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### ORIGINAL RESEARCH: PEER-REVIEWED ARTICLE

#### Why We Need Stricter Oversight of Research Involving Human Subjects Affected by Conflict

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##### Abstract

**Background:** Despite the potential for ethical violations when research is conducted with conflict-affected populations, there is limited information on how and the extent to which ethical considerations specific to doing research with these populations are integrated into national and international ethics guidelines and, in turn, how these guidelines translate into practice. This study aims to fill this gap by systematically analyzing the existing research ethics guidance of humanitarian donor countries, conflict-affected countries, United Nations (UN) agencies, and funding agencies, as well as ethics reporting in research articles on conflict-affected populations published in peer-reviewed journals.

**Methods:** A review of 32 research ethics guidelines and granting regulations from UN agencies, donor agencies, and governments was conducted, and the reporting of ethics procedures and practices of 498 articles published in peer-reviewed journals was analyzed.

**Results:** Of the reviewed guidelines and regulations, 87.5% did not mention conflict-affected populations, and only one guideline (3.1%) catalogued any of the complexities of conducting research with conflict-affected populations. Among the reviewed published research articles on conflict-affected populations, obtaining ethics approval or a waiver was reported in only 48.2% of articles, and obtaining informed consent was reported in only 46.6% of studies. In the subset of articles that did not report receiving ethics approval, 88.5% were published in journals that required reporting of ethics approval.

**Conclusions:** This study highlighted a gap in current research guidelines and granting regulations on the ethical conduct of research with conflict-affected populations and illustrated the need for such guidance to be integrated into governing documents and research practices. Moreover, this study demonstrated that there is a need for stricter enforcement of

reporting requirements by journals to ensure that research with conflict-affected populations meets the required ethical standard. Partnerships among institutional ethics committees, donor agencies, and journals can ensure that the rights of conflict-affected populations are protected.

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### Unique Vulnerabilities

Individuals from conflict-affected populations have unique vulnerabilities due to a variety of different circumstances, including their personal history, citizenship status, displacement trajectory, and socioeconomic status.<sup>1</sup> This population includes individuals who are refugees or internally displaced persons and those living in areas of conflict. As the number of individuals affected by conflict grows to unprecedented heights,<sup>2</sup> research focusing on this group has also increased.<sup>3,4,5,6,7,8,9,10</sup> The increased risks of exploitive research practices experienced by refugees and conflict-affected populations have been described.<sup>11</sup> This body of literature has highlighted the complexities of **obtaining informed consent** and the potential for unintentional coercion, given power differentials.<sup>1,12,13,14,15</sup> In order to safeguard the rights of conflict-affected populations, rigorous ethics approval procedures are necessary. However, despite the potential for ethically fraught research practices (see Table 1), mechanisms to oversee research with conflict-affected populations are limited.<sup>13</sup> Often, institutional ethics committees do not have the capacity to monitor research practices and must rely upon insufficient scientific and technical guidance for conflict-affected populations.<sup>1,13</sup>

**Table 1.** Examples of Ethical Considerations in Research With Conflict-Affected Populations

Ethical Issue	Examples
Informed consent	A mistrust of authorities might contribute to individuals' reluctance to sign forms out of fear that they might be used to take advantage of them. <sup>1</sup> Individuals who are fleeing countries where governments are known to engage in coercive practices and violate human rights might not understand that they are able to refuse participation in studies. <sup>12</sup> The reliance on humanitarian actors to provide housing, provisions, and medical services might also unintentionally coerce individuals into participating in research. <sup>13,14</sup>
History of ethical violations	Instances of violations of confidentiality have generated a mistrust of foreign scholars and reluctance to participate in research. <sup>15</sup> At times, these breaches of trust have caused irreparable harm to participants, including instances in which research groups have disclosed the identities of women who were raped, leading to these women being shamed and scorned by the community, or disclosed the identity of a refugee and activist, placing them in immediate danger. <sup>14</sup>
Nonfunctional IRB	In some conflict settings, ethics review boards might not be functioning or might be entirely absent. In these cases, agencies might rely on their own ethics review policies, which might not conform to international human rights standards or law. <sup>16</sup>
Political pressure	Political pressure to withhold or alter data can introduce ethical dilemmas and have severe implications for the safety of researchers. <sup>1</sup> A recent and well-known example was the arrest of Paul Foreman, the head of Médecins Sans Frontières Holland, and Vincent Hoedt, Darfur regional coordinator in South Sudan, for publishing a report on rapes in Darfur. <sup>17</sup>
Tensions with impartiality	In conflict situations, being perceived as impartial might not be possible, especially when polarization in the community is so strong that if one does not favor a certain group, one is seen as the enemy. <sup>18</sup>

