Guidelines for Classification of Prospective Research with Respect to Research Ethics

DUT classifies research into 3 ethics categories in relation to degree of risk (see below – extracted from the official PG4a research proposal document)

Humans		Organisations		Animals		Environment	
Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
Indicate Category (X)							
1.	**Exempt from Ethics and Biosafety Research Committee Review (straightforward research without ethical problems)**						
2.	**Expedited review (minimal risk to humans, animals or environment)**						
3.	**Full Ethics and Biosafety Research Committee review required (risk to humans, animals, environment, or a sensitive research area)**						

- Faculty Research Committees/ Faculty Research Ethics Committees must classify the prospective research accordingly.
- Research classified as Category 1 is exempt from IREC review however ethical review must still take place but at the level of FRC/ FREC. It is thus imperative that FRC/ FREC members are trained in research ethics and the South African requirements in this regard e.g. requirements for informed consent.
- Research classified as category 3 must serve at IREC after FRC/ FREC approval has taken place.
- Research classified as category 2 may serve at IREC after FRC/ FREC recommendation for ethical clearance.
- If FRC's/ FREC's are unsure with respect to the classification of the proposed research the IREC will provide clarity if it is requested to do so.

1. **The following types of research require additional attention with respect to ethical review and constitute minimally an ethical classification of Category 2 or above i.e. IREC review compulsory:**

   Research involving: [1]
   - **children**
   - **adolescents**
   - **persons in dependant relationships or comparable situations** e.g. those in a junior or subordinate position in a hierarchically structured group including relationships between elderly and their caregivers, students and teachers, prisoners and correctional service officers, employees and employers, those with chronic disease and their caregivers, patients and their doctors etc.
   - **women** (of reproductive age where research may pose a risk to the foetus)
   - **pregnant women**
   - **foetuses**
   - **indigenous medical systems**
   - **emergency care research** (if research includes those who are experiencing medical emergencies i.e. they are a vulnerable population)
   - **innovative therapy or intervention**
   - **prisoners**

- **vulnerable communities/groups** e.g. the elderly, disabled, those who are ill, institutionalised, orphans, illiterate, impoverished, victims of violent crimes or other traumatic events etc.
- **collectives** (using groups of participants distinguished/ characterised by common beliefs, values, social structures etc. or where customary collective decision making according to traditional beliefs is performed)
- persons highly dependent on medical care e.g. those admitted to hospital, or in ICU, receiving terminal care etc.
- other special groups e.g. intellectually or mentally impaired, disabled, unconscious or unable to provide informed consent.
- ambiguity of information for participants
- human tissues
- Where there is conflict of interest – researcher(s) has beneficial affiliation or financial involvement in any entity with direct interest in the research subject matter or outcome
- Where researchers are incentivised to conduct research
- Participants in research are incentivised
- Accessing databases/ records subject to privacy legislation or containing personal/ sensitive information e.g. medical, financial records without consent of individuals
- Research gathering sensitive data (with or without consent)
- Where there is risk to confidentiality of participants e.g. in data collection, storage or dissemination
- Participation in research may place the participant at risk of criminal or civil liability, potentially damage their financial standing, social standing or employability
- Data collection which may be perceived as stressful, embarrassing, compromising, diminish self-esteem or cause participants to experience regret
- Participation involves physically invasive, or potentially harmful procedures
- Participation where the probability or magnitude of harm or discomfort anticipated is equal to or greater than that encountered in daily life or during performance of routine psychological examinations or tests

2. The following research types <u>may</u> be classified as Category 1 and <u>may</u> be exempt from IREC review:

- Research on data/ material in the public domain e.g. meta-analysis
- Research involving humans may be classified as category 1 in the following circumstances:
    - *Anonymous** survey-type research involving the gathering or eliciting of non-sensitive data, where the requirements for informed consent are met, gatekeeper permission is obtained and the target population is other than those listed in section 1 above. Contentious issues or use any form of concealment or deception [2]
    - It is 'negligible risk' research: there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than that of inconvenience [2] [3]
    - It involves the use of existing collections of data or records that contain only non-identifiable data about human beings [2]
- Quality Assurance or Performance Review: Activities that are inherent in the mandate of an organization or are required by law [4] and does not involve the collection of or access to any private, sensitive or personal health related data, may

be exempt from review [5]. The primary intent of conducting these types of activities is to assess how the organization/ department/ programs are doing, to better serve its clients/ students. Typically, final reports remain internal to the organization [4]. However, if the findings of the assessments/ review process are to be further manipulated and/or published, clarity on whether or not ethical approval is required should be sought before undertaking the work [6].

