The Post-Research Ethics Analysis (PREA) is proposed as a framework for good ethical practice in health research in humanitarian crises.

http://PREAportal.org
R2HC/Elrha Research Funding

- Annual Call in June for research proposals involving humanitarian and academic partners.
- www.elrha.org/r2hc/home/
<table>
<thead>
<tr>
<th>Acknowledgements</th>
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<tbody>
<tr>
<td>Nawaraj Upadhaya</td>
</tr>
<tr>
<td>Rimal Damodar</td>
</tr>
<tr>
<td>Abdul Majeed Siddiqi</td>
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<tr>
<td>Tine Van Bortel</td>
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<tr>
<td>Sapfo Lignou</td>
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<tr>
<td>Chesmal Siriwardhana</td>
</tr>
</tbody>
</table>
Scoping overview of Humanitarian Research Ethics Issues

PREA Systematic Review

Steven Martin
Anglia Ruskin University

Gasim Abd-Elfarag
HealthNet TPO South Sudan

Sapfo Lignou &
Isla Kuhn
Anglia Ruskin University

Haley Roberts
The Ohio State University

Dónal O’Mathúna
The Ohio State University and Dublin City University
Systematic Review Methods

Systematic review of published ethical challenges in health research in humanitarian settings.

1. All types of studies and literature.

2. Settings: disasters, conflicts, on-going humanitarian crises

3. Perspectives of researchers, IRB/REC members, academics, NGOs, health and social care professionals, policy
   a. Grey literature search
   b. Electronic databases
   c. Analysis with NVivo
Structured Searches

- Grey Literature: selected websites
- Key words: humanitarian, health, research, ethics
- Google commands 'site:' and 'filetype:pdf'
- Electronic Databases: structured search strategy thanks to Ms. Isla Kuhn, Anglia Ruskin University Library, UK
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<tr>
<th>Website</th>
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<td>UNESCO</td>
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<tr>
<td>MSF</td>
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<tr>
<td>Humanitarian Health Ethics</td>
<td>380</td>
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<tr>
<td>PAHO</td>
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<td>UNISDR</td>
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<td>CDC</td>
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<td>Global Forum on Bioethics in Research</td>
<td>110</td>
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<td>International Conference on Harmonization</td>
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<td>Global Health Trials</td>
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<td>NLM</td>
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<td>Sphere Project</td>
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<td>UNICEF</td>
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<td>Specialised Information Services</td>
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## Database Results

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<td>Embase via OVID</td>
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<tr>
<td>Global Health via Ebsco</td>
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<tr>
<td>CINAHL via Ebsco</td>
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<td>PsycINFO via Ebsco</td>
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<tr>
<td>Scopus</td>
<td>6867</td>
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<td>SciELO via Web of Science</td>
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<tr>
<td>ASSIA via Proquest</td>
<td>297</td>
</tr>
<tr>
<td>Sociological abstracts via Proquest</td>
<td>1145</td>
</tr>
<tr>
<td>Cochrane Database of Systematic Reviews</td>
<td>258</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>22634</strong></td>
</tr>
<tr>
<td><strong>Total de-duplicated</strong></td>
<td><strong>15881</strong></td>
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Records identified through academic database searching (n = 22,634)

Additional records identified through other (grey) sources (n = 1,439)

Records after duplicates removed (n = 17,387)

Records screened (n = 17,320)

Full-text articles excluded, with reasons (n = 15,203)

Full-text articles assessed for eligibility (n = 2,117)

Records excluded (n = 974)

Studies included in qualitative synthesis (n = 676)
Systematic Review Themes

1. Community, communication and dialogue
2. Design and methods
3. Information, data and data management
4. Organisational
5. Patient and public
6. Perceptions
7. Philosophical Principles
8. Practical
9. Professional
10. Publication and dissemination
11. Relevance
12. Review process
13. Treatment and intervention
## 6. Perceptions

