind of community or stakeholder engagement activity may be required prior to the initiation of the research project and results will need to be given back to the community in an appropriate manner.

- Researchers may be placed at some risk while conducting the research (e.g. a spiral community mapping walk in an area that is not considered safe or recruiting participants in potentially unsafe public spaces such as taxi ranks).

High Risk

Research falling into a high-risk category should be reviewed at a convened REC meeting.

- Research involving highly sensitive topics and/or very vulnerable and marginalised communities.
- Research involving the deception of the participants.
- Research investigating illegal activities
    - e.g. involving participants who are illegal immigrants or engaged in illegal activities (drug use, sex work, poaching or illicit wildlife trade), by agreeing to participate in the research participants will be placed at real risk of harm.
- The researcher may be placed at risk of breaking the law by carrying out certain activities
    - e.g. research investigating gang activities and possession of illegal firearms, wildlife trafficking and/or poaching
- The research may reveal information that requires action on the part of the researcher that could place the participant or others at risk
    - e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc.
- Communities may well be stigmatized by the outcomes of the research
    - e.g. research reporting on incidence of gender-based violence in multiple relatively small identified neighbourhoods; reporting of various illegal activities etc
- Communities may be subject to unwanted attention
    - e.g. from the police because the research has drawn attention to activities (e.g. perlemoen poaching etc)
- The 'community' that is the subject of the research may be one that is historical or viewed negatively and hence negative outcomes are viewed as justifiable.
    - e.g. research that proposes to contact and interview apartheid-era policeman. Careful consideration of the ethics of such research is never-the-less warranted prior to proceeding.
- Researchers place themselves at definite risk by conducting risk activities in unsafe environments.
- Institution (UCT) is placed at risk by having particular research projects and activities associated with it. Particularly relevant within the context of covert/undercover research. Funding of research by 'dubious' sources may also contribute to institutional risk. Potential for legal action against the university by aggrieved parties.

Screening Questions

These are examples and should be adapted as appropriate:

1. Does your research involve human participants, or their personal information? **YES/NO**
2. Does your research involve human data that is coded or potentially identifiable? **YES/NO**
3. Does your research involve indigenous or community knowledge systems? **YES/NO**
4. Does your research involve social media platforms? **YES/NO**

If **NO** to all four questions an ethics exemption letter can be generated.

If **YES** to any questions, please proceed with answering the following. Your project requires ethics review and approval.

5. Orange flag questions: Does your research:
    a. Involve any vulnerable groups (see list)?
    b. Gather information about a topic considered 'sensitive'? Such as participants religious or political beliefs, sexual activity, mental health, criminal record etc
    c. Require collection of personal identifying information?
    d. Does your research specifically collect information on gender, race and/or ethnicity?
    e. Use race as a variable of analysis?
    f. Collect personal information, not just opinions or attitudes (e.g. when last did you have an HIV; can you tell me the result test vs what is your view on HIV testing?)
    g. Involve interviews that could cause psychological distress
    h. Involve photographs, videoing or recording?
    i. Involve any interventions?
    j. Potentially risk stigmatizing communities (geographic or other)

6. Red flag questions: Does your research:
    a. Request a waiver of informed consent? (e.g. research involving 16-18 yr. old adolescents where you do not wish to get consent from their parents?)
    b. Involve covert observation in contexts where privacy is reasonably expected
    c. Involve deception of any kind (e.g. not providing full information in the consent form?)
    d. Involve investigating illegal activities
    e. Involve situations that may well place the researcher at risk of personal harm?
    f. Involve funding sources that may be regarded by UCT as undesirable?
    g. Present a risk to UCT as an institution associated with this research that could result in legal action against the university?

Section B: Risk-Benefit Assessment and Risk Mitigation

Risk-Benefit Assessment

One of the core tasks of a research ethics committee is to conduct a risk-benefit assessment of each project that it reviews. Ideally, research projects should have a favourable or neutral risk/cost-benefit assessment, meaning the expected benefit gained from the research (for individuals, communities science and the 'common good') can justify the risk and risk-mitigation steps taken by the research team, and balance out the risk-benefit equation (i.e. the risk- benefit equation should be assessed as favourable or neutral). If the risk-benefit equation is evaluated as negative then the REC should, in conjunction with the researchers, identify risk mitigation factors that can be implemented to reduce risk and enable the project to go ahead. REC members and research must always remain aware that, as discussed previously, risk can also evolve and hence reflection and re-appraisal is required throughout the duration of the project.