- Reflective Practice / Professional Development: Reflective Practice / Professional development may involve research-like activities where others (e.g. students, colleagues and supervisors) are engaged in order to solicit information that can be used for self-evaluation and growth, provided no information about these other individuals is made public or identifiable [4] and it does not involve the collection of or access to any private, sensitive or personal health related data [5]. However, if the findings of the assessments/ review process are to be further manipulated and/or published, clarity on whether or not ethical approval is required should be sought before undertaking the work [6].
- Research-like' activities that take place within the acceptable standard practice of the respective profession. Typically, professional ethics codes cover these activities. An example of such an activity is evaluating the benefits of a change in teaching method in the professional setting, where the change is recognized within standard practice. However, the testing of activities that are novel, or used differently than is accepted as part of standard professional practice, or is conducted outside of the professional setting is defined as 'research' and is not exempt from ethical review [4].
- Research involving observation/ recording of public behaviour providing the persons being observed cannot be identified directly or indirectly [6] and any disclosure of the human participants' responses outside the research would not reasonably place the participants at greater risk of criminal or civil liability, or would not be damaging to the participants'[7].
- The collection and use of material requested from an officer of an organisation, where their response and opinions reasonably fall within their position description or role [5].
- Research involving the use of educational tests, survey procedures, interview procedures unless information obtained is recorded in such a manner that human participants cannot be identified [7].
- Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level known to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe by the appropriate government regulators [7].

3. For research proposals classified as Ethics Category 1

The following must be ensured:

- there is no conflict of interest
- the researcher is not incentivized to conduct the research
- the requirements for written informed consent are met
- gatekeeper permission is obtained
- there is no foreseeable risk of harm or discomfort to participants
- *anonymity** of participants is maintained
- confidentiality of responses and data collected is maintained
- data is not gathered on personally sensitive or contentious issues
- there is no use of any form of concealment or deception; and
- the researcher must complete the Ethics Checklist to serve with their research proposal at the respective FRC

In such circumstances where a proposal is classified as Ethics Category 1 (**Exempt from Ethics and Biosafety Research Committee Review (straightforward research without ethical problems)** liability and responsibility arising as a result of such decisions based on ethics are borne by the respective FRC/ FREC. In such circumstances, the IREC is not in a position to issue an ethics clearance certificate. Furthermore, retrospective ethics clearance cannot be granted.

***Anonymous data is obtained and recorded in a manner so that the information can never be linked to the research participant who supplied it i.e. not even the researcher(s) is/are able to link the data or trace its origin to a research participant.[8]*

Confidential data is obtained and recorded in a manner that the information is not immediately identified with the research participant who supplied it, but such a link is possible by the researcher if required or necessary. Confidential data is usually "coded"- that is, the research participant is assigned a unique identifier or code that will be used to identify the data. The unique code identifies the data and the participant's identity is kept separate from the code and data. Coded data is not anonymous.[8]

List of References

1. *DOH, Ethics in Health Research: Principles, Structures and Processes, D.o.H.S. Africa, Editor 2004: Pretoria.*
2. *Research Ethics, Compliance and Integrity - Levels of Ethical Review. 2012 [cited 2012 18.06.2012]; Available from: http://www.adelaide.edu.au/ethics/human/guidelines/levels/.*
3. *NHMRC. National Statement on Ethical Conduct in Human Research. 2007 [cited 2012 18.06.2012]; Available from: http://www.nhmrc.gov.au/book/chapter-2-1-risk-and-benefit.*
4. *Toronto, U.O., Principles to Determine Exemptions from Research Ethics Review, 2012, University of Toronto: Toronto.*
5. *Research Ethics and Integrity Human Research Ethics - Is my research proposal exempt from ethical review? 2012 [cited 2012 19.06.2012]; Available from: http://www.latrobe.edu.au/research-services/ethics/test_exempt.htm.*
6. *Pope, A. How to Tell Whether Your Planned Research must Undergo Ethics Review? 2011; Available from: http://ern.nrf.ac.za/control/ViewBlogArticle?articleContentId=11171&blogContentId=10934.*
7. *Research Ethics at UCL. 2009 [cited 2012 19.06.2012]; Available from: http://ethics.grad.ucl.ac.uk/forms/leaflet.pdf.*
8. *University of Massachusetts Amherst.Research & Engagement FAQ's. 2010 [cited 2013 29.04.2013]; Available from: http://www.umass.edu/research/faqs-human-subjects/frequently-asked-questions-faqs-human-subjects#11.*