<table>
<thead>
<tr>
<th>Theme</th>
<th>Sub theme</th>
<th>No. of references</th>
<th>Total</th>
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<tbody>
<tr>
<td><strong>Perceptions</strong></td>
<td>• Media mindset</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Public authorities’ attitude</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Rumours, mistrust and perceptions of risk</td>
<td>24</td>
<td>38</td>
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</table>
## Example: 3. Information & Data

<table>
<thead>
<tr>
<th>Theme</th>
<th>Sub theme</th>
<th>No. of references</th>
<th>Total</th>
</tr>
</thead>
<tbody>
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<td>Information, data and data management</td>
<td>• “proxy” data</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>• Access to the data</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Collection, storage and future use of blood samples</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data accuracy</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data analysis</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data collection</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data ownership</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data protection</td>
<td>8</td>
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</tr>
<tr>
<td></td>
<td>• Data transparency</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Eliciting participant information</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Fabrication or falsification of research data or outcomes</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Group privacy</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Neutrality of data</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Observational data</td>
<td>1</td>
<td></td>
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<tr>
<td></td>
<td>• Open data and data sharing</td>
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<tr>
<td></td>
<td>• Relevance of data</td>
<td>4</td>
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</tr>
<tr>
<td></td>
<td>• Sensitive data</td>
<td>3</td>
<td></td>
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</table>

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Qualitative Research Training

• 6-8 November 2017, Anglia Ruskin University, London, UK
Experiences of coordinating PREA qualitative research study in Afghanistan, Nepal and South Sudan
- Nawaraj Upadhaya
HealthNetTPO, South Sudan
# Key learning

<table>
<thead>
<tr>
<th></th>
<th>Afghanistan</th>
<th>Nepal</th>
<th>South Sudan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous background of the data collector</td>
<td>Senior management staff</td>
<td>Researcher</td>
<td>PhD student</td>
</tr>
<tr>
<td>Regular contact with field data collectors</td>
<td>Via Skype</td>
<td>Via Skype</td>
<td>Face to face</td>
</tr>
<tr>
<td>Previous experiences of interview coordinator in all countries</td>
<td>3 years</td>
<td>Native</td>
<td>2 years</td>
</tr>
<tr>
<td>One by one discussion on questions, pre-test/feedback/revision</td>
<td>One country specific questionnaire</td>
<td>Country specific with additional for each group</td>
<td>One country specific</td>
</tr>
<tr>
<td>Data collection, translation, feedback simultaneously helped determine data saturation and increase number of interviews</td>
<td>From 8 to 20</td>
<td>From 8 to 20</td>
<td>From 8 to 19</td>
</tr>
</tbody>
</table>
Key learning....

<table>
<thead>
<tr>
<th>IRB approval process</th>
<th>Afghanistan</th>
<th>Nepal</th>
<th>South Sudan</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB approval process</td>
<td>Only a few minor comments-once</td>
<td>Revision up to 4th round with several comments</td>
<td>No comments- direct approval</td>
</tr>
<tr>
<td>Interviews with IRB/MoH</td>
<td>1+2</td>
<td>3+1</td>
<td>1+4</td>
</tr>
<tr>
<td>Review of translations by listening to the audio tapes</td>
<td></td>
<td>Translated by translator and reviewed by data collector</td>
<td>Not translated as interviews in English</td>
</tr>
<tr>
<td>Interview period had to be extended due to various factors</td>
<td>Security incidences</td>
<td>Busy schedule of some senior officials</td>
<td>Security/appointment difficulties</td>
</tr>
<tr>
<td>Relationship with national IRBs/MoH</td>
<td>Facilitated PREA interviews</td>
<td>Supported PREA interviews and showed commitment for future projects</td>
<td>Facilitated PREA interviews and has potential for integration</td>
</tr>
</tbody>
</table>
Reflections from the Field

