



Research Ethics Guidelines in Least Developed Countries

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Introduction

The most vulnerable populations for human subjects research are those living in the most resource poor settings. As technology has progressed to support convenient long-distance travel, international communication, and data sharing via the internet, international research has become a more manageable task. While some dismiss the ethical guidelines for human subjects research as necessary only for the most barbaric researchers, history demonstrates the need for ethical guidelines as well as oversight of adherence to such guidelines.

Research Question

How do guidelines for ethical treatment of research subjects in least developed countries compare with the Council for International Organizations of Medical Sciences International Ethical Guidelines for Health-related Research Involving Humans?

Materials and Methods

Forty-eight countries designated as least developed countries (LDCs) according to the United Nations Statistics Division were identified and selected for analysis. From January 2017 - December 2019, an internet search was utilized to identify research guidelines for LDCs available online or primary research studies conducted in such countries to determine to what extent authors noted ethical considerations. Council for the International Organizations of Medical Sciences (CIOMS) guidelines were distilled into keywords by the authors and compared to guidelines for LDCs for the 16 countries with guidelines available online. Frequencies and percentages in comparison to CIOMS guidelines (fourth version, 2016) were tabulated. A PubMed search was conducted for countries with no available ethical guidelines and results were tabulated.

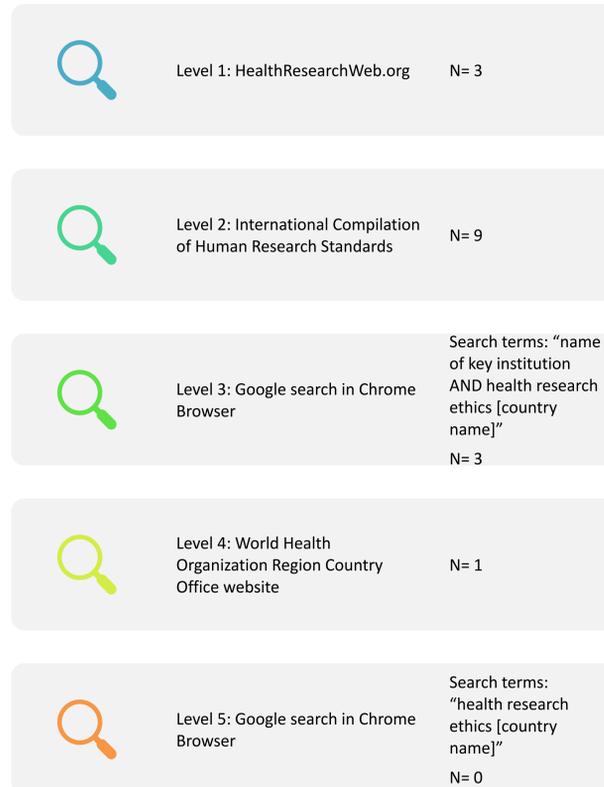


Figure 1: Search strategy for identifying ethical guidelines for each LDC.

Results

Of the 48 LDCs identified, 17 did not have published research guidelines or mention of a Research Ethics Committee (REC). An additional 15 countries had documentation of some sort of REC, 3 countries had at least one ethical guideline in addition to a REC, and 13 countries had no mention of a REC but did have established ethical guidelines available online. In all, 16 countries of the 48 LDCs identified had guidelines that were analyzed in comparison to the CIOMS guidelines.

On average, the 16 research ethical guidelines reviewed from LDCs complied with only 5 (SD 4.11) of the 25 individual CIOMS Ethical Guidelines.

Guideline Number	Guideline Key Words	Number of countries including guideline (%)
1	Scientific value, social value, respect for rights	9 (56)
2	community responsiveness, sustainability, cultural competence	8 (50)
3	Equitable distribution of benefit/equitable distribution of burden	5 (31)
4	Minimized risk/ balanced risk in relation to value of knowledge gained	10 (62)
5	Control group (effective intervention vs placebo)	2 (12)
6	Provision of health needs (during and after research)	2 (12)
7	Community engagement (in process, dissemination of results)	7 (44)
8	Capacity-building for research and ethics	1 (6)
9	Informed consent	15 (94)
10	Waiver of informed consent, modification of informed consent	3 (19)
11	Use of biological materials, storage of biological materials	2 (12)
12	Use of data, storage of data	2 (12)
13	Reimbursement, compensation, research participation	7 (44)
14	Treatment, reimbursement, research related harms	6 (38)
15	Protection of vulnerable populations/individuals	10 (62)
16	Adults not capable of giving informed consent	10 (62)
17	Research involving children and adolescents	10 (62)
18	Women as research participants	4 (25)
19	Pregnant and breastfeeding women	9 (56)
20	Research in disasters and disease outbreaks	1 (6)
21	Cluster randomized trial	0 (0)
22	Use of data obtained online and digital tools	0 (0)
23	Requirements for establishing ethics committee	7 (44)
24	Public accountability for research	1 (6)
25	Conflicts of Interest	1 (6)

Table 1: CIOMS guideline key words with numbers and percentages of guidelines including them.

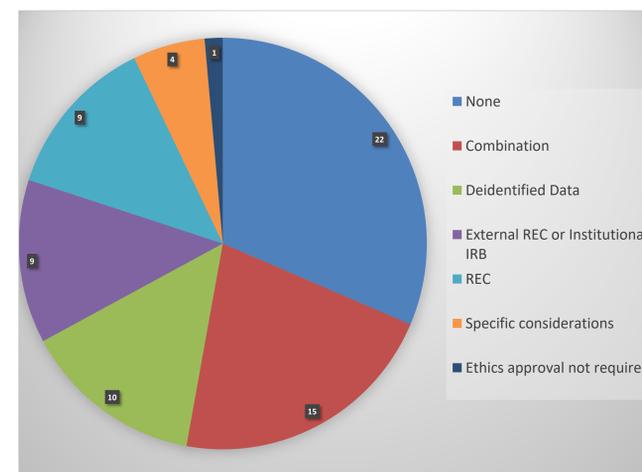


Figure 3: Analysis of results of PubMed search for articles in the cases of countries without available ethical guidelines.

Conclusion

Over half of countries had online documentation of limited ethics oversight for research, indicating a clear lack of thoroughness in the available guidelines as compared to the international gold standard guidelines from CIOMS. The majority of primary research articles reviewed showed no mention of ethical considerations despite some of the articles using chart review or engaging in patient care interventions. Based on the findings of this study, authors recommend the adoption of existing ethical guidelines by countries still lacking individualized guidelines, as well as a movement toward journals requiring documentation of ethical approval or ethical considerations as a requirement prior to approving articles for publication.

Summary

- Only 33% of countries categorized as Least Developed had ethical guidelines for human subjects research available online.
- Of the 16 countries with available research ethics guidelines, the average number of guidelines corresponding to CIOMS guidelines is 5, with the most common being informed consent.
- Most primary papers published in Least Developed Countries without research ethics guidelines contained no mention of ethical considerations in their studies.

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