"The complexity of risk, as well as the uncertainty of the potential benefits of research, make the process of risk/benefit assessment a significant challenge for research ethics committee…Evaluation of the benefits of research must distinguish between direct benefits for the individuals who participate in the study, expected benefits for the community in which the study will take place and potential benefits to science and the world at large."[2]

The WHO guideline on this topic further states that "RECs are tasked to do a risk-benefit assessment of proposed research for at least two reasons: to verify the scientific/social validity of the research; and to ensure that the risks that the participants are exposed to are necessary, justified, and minimized…..identifying and evaluating risks and benefits is not a purely scientific endeavour. It requires the involvement of all stakeholders in research, including investigators, community and civil society representatives, legal, health authorities, etc."[3] In further guidance the WHO note that RECs need to avoid two common pitfalls:

- "underestimating the risks and/or overestimating the potential benefits, either of which can result in exposing participants to unjustified harm"[4]
- "overestimating the risks and/or underestimating the potential benefits, thereby holding back potentially beneficial research."[5]

The WHO goes on to remind RECs that even risk/benefit assessments based on reliable data and information are challenging and result in a decision that "cannot completely exclude uncertainty. In addition, differences deriving from the different social and cultural environments in which the research is carried out have to be taken into account, further complicating this evaluation."[6] They note that one of the best mechanisms to make a well-informed decision is to ensure that risks are described in detail. See example of a risk matrix below.

[2] World Health Organization. (2009) Research ethics committees: basic concepts for capacity-building. Ethics and Health Unit, Department of Ethics, Equity, Trade and Human Rights. Geneva Switzerland. [Accessed 4 September 2020], page 29
[3] Ibid, pg. 29
[4] Ibid. pg. 32
[5] Ibid. pg. 32
[6] Ibid, pg. 33

"Quantitative and qualitative evaluation of the risks and benefits for participants and their community presupposes that the members of the committee are properly trained and well-acquainted with the social cultural and economic context. A multidisciplinary approach is essential to the quality of the evaluation, and the composition of the committee must ensure that the required skills are represented. Continuing education for committees, together with sharing and critical analysis of experiences with other committees, help considerably in enhancing their skills."[7]

Conflict of interest in research can undoubtedly negatively influence the accurate ethical risk/benefit appraisal of projects. This topic is beyond the scope of this guideline. The UCT Policy on Conflict of Interest can be found here.

Some researchers may find the assessment table below[8] useful when thinking about risk and assist them in assigning the appropriate rating to the risks they identify in their proposed research.

(Note: It is not mandatory that researchers or RECs use this table; it is offered as a guide only).

	Affects			**Likelihood**					**Severity**					**Rating**			
Risk (List potential risks under each category)	Participant	Researcher	Other	Unlikely	Seldom	Occasional	Likely	Definite	Insignificant	Minor	Moderate	Critical	Catastrophic	Low	Medium	High	Extreme
Discomfort: which can involve body and/or mind: e.g. minor side-effects of medication, discomfort related to measuring blood pressure, and mild anxiety induced by an interview.																	
Physical harms: including potential for injury, illness, pain, chemical exposure, infection.																	
Psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information.																	
Devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly.																	
Social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation.																	
Economic harms: including the imposition of direct or indirect costs on participants.																	
Legal harms: including discovery and prosecution of criminal conduct; mandatory reporting requirements.																	
Reputational harms including loss of reputation and credibility to any and all parties, and to the research findings.																	

Risk Mitigation

Risk mitigation is the process that can be undertaken by either researchers, when developing their research proposal and during the research process, RECs at the time of reviewing the research or researchers and RECs working together. It involves identifying steps that can be taken to reduce the risk of a project and include many different aspects of the research depending on each project and context. Risk mitigation steps can be implemented at several stages for example:

- during the consent process to safeguard and ensure valid consent,

[7] Ibid, pg. 33

[8] Southern Cross Univeristy, Human Research Ethics Committee: Risk Assessment Guidelines and Matrix. Prepared by Dr Liz Baker, with input from HREC members January 2019 [Accessed 4 September 2020], pages 4-5

- during the data collection phase for example by providing access to counselling if data collection processes are anticipated to possibly cause emotional distress
- during the data management, storage, analysis, and reporting phases to ensure that data privacy and integrity is maintained.