Yimtubezinash Woldeamanuel Mulate
Addis Ababa University
Ethiopia
PREA Conference: Ethics in Health Research in Humanitarian Crises
Ohio State University, USA
25\textsuperscript{th}-26\textsuperscript{th} March 2019

PREA QUALITATIVE ANALYSIS RESULTS

Dr. Ainul Hanafiah and Prof. Tine Van Bortel

Institute for Health and Human Development
University of East London, UK
Qualitative data sample - Demographic information

Total sample = 67 in-depth face-to-face interviews

4 research sites
  - Afghanistan (n=20)
  - Ethiopia (n=8)
  - Nepal (n=20)
  - South Sudan (n=19)

67 respondents
  - Male (n=51)
  - Female (n=16)

7 roles of respondents
  - IRB representative (n=6)
  - Lecturer (n=1)
  - Ministry of Health representative (n=6)
  - Non-governmental organisation (n=4)
  - Principal investigator (n=21)
  - Researcher (n=29)
Method of data analysis

Interpreting the data
- Characteristics of, and differences between the data are identified
- Mapping connections between categories

Charting data into the framework matrix
- Reducing the voluminous data into meaningful constructs
- Includes references to interesting or illustrative quotations
- Using automatic tagging by the NVivo software

Establish initial codes
- Classify all data into meaningful ‘categories’
- Conducted line-by-line using NVivo software

Develop a working analytical framework
- ‘Codes’ applied in the few initial sets of transcripts
- Grouped together into clearly defined categories – working analytical framework or ‘themes’

Applying the analytical framework
- Index the working analytical framework into subsequent data sets

Framework Method
- Content analysis approach
- Matrix output: rows, columns and ‘cells’ of summarised data
Results

• 10 overall themes/framework
  1. Ethical issues
  2. Suggestions for research ethics improvement
  3. Measures to overcome ethical issues
  4. Research ethics training
  5. Dissemination initiatives
  6. Ethical approval process
  7. Role of stakeholders
  8. Suggestions for ethical approval improvement
  9. Research challenges
  10. Learning from ethical issues
1. Overarching issues
   1.1. Cultural barriers or insensitivity
   1.2. Ethical issues not given priority
   1.3. Lack of ethics guideline or tools
   1.4. Lack of ethics knowledge or expertise
   1.5. Lack of ethics training
   1.6. Privacy & confidentiality

2. Pre research
   2.1. Ethical approval not obtained or required
   2.2. Ethics approval process too long or slow
   2.3. Inadequate capacity of IRB
   2.4. Inadequate ethics approval process
   2.5. More emphasis on methodology than ethics

3. In fieldwork
   3.1. Accessibility
   3.2. Bribery
   3.3. Coercion
   3.4. Conflict of interest
   3.5. Consent
   3.6. Data issues
   3.6.1 Exploitation
   3.6.2 Forgery
   3.6.3 Poor quality
   3.7. Gender sensitivity
   3.8. Inadequate research information
   3.9. Insecurity & vulnerability
   3.10. Insensitivity towards participants
   3.11. Lack of monitoring & supervision
   3.12. Language or communication barrier
   3.13. Mismatched participants' expectations
   3.14. Participants' lack of education or awareness
   3.15. Recruitment & retention of participants
   3.16. Safety & security issues
   3.17. Violation of ethical approval
   3.18. Violation or abuse

4. Post research
   4.1. Data management or ownership
   4.2. Inappropriate outcome sharing
   4.3. Lack of dissemination strategy
   4.4. Lack of community engagement & empowerment
   4.5. Negative response towards results
   4.6. No ethical issues debriefing
   4.7. Publication issues

5. Negative impact
   5.1. On participants
   5.2. Researchers' moral distress

“There will also be issues of language. Sometimes we might be very well trained, competent but there might be issues of language barrier or cultural barrier. For those who have to conduct research in a new environment, there will be question on how much they have understood the community and how much do people in that community trust the research team. We have to think about it.” –[P42, male researcher from Nepal with experience in natural disaster research].

