# How to Complete Ethics Application Form

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#### **Ethics**

"Working with people in research is a privilege, not a right"

"Do unto others as you would have them do unto you "

"First of all, do no harm "

Ethics: norms for conduct that distinguish between acceptable and unacceptable behavior





#### What is Research?

"Structured inquiry that utilizes acceptable scientific methodology to solve problems and create new knowledge that is generally applicable"



## **Research Ethics - Definition**

• 'Research ethics' refers to the moral principles guiding research from its inception through to completion and publication of results.

(British Psychological Society)

 Application of fundamental ethical principles to research



#### **Research Ethics**

- Research ethics is most developed as a concept in medical research, but in some form is essential for all research.
- Medical and biological research ethics includes the design and implementation of research involving:
  - human experimentation
  - animal experimentation
  - various aspects of academic scandals including scientific misconduct (such as fraud, fabrication of data and plagiarism), regulation of research, etc.
- Research in the social sciences presents a different set of issues than those in medical research
  - various aspects of academic scandals including scientific misconduct (such as fraud, fabrication of data and plagiarism), regulation of research, etc



## What Makes a Good Research?

## Good Science

- Problem selection
- SMART objectives
- Proper methodology
- Proper analysis

## **Good Ethics**

- Fair subject selection
- Favorable Risk-Benefit Ratio
- Independent Review
- Informed Consent



## Why Ethics?

- Promote the aims of research
  - knowledge, truth, and avoidance of error
  - prohibitions against fabricating, falsifying, or misrepresenting research data
  - promote the truth and minimize error.
- Promote the values that are essential to collaborative work
  - trust, accountability, mutual respect, and fairness
  - authorship guidelines
  - copyright and Patenting policies



## Why Ethics?

- Ensure that researchers can be held accountable to the public
  - policies on research misconduct, conflicts of interest, the human subjects protections, and animal care and use are necessary
- Help to build public support for research
  - policies on research misconduct, conflicts of interest, the human subjects protections, and animal care and use are necessary
- promote a variety of other important moral and social values
  - social responsibility, human rights, animal welfare, compliance with the law, and public health and safety.



## **Concepts Checked by ERC**

- 1. Collaborative partnership
- 2. Social value
- 3. Scientific validity
- 4. Fair participant selection
- 5. Favorable risk-benefit ratio
- 6. Independent review
- 7. Informed consent
- 8. Respect for participants



## **Objectives of Research Ethics Review**

- Ensures that the highest ethical standards in the conduct of research involving human participants are maintained.
- Reviews all proposed research to ensure meets ethical standards.



## Research Requiring Ethics Review

All research involving living human subjects

- Research with human remains, cadavers, tissues, biological fluids, embryos and foetuses
- Interviews, surveys and questionnaires
- Secondary data analysis of data from living human subjects



## Research Not Requiring Ethics Review

- Research about living individuals in the public arena or artists, based exclusively on publicly available information
- Participant observation of public demonstrations, political rallies and public meetings
- Quality assurance studies, performance reviews or normal educational testing



## How to Apply

copies)

#### Deadline – Last working day of each month

June, 2018 (2005 Prospectus)

UOC • MAIL • OFFICE 365 • PGIM EMAIL • LMS • ALUMNI • ORATIONS & AWARDS • SITE MAP • CONTACT US **PGIM** Postgraduate Institute of Medicine University of Colombo, Sri Lanka HOME **ABOUT ACADEMIC EXAMINATIONS OVERSEAS TRAINING** LIBRARY BOARD CERTIFICATION **PAYMENTS** Search for: Search **ETHICS APPROVAL** ETHICS REVIEW EVALUATION **ETHICS REVIEW COMMITTEE** Notices Submission Guidelines Please note that the ERC Application submission procedure has been changed with effect from 15th Course in Computer Applications-May 2018. Postponed to 26th May, 2018 (3 Vacancies available) You must submit the ERC Applications to the ERC Office in the prescribed format and shall include Posted on: May 22nd, 2018 the following documents. MD(Comm. Medicine/Dentistry) by Thesis Exam.-May 2018(Re-1.Covering letter: covering letter should be signed by the applicant. If the applicant is a postgraduate Scheduled Dates) trainee of the PGIM, covering letter should be submitted through the supervisor who is officially Posted on: May 15th, 2018 assigned to the applicant. Eligibility to sit the Final Examination for PG Dip. in 2.Declaration of Applicant Tuberculosis & Chest Diseases -June, 2018 (2016 Prospectus) 3. Submission Check List Posted on: May 10th, 2018 Eligibility to sit the Final 4. Research Protocol (03 copies). Examination for PG Dip. in Tuberculosis & Chest Diseases -

