- **UNIVEN classifies research into 3 Research Ethics Committees and 3 categories in relation to degree of risk (see below –)**

Humans and Clinical		**Social Sciences**		**Animals, Environment and Biosafety Research**	
Indicate Category (X)					
1	Exempt from Research Ethics Committee (straightforward research without ethical problems)				
2	Expedited review (minimal risk to humans, animals or environment)				
2.1.	Expedited review: External Factors (Attach Motivation)				
3	Full Ethics review required (risk to humans, animals, environment, or a sensitive research area)				

Faculty/Departments shall classify the prospective research accordingly.

Research classified as Category 1 is exempt from RECs review however ethical review must still take place but at the Faculty level. Faculties are charged with the responsibility of reviewing and approving research classified as category 1 and a record of approved research should be submitted to the relevant RECs on a quarterly basis. It is thus imperative that committee members at the Faculty level are trained in research ethics and the South African requirements in this regard e.g. requirements for informed consent.

1. Research classified as Category 1 will be given ratification/noting from Research Ethics Committees (RECs). (straightforward research without ethical problems)
2. Research classified as category 2 may serve at RECs after Faculty' recommendation for ethical clearance. (Minimal risk to humans, animals or environment)
3. Research classified as category 3 must serve at RECs after Faculty' recommendation for ethical clearance (risk to humans, animals, environment, or a sensitive research area)

If Faculty/Department are unsure with respect to the classification of the proposed research the RECs 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 2/3 or above i.e. RECs review compulsory:**

Research involving:

- 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 participant's 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 may be classified as Category 1 and may be provided a ratification/noting from schools RECs reviews:

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].

- Research on data/material in the public domain e.g. meta-analysis

- 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. <u>For research proposals classified as Ethics Category 1</u>

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 faculty RECs.

In such circumstances where a proposal is classified as Ethics Category 1 (Exempt from Research Ethics Committee Review (straightforward research without ethical problems) liability and responsibility arising as a result of such decisions based on ethics is borne by the respective Schools/Department. In such circumstances, the RECs are 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=1 0934.*
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.*

Review process

The RECs when reviewing a proposal must protect the rights, safety and well-being of the research participants and their communities. It will do this by evaluating all factors that may influence the scientific validity and ethical acceptability of the proposal by applying the various ethical benchmarks mentioned below:

Collaborative partnership:

- Develop partnerships with researchers, makers of health policies and the community.
- Involve partners in sharing responsibilities for determining the importance of a health problem, assessing the value of research, planning, conducting and overseeing research, and integrating research into the health-care system.
- Respect the community's values, culture, traditions and social practices.
- Develop the capacity for researchers, makers of health policies and the community to become full and equal partners in the research enterprise
- Ensure the recruited participants and communities receive benefits from the conduct and results of research
- Share fairly financial and other rewards of the research

Social value:

- Specify the beneficiaries of the research, i.e., who?
- Assess the importance of the health problems being investigated and the prospective value of the research for each of the beneficiaries, i., what?
- Enhance the value of the research for each of the beneficiaries through dissemination of knowledge, product development, long- term research collaboration and/or health system improvement.
- Prevent supplanting the extant health system infrastructure and services.
- Ensure that the study is relevant to the community involved or the greater South African population

Scientific validity:

- Ensure that the scientific design of the research realizes social value for the primary beneficiaries of the research
- Ensure that the scientific design realizes the scientific objectives while guaranteeing research participants the health-care interventions to which they are entitled.
- Ensure that the research study is feasible within the social, political and cultural context or with sustainable improvements in the local health-care and physical infrastructure
- Researchers should have the appropriate qualifications and expertise to conduct the proposed research
- Researchers must be registered with their relevant statutory council g. Health Professions Council of South Africa. Where this is not available a motivation must be given from a person registered with the relevant professional body.
- In studies where there is a large clinical component and the principal investigator is not a clinician, a co-investigator who is a clinician must be appointed.
- All international collaborative research must have a local principal investigator/supervisor.

Fair selection of the study population:

- Select the study population to ensure scientific validity of the research
- Select the study population to minimize the risks of the research and enhance other principles, especially collaborative partnership and social
- Select the study population fairly and without coercion
- Identify and protect vulnerable populations.

Favourable risk-benefit ratio:

- Assess the potential risks and benefits of the research to the study population in the context of its health risks.
- Assess the risk-benefit ratio by comparing the net risks of the research project with the potential benefits derived from collaborative partnership, social value, and respect for study populations.
- Risk to participants and/or the environment must be minimised

Independent Review:

- Ensure public accountability through reviews mandated by laws and regulation
- Ensure public accountability through transparency and reviews by other international and non- governmental bodies, as appropriate
- Ensure independence and competence of the reviews.

Informed Consent:

- Involve the community in establishing recruitment procedures and incentives.
- Disclose information in culturally and linguistically appropriate formats.
- Implement supplementary community and familial consent procedures where culturally appropriate.
- Obtain consent in culturally and linguistically appropriate formats.
- Ensure the freedom to refuse or withdraw
- The method utilised must be ethically and legally acceptable.

Respect for Recruited Participants and Study Communities:

- Develop and implement procedures to protect the confidentiality of recruited and enrolled participants.
- Ensure the participants know they can withdraw without penalties
- Provide enrolled participants with information that arises in the course of the research
- Monitor and develop interventions for medical conditions, including research-related injuries, for enrolled participant's at least as good as existing local norms.
- Inform participants and the study community of the results of the research

(Emanuel et al., 2004)

Review of research proposals

- Members of the RECs will be responsible for reviewing all categories of research proposals submitted for that particular meeting.
- Research involving minimal risk to participants (category 2) will follow the expedited review process.
- Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine psychological examinations or tests.
- When category 3 proposals are reviewed at the meeting each member present will have an opportunity to raise any comments, he/she may have. These will be discussed, and a decision reached.
- The RECs will strive to have consensus on all decisions made; however, in instances where there is no consensus, the matter will be put to vote. A minimum of 70% of the members present will need to be in favour of the matter to result in an approval.
- Category 2 proposals will be allocated to respective members for in-depth review as delegated by the Chairperson. The decisions from the expedited review will serve at a scheduled RECs meeting for noting.
- The RECs will not review proposals for ethical approval if data collection has already begun. In such instances, this will be reported to the relevant Oversight Committee.
- On completion of the review process the researcher, the supervisor will be informed of the outcome of the review, according to the following criteria:
    - Full Approval: No changes to proposal.
    - Provisional approval: This is subject to minor changes - the changes and/or clarifications are to be made by the researcher and re-submitted to the Chairperson for final approval.
    - Provisional approval subject to piloting of the data collection tools.
    - Re-submission: The ethical issues need to be further addressed and the revised proposal will need to be re-evaluated by a full RECs.
    - Rejected: The proposal does not meet the ethical requirements, the specific reasons will be accurately recorded.
    - Termination or suspension of prior approval: The specific reasons will be accurately recorded.