“When it is gender based violence there is usually a problem. I see one problem with the women data collectors who do the interview. When they see the scars and the women crying, that makes them also, that is the interviewer to cry and sometimes they can leave us.” –[P21, male PI from Ethiopia with experience in refugee, natural disaster and gender-based violence research].
# Suggestions for research ethics improvements

1. Adequate ethical approval
2. Active involvement of IRB
3. Adequate financial support for research
4. Adequate research & ethics training
   4.1 Assessment or certification
5. Appropriate experts or expertise
6. Communication & discussion
   6.1 In group
   6.2 One-on-one
7. Community engagement & empowerment
   7.1 Community involvement
   7.2 Outcome sharing
   7.3 Provide adequate research information
   7.4 Provide participant support
8. Contextualise research
9. Establish appropriate environment
10. Foster inter-agency collaborations
11. Include integrative dissemination strategy
12. Maintain privacy & confidentiality
13. Monitoring & supervision
14. Research ethics guideline or tools
   14.1 Content
15. Stakeholder consultations
16. Understand research context
17. Uphold ethical accountability

---

**Adequate research & ethics training:**

“Research ethics are important because we come from different cultures; you find that what may be good for your culture may not be good for other cultures. When you look at research ethics, it is good to look at them first before you do a research or question someone. I think it is important to have a research ethics training.” —[P50, female researcher from South Sudan with experience in biomedical/health sciences research].

**Research ethics guideline or tools content:**

“In the ethical tool, we want to look at issues related to the study and what harm it can cause to the community especially when you really deal with humans or you are going to administer anything to a human, this kind of things. The other issue is regarding of course the community where you are going to implement your survey.” —[P51, female MOH representative from South Sudan with experience in conflict and outbreak research].
# Measures to overcome ethical issues

| 1. Adequate research & ethics training |
| 2. Appropriate expert or expertise |
| 3. Communication & discussion |
| 3.1. With IRB |
| 3.2. With stakeholders or community |
| 3.3. Within research group |
| 4. Community engagement & empowerment |
| 4.1. Community involvement |
| 4.2. Outcome sharing |
| 4.3. Presence of participant support |
| 4.4. Provide adequate research information |
| 5. Cultural or contextual sensitivity |
| 6. Documentation of research limitations |
| 7. Establishment of appropriate environment |
| 8. Ethical accountability |
| 9. Feasibility or pilot studies |
| 10. Gender sensitivity & awareness |
| 11. Inter-agency collaborations |
| 12. Language or communication adaptations |
| 13. Maintain privacy & confidentiality |
| 14. Monitoring & supervision |
| 15. Obtain consent |
| 16. Research debriefing or reflection |
| 17. Research ethics guideline or tools |
| 18. Sound research methodology |

“Normally with the approval letter we give them an open door, like if there is an issue arise in the field, you have to get back to us.” –[P58, female IRB member from South Sudan with experience in biomedical/health sciences research].
## Research ethics training

### Content
1. Community benefit
2. Consent
3. Privacy & confidentiality
4. Safety & security

### Medium of training
1. By IRB
2. By NGO
3. Job requirement
4. Part of university course
5. Short course

### No formal training received
1. No
2. Unsure
3. Yes

### Presence of training course

## Dissemination initiatives

### General audience
1. Awareness programme
2. Conference
3. Presentation
4. Publication
5. Workshop

### Government authorities
1. Presentation
2. Report

### Participants
1. Presentation
2. Workshop

### Research stakeholders
1. Presentation
2. Report
3. Workshop
Ethical approval process

1. General procedures

2. Requirements

3. Importance of ethical approval

   3.1. Accountability
   
   3.2. Cultural facilitation
   
   3.3. Obtaining consent
   
   3.4. Protection & risk management

Importance of ethical approval – protection and risk management:

“Ethics is all about is it really doing harm or is it really giving benefits! So in that part it feels like they have not been doing it openly. Likewise, ethics is not only limited to give approvals. Follow-up is necessary after that also. They have to follow whether the research is being carried out in a same way they submitted in review or not. These types of follow ups are not done.” —[P30, female researcher from Nepal with experience in natural disaster and biomedical/health sciences research].