5.Information Sheet and Consent Form in English, and in Sinhala and Tamil where appropriate (03



## **Applicable Fees**

Category	Fee
Trainers and Staff of the PGIM/UOC	Free
Trainees of the PGIM/UOC	Rs. 2000
Extended Faculty of the PGIM/UOC	Rs. 5000
Industry sponsored projects	Rs. 7500

PGIM accepts only online payments via PGIM online payment system



#### **Documentation**

- 1. Check list
- 2. Application
- 3. Research proposals
- 4. CVs
- 5. Information sheet
- 6. Consent form
- 7. Questionnaire
- 8. Other relevant documents



## **Information Sheet**

- 1. Title of the research project
- 2. Invitation to participate in the research
- 3. Purpose and significance of research
- 4. Time commitments
- 5. Termination of participation, indication voluntary contribution
- 6. Risks involved
- 7. Costs and compensation
- 8. Anonymity and confidentiality



#### **Consent Form**

What is the purpose of informed Consent?

To make sure the potential research participant has adequate decision making capacity, and that they are able to make a voluntary choice to be in or out of the study



## **Informed Consent**

- The following points must be followed:
  - 1. Subjects are made fully aware of the nature and purpose of the research project
  - 2. Consent is voluntarily given
  - 3. The person involved has the legal capacity to give consent
  - 4. The responsibility for obtaining consent rests with the researcher
- \* Sometimes, because of the Hawthorne Effect (the alteration of behaviour by the subjects of a study due to their awareness of being observed), it may be necessary to use some deception in telling subjects about the study.

## **Informed Consent**

- Voluntary Informed Consent is essential for research involving human subjects
- Informed Consent should include:
  - Description of the nature of the research
  - Statement that the research is voluntary and participants can withdraw at any time
  - Identification of Risks and Benefits
  - Description of protection of confidentiality
  - Description of compensation
  - Description of what info researchers will share with participants
  - Identification of who is responsible for research with contact information



## **ERC Review**

#### Exempt

No risk

#### **Expedited Review**

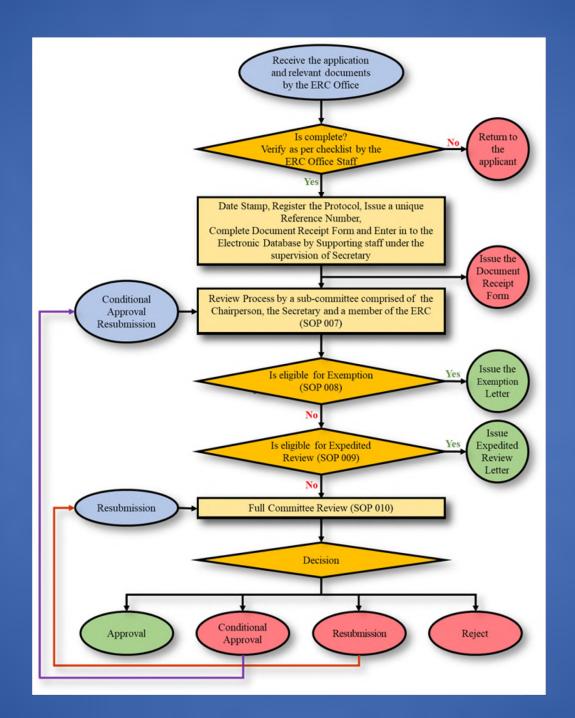
 Review by one or more IRB members of research that within certain prescribed categories and presents no more than minimal risk. Full review standards are applied

#### **Full Board Review**

 Convened meeting of board, usually reserved for protocols presenting more than minimal risk, research that cannot be expedited, or projects presenting issues not previously considered by ERC



## **Process**





#### What ERC is Not?

- NOT the 'Research Police'
- NOT a committee set up for the prime purpose to critique and mandate research design
- NOT an overly burdensome, bureaucratic hoop to discourage research.



## **Reading Materials**

- What is Ethics in Research & Why is it Important? by David B. Resnik, J.D., Ph.D. http://www.niehs.nih.gov/research/resources/bioethics/whatis/
- Research Ethics Timeline (1932-Present) by David B. Resnik, J.D., Ph.D. http://www.niehs.nih.gov/research/resources/bioethics/timeline/index.cfm
- Glossary of Commonly Used Terms in Research Ethics. David B. Resnik, National Institute of Environmental Health Science, National Institutes of Health, May 2015 http://www.niehs.nih.gov/research/resources/bioethics/glossary/index.cfm





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