Dynamic context	In contrast to humanitarian contexts, in which the needs of populations can rapidly evolve, ethics review processes can be lengthy, slow, and create a disconnect between research design and implementation. <sup>19</sup>
Dual imperative	The increased vulnerabilities and risks associated with participating in research in conflict settings require that any research must be driven by the needs of the population and meet a higher standard of benefit to the population. <sup>20</sup>

With limited guidance on the ethical tensions that can emerge when research is conducted with conflict-affected populations, many ethics review boards struggle with reviewing applications outlining research with these populations.<sup>14,19</sup> Recognizing this gap, there have been increasing global efforts to codify and create guidelines for ethical research with conflict-affected populations. Among these efforts is the work of Enhancing Learning and Research for Humanitarian Assistance, a nonprofit organization that has created a research ethics tool in the form of a series of questions that allows researchers to reflect on the ethics of their work at different stages of the research process, from planning to dissemination.<sup>21</sup> Moreover, the Nuffield Council on Bioethics report, *Research in Global Health Emergencies: Ethical Issues*, created an ethical compass to guide research practices that highlights principles such as fairness, equal respect, and reducing suffering.<sup>22</sup> Similar efforts have also been initiated by independent ethics review boards, such as the one established by Médecins Sans Frontières.<sup>1</sup>

Despite such efforts by independent organizations, little is known about the extent to which and the ways in which national and international ethics guidelines incorporate guidance for research on conflict-affected populations. Our study aimed to fill this gap by systematically analyzing the existing ethics guidelines of humanitarian donor countries, conflict-affected countries, United Nations (UN) agencies, and funding agencies. We also aimed to understand how guidelines translate into practice by analyzing research practices in empirical articles on conflict-affected populations. Through a comprehensive review of guidance and its translation into practice, our study adds to a small but growing body of literature on research ethics for conflict-affected populations.<sup>23</sup>

## Methods

**Data sources.** Using targeted Google searches and search functions on agency websites, we found national research guidelines for 17 humanitarian donor countries and unions (Australia, Belgium, Canada, Denmark, the European Union, France, Germany, Ireland, Italy, Japan, the Netherlands, Norway, Sweden, Switzerland, the United Kingdom, Spain, and the United States) that were drawn from the list of top 20 countries contributing to humanitarian assistance as identified in the 2018 Global Humanitarian Assistance Report.<sup>24</sup> Furthermore, using targeted Google searches and search functions on government websites, we found national guidelines from 8 conflict-affected countries (Bangladesh, Lebanon, Liberia, Nigeria, Pakistan, the Democratic Republic of Congo, Mali, Ukraine) of 20 identified. Sixteen conflict-affected countries were identified using the 2018 Harmonized List of Fragile Situations,<sup>25</sup> and 4 were identified by other means. Two guidelines from humanitarian donor countries (Spain, Germany) and 3 guidelines from conflict-affected countries (Democratic Republic of Congo, Mali, Ukraine) were not extracted because they were not in English. Using similar searches, research guidelines were included in the analysis from 3 UN agencies—the UN Office for the Coordination of Humanitarian Affairs, the World Health Organization (WHO), and UNICEF—of the 9 such agencies active in conflict settings that were identified from the 2018 Global Humanitarian Assistance Report,<sup>24</sup> and granting

regulations were included in the analysis from 9 donor agencies (the Bill and Melinda Gates Foundation, the Wellcome Trust, the Medical Research Council, the National Institutes of Health, the North American Aerospace Defense Command, the Swedish International Development Cooperation Agency, GAVI, the Global Fund, and the International Development Research Centre) (see [Supplementary Appendix](#)) from a list of 10 of the major research funding bodies and national funders (the Global Financing Facility was excluded).

We utilized the BRANCH Consortium database to identify articles for review. The BRANCH database contains articles published between January 1, 1990, and March 31, 2018, on a range of health interventions delivered to women, children, and adolescents in conflict-affected populations in lower and middle-income countries.<sup>3,4,5,6,7,8,9,10</sup> The database drew on 6 searches that were conducted in MEDLINE, Embase, CINAHL, and PsychINFO using keywords and medical subject heading terms (MeSH) related to conflict, health, and women, children, and adolescents. (Final searches were run between April 2018 and July 2018 for papers published between January 1, 1990, and March 31, 2018.) Articles that were not published in English or in peer-reviewed journals, that reported on military personnel, and that were single-patient case reports were excluded. Systematic reviews, editorials, opinion pieces, guidelines, and economic or mathematical modeling studies were also excluded. The analysis included a total of 498 articles published in peer-reviewed journals.