“Research ethics are important because we come from different cultures; you find that what may be good for your culture may not be good for other cultures. When you look at research ethics, it is good to look at them first before you do a research or question someone. I think it is important to have a research ethics training.” —[P50, female researcher from South Sudan with experience in biomedical/health sciences research].
“And as humanitarian as well as different organizations working in that area, we have a responsibility to protect the refugees from further harm from various directions that we don’t know at that point in time. Therefore getting that approval will help us to know the risk areas as well as how we can keep the confidentiality of the refugees and protect them, so I believe that it helps.” –[P24, female NGO member from Ethiopia with experience in gender-based violence research].

“Yes it does. It is mandatory. We provide refresher training to ethical review board. We have to provide training in international collaboration. We have to provide at least two trainings in a year. We are starting that in near future probably next week.” –[P47, female IRB member from Nepal with experience in natural disaster research].

“Generally, we have to take ethical approval from ethical review board. From what I see, it is mandatory to do the paper work and after the paper work is done, it’s over. I saw this in many settings.” –[P41, male MOH representative from Nepal with experience in natural disaster research].

Role of IRBs:

1. Role of academic journals
2. Role of government authorities
3. Role of IRBs
   3.1. Dissemination of study outcome
   3.2. Ethics approval in emergencies
   3.3. General ethics approval
   3.4. Monitoring & quality assurance
   3.5. Protection & risk management
   3.6. Support for researchers
   3.7. Training
Suggestions for ethical approval improvement

1. Adequate & appropriate expertise for reviews
2. Alternative means of research approval
3. Contextualise proposal
4. Establish dedicated ethics review group
5. Information on ethics approval process
6. Presentation & discussion of proposal
7. Raise quality of ethics approval
8. Research guideline or tools
9. Training on ethics and approval process
10. Uphold timeliness & effective review system

Adequate & appropriate expertise for reviews:

“What is really needed to be available is a functional ethical group, whereby someone can have access to them not 24/7 but during working days; call and talk to people because that would improve a lot the quality of our research.” – [P59, female MOH representative from South Sudan with experience in outbreak research].

Establish dedicated ethics review group:

“Well, I propose that there should be just a department for research with assigned and dedicated people and well trained. There should be capacity building and training of the staff that are reviewing proposals for ethics approval, so there is improvement in their work.” – [P59, female MOH representative from South Sudan with experience in outbreak research].
Research challenges

1. Collaboration issues
2. Resource challenges
3. Financial constraints
4. Limited support
5. Time restriction

Financial constraints:

“The second thing is as far as budget allocation is concerned, what is being given is quite insufficient and I don’t know how that can be addressed in light of ethics but it has to be considered.” —[P26, male PI from Ethiopia with experience in refugee research].

Learning from ethical issues

1. Adaptability & adjustment
2. Improved cultural & contextual understanding
3. Increased ethics knowledge

Adaptability & adjustment:

“Sometimes, based on these kinds of meetings, the researchers can act on his own in a very effective way during the emergency settings and some situations where one has to improvise a little during the collection of the sample.” —[P33, male researcher from Nepal with experience in natural disaster research].
Key Conclusions from PREA Qualitative and Systematic Review Data

• Tension between ‘Procedural ethics’ (documents, IRB) and ‘Pragmatic ethics’ (fieldwork).

• Need for ethics understanding and training of all key stakeholders involved.

• Focus on process (dynamic from pre-inception to post completion).

• Need for an ‘Ethics Tool’, Help-Desk and more.

• Cultural change in global society: Ethics imbedded in all our education, training, work, all aspects of life (being and doing).
Feedback & Training
Questions – Comments