

### Ethical clearance in practice

Eline D'Haene

Department of Agricultural Economics

Rural Development Economics

### 1. Why do you need ethical clearance?

### Confidentiality

Maintaining confidentiality of information collected from research participants means that <u>only the investigator(s)</u> or individuals of the research team can identify the responses of <u>individual subjects</u>; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

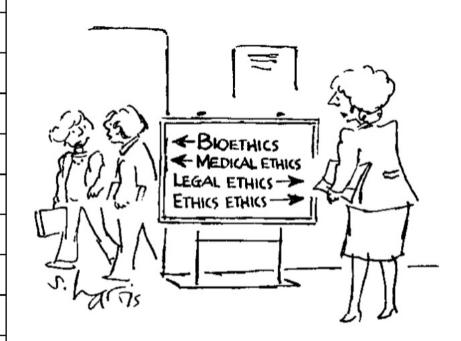
### **Anonymity**

Providing anonymity of information collected from research participants means that <u>either the</u> <u>project does not collect identifying information of individual subjects</u> (e.g., name, address, Email address, etc.), or the <u>project cannot link individual responses with participants' identities</u>. A study should not collect identifying information of research participants unless it is essential to the study protocol.



### 2. Where to go?

Faculty	Own ethical committee?
Arts and Philosophy	✓
Law and Criminology	✓
Sciences	×
Medicine and Health Sciences	✓
Engineering and Architecture	X
Economics and Business Administration	✓
Veterinary Medicine	✓
Psychology and Educational Sciences	✓
Bioscience Engineering	×
Pharmaceutical Sciences	×
Political and Social Sciences	✓



### 3. Which steps to take

- Identify and contact the relevant committee(s)
- ! Seek approval in your study country if this one differs from the one you're affiliated
- Seek guidance on rules, submission processes and procedures, committee sitting times, expected timeframe for approval
- Start drafting a formal submission (use templates if available)



Golden rule: start up this process as SOON as possible! You need to receive approval **before** starting your data collection

### 4. My own submission

- Sensitive personal and familial information
  - Religiosity questions
  - Family characteristics (income; expenses)
- @ Bimetra and @ Ethiopian Bimetra
- Informed consent
- Protocol
- Questionnaire
- Pretest & changes

### Academisch Onderzoek interventioneel academisch onderzoek → richtliinen document A 🔎 → document A w retrospectief academisch onderzoek → richtliinen document B → document B w → informatie- en waarschuwinsnota 🔀 academisch prospectief observationeel onderzoek (enkel gegevensverzameling, afname vragenlijsten/interview) → richtlijnen document C → document C W → informatie- en waarschuwinsnota 🔎 scriptie → richtlijn document D → richtlijn document E → document D 🕅 → document E W → informatie- en waarschuwingsnota 🔼 de aanvraag dient vergezeld te zijn van een begeleidende brief

en ontvangstbewijs met vermelding van de bijgevoegde documenten

→ begeleidende brief w

Industrie gesponsord onderzoek

→ richtlijnen document A 🔎

→ document A w



Dear participant,

WELCOME to our survey! We are researchers from the department of Agricultural Economics of Ghent University in Belgium. In this questionnaire, we would like to ask you questions on your household's milk consumption, production and purchase. Your participation to this study will give us more insight in how the dairy market functions in Ethiopia.

The survey will take about 20 minutes to complete.

Your participation is **entirely voluntary** and you are under no obligation to participate. Refusing to participate will not affect you or your family in any way. We would like you to answer as honestly as possible. There are **no right or wrong answers**. We want to emphasize that your responses will be kept strict **confidential** and processed anonymously.

If you would have further questions or comments about this study, please contact:

Eline D'Haene

Are you willing to participate in this study?

O Yes

ON O

If No is selected, the questionnaire stops here.

### Some interesting readings...

### African Social Science Review

Volume 7

Number 1 Fall 2014 Edition of African Social Science Review, Volume 7, Number 1

Article 3

January 2015

Ethical challenges in cross-cultural field research: A comparative study of UK and Ghana

Jones Adu-Gyamfi University of Bradford

## PART I - RESEARCH ETHICS IN AFRICA

12 Research vulnerability
Lyn Horn , Hany Sleem, Paul Ndebele
3 13 Children as research participants
Mariana Kruger, Boitumelo Mokgatla-Moipolai
14 Public Health Research (including community cluster randomised trials) 99
11 Lyn Horn, Gabriel Mwaluko
15 Traditional medicine research109

# PART II . THE RESEARCH ETHICS COMMITTEE (REC)

Lazare Kaptue, Marceline Ngounoue Djuidje, Charles Fokunang

		16 Ethics review of social and beharioural research in an African context117
4 The REC meeting and REC member responsibilities	21	Fairirai Mutenherwa, Douelas Wassenaar
Caroline Kithinji, Joyce Ikingura		FC.
		17 Evaluating genetic and genomic research proposals in Africa
5 The REC Standard Operating Procedures in Africa	29	Paulina Tindana, Christine Wasunna
Jovce Rinoura. Caroline Kithimii		
		18 Payment of research participants
6 A stepwise approach to protocol review	33	Khama Mita, Paul Ndebele
Christine Wasunna, Elizabeth Anne Bukusi		
		19 Community engagement
7 Safety and adverse event monitoring	41	Musonda Sinnwinga, Cuthbert Kabero
Rosemary Musesengwa		
		20 Ancillary care in research
8 On-going Monitoring of Research, Post REC Approval	47	Mariana Kruger, Nicola Barsdorf
Ofmen Baston Dani Machale Dan Maneiga Vanasan		

### PART III - SPECIFIC TOPICS

9 Informed consent in an African context	Lyn Horn
Vdebele	22 Educational resources for Rese
63	Odile Ouwe Missi Oukem-Boyer, Elizabe
Horn, Mariana Kruger	23 A self-assessment tool to assess
11 Clinical trials	Research Ethics Committees in
Lyn Horn, Moses Zimba	Henry Silverman, Hany Sleem

THICS CA	cs Committees
RESEARCH ETH IN AFRICA	A Resource for Research Ethics Committees Mantana Ringer   Paul Notiteer   1ye Hom
RE	A Resc

....125

81

18 Payment of research participants	A Resource
19 Community engagement	Attac
20 Ancillary care in research	
PART IV • RESOURCES	
21 Guidelines for RECs reviewing US and EU funded research	
22 Educational resources for Research Ethics	
23 A self-assessment tool to assess operational characteristics of Research Ethics Committees in developing countries	
PART V. APPENDIX	
24 Appendix A: Review form189 Lyn Horn, Nicola Barsdorf	
25 Appendix B: Informed consent and assent templates	



### Eline D'Haene

Assistant

DEPARTMENT OF AGRICULTURAL ECONOMICS
RURAL DEVELOPMENT ECONOMICS

E eline.dhaene@ugent.be

**f** Ghent University

@ugent

in Ghent University

rde.ugent.be