*Data extraction and analysis.* Guidance from donor countries and conflict-affected countries was reviewed for mention of ethical principles and related terms, such as researcher safety, confidentiality, scientific validity, collaborative partnerships, informed consent, security risks, social value, postresearch conduct, community engagement, and harm-benefit ratio. Data were also extracted on the local ethics review process and how to proceed when in-country ethics boards are not functioning. In addition, we reviewed research ethics guidelines or granting regulations from UN agencies and funding bodies to determine if studies must consider any of the ethical principles mentioned above to be eligible for funding as a way to help disentangle the role that granting agencies play in determining ethical research practice. Single data extraction was performed by 3 of the authors (S.L., M.H.A., N.A.S.).

From the articles, we extracted data on the reporting of ethics approval, informed consent, types of informed consent, funding, and collaboration. Additional searches identified ethics requirements for publication. Descriptive statistics were used to summarize key indicators related to the reporting of ethics approval and informed consent.

## **Results**

*Review of guidelines.* Conflict-specific guidance was overwhelmingly absent from research guidance issued by governments, donor agencies, and UN agencies. Of the 32 research ethics guidelines and regulations reviewed, only 4 mentioned conflict-affected populations—UNICEF, WHO, the Australian National Statement on Ethical Conduct in Human Research, and the US Agency for International Development (USAID) Scientific Research Policy. None of the research guidelines from conflict-affected countries mentioned conflict-affected populations. Three guidelines grouped conflict-affected populations and/or refugees as vulnerable groups, including the USAID Scientific Research Policy, UNICEF guideline, and WHO guideline. However, these guidelines failed to highlight any specific vulnerabilities of conflict-affected populations related to their

displacement history or experiences of violence in comparison to other vulnerable groups (see Table 1 for examples).

Even fewer guidelines explicitly described procedures for research with conflict-affected populations. Only the Australian National Statement on Ethical Conduct in Human Research noted how specific ethical principles, such as researcher and participant confidentiality, fair selection of participants, and the **particularities of informed consent** with refugees, should be considered. The UNICEF guideline added that any research with refugees or people in conflict or in postconflict settings requires additional review but did not specify what that would entail.

Lastly, only 3 guidelines—the Australian National Statement on Ethical Conduct in Human Research, the second edition of the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and the Wellcome Trust’s policy on research involving human participants—described how to proceed when there is a nonfunctional or absent institutional review board (IRB). However, the Canadian Tri-Council Policy and Wellcome Trust policy did not explicitly link an absent IRB to research in conflict settings or with conflict-affected populations.

*Review of research practices.* The majority of the 498 articles published in peer-reviewed journals focused on infectious disease (20.5%); maternal, newborn, sexual, and reproductive health (19.9%); and mental health (18.7%). The geographic regions of investigation included Sub-Saharan Africa (35.7%), Western Asia (20.3%), South Asia (16.5%), and Southeastern Asia (15.5%). Many articles focused on the health of refugees (37.6%), and the most common study type was observational (73.3%) (see Table 2).

**Table 2.** Analysis of 498 Articles in Peer-Reviewed Journals

Variable	No. (%)
<b>Publication year</b>	
1990-1994	24 (4.8)
1995-1999	51 (10.2)
2000-2004	59 (11.8)
2005-2009	87 (17.5)
2010-2014	145 (29.1)
2015-2018	132 (26.5)
<b>Region</b>	
Africa	
Northern Africa	18 (3.6)
Sub-Saharan Africa	178 (35.7)
Americas	
Latin America/Caribbean	6 (1.2)
Asia	
Southeastern Asia	77 (15.5)
South Asia	82 (16.5)
Western Asia	101 (20.3)
Europe	

Eastern Europe	1.0 (0.2)
Southern Europe	23 (4.6)
Oceania	
Melanesia	1 (0.2)
Multiple countries	11 (2.2)
<b>Study type</b>	
Mixed methods	22 (4.4)
Observational methods	365 (73.3)
Qualitative methods	23 (4.6)
Quasi-experimental/nonrandomized control trial	18 (3.6)
Randomized control trial	70 (14.1)
<b>Research participants</b>	
Internally displaced persons	77 (15.5)
Mixed	89 (17.9)
Nondisplaced persons	54 (10.8)
Refugees	187 (37.6)
Returning refugees	4 (0.8)
Not reported	87 (17.5)
<b>Health area focus</b>	
Infectious diseases	102 (20.5)
Injuries	71 (14.3)
Mental health	93 (18.7)
Noncommunicable diseases	23 (4.6)
Nutrition	31