The categories in the matrix above provide additional pointers to areas where risk mitigation steps can be implemented. Again, it is important to emphasise that steps identified during the ethics review process may well require review and adjustment during the course of the project and this remains primarily the responsibility of researchers.

Risk-benefit assessment in the broader context of institutional risk

UCT institutional Risk Management Committee, is responsible for maintaining UCT's risk schedule, of which, the URC is the custodian. UCT risk tolerance (ability, or readiness, to bear a risk after all responses have been put in place) and risk appetite (level of risk it is willing to accept in all spheres) should also be considered when assessing, evaluating and mitigating risks.

The governance of risk and number of principles that address accountability and responsibility for identifying and mitigating risk are presented in the UCT Risk Management Policy.

Bibliography and Additional Resources

Many of these references are focused on health research but they never-the-less contain valuable insights on the broader topic of risk in human research.

Bernabe RD, van Thiel GJ, Raaijmakers JA, van Delden JJ. *The risk-benefit task of research ethics committees: an evaluation of current approaches and the need to incorporate decision studies methods.* BMC Med Ethics. 2012;13:6. Published 2012 Apr 20. https://doi.org/10.1186/1472-6939-13-6

Chi PC, Horn L, Kruger M *Risk-Benefit Assessment in Research Ethics in Africa: A Resource for Research Ethics Committees*. Kruger M, Ndebele P, Horn L. 2014 Sun Media. Pages 63-70. (Open Access) https://books.google.co.za/books/about/Research_Ethics_in_Africa.html?id=Ge72AwAAQBAJ&redir_esc=y

Department of Health South Africa. *Ethics in Health Research: Principles Structures and Processes*. 2015 http://nhrec.health.gov.za/index.php/grids-preview

See 2.3.4. page 15 Favourable risk-benefit discussed as a core principle

Levine RJ, Risk Benefit Criteria. Appendix to Belmont Report Volume IV. 1975.

These papers are of historical significance as they are probably the first published papers on the topic of risk-benefit assessments in the context of human research. https://repository.library.georgetown.edu/bitstream/handle/10822/779133/ohrp_appendix_belmont_report_vol_1.pdf#page=57

Miller FG, Joffe S Limits to Research Risk J Med Ethics 2009;35:445–449. doi:10.1136/jme.2008.026062

Mutenherwa F., Wassenaar D., *Ethics review of social and behavioural research in an African context in Research Ethics in Africa: A Resource for Research Ethics Committees.* In Kruger M, Ndebele P, Horn L. 2014 Sun Media. Pages 117-125

Resnik DB. *Examining the Social Benefits Principle in Research with Human Participants*. 2018 - Health Care Analysis 26 (1):66-80

Rid A, Wendler D. *Risk–benefit assessment in medical research—critical review and open questions*. Law, Probability and Risk (2010) 9, 151–177 doi:10.1093/lpr/mgq006

Southern Cross University. (2019) *Human Research Ethics Committee: Risk Assessment Guidelines and Matrix*. Australia. https://www.scu.edu.au/research/research-ethics/ Pages 4-5

The Ethics Institute. (2016) *Ethics Risk Handbook*. Pretoria, South Africa. https://www.tei.org.za

The Institute of Risk Management South Africa (IRMSA) https://www.irmsa.org.za/page/practise

University of Stellenbosch. Research Ethics Committee: Social Behavioural and Education Research (2020) *Terms of Reference and Standard Operating Procedures and Guidelines*.

http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/human-research-(humanities)-ethics

See Section 5.4 Page 66-68 for a discussion on Risk and Benefit requirements.

Wendler D, Rid A. *A framework for risk-benefit evaluations in biomedical research*. Kennedy Institute of Ethics Journal 21 (2):141-179 (2011)

World Health Organization. (2009) *Research ethics committees: basic concepts for capacity-building*. Ethics and Health Unit, Department of Ethics, Equity, Trade and Human Rights. Geneva Switzerland. https://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf

World Health Organisation (2011). *Standards and operational guidance for ethics review of health-related research with human participants*. Geneva Switzerland. https://www.who.int/ethics/publications/9789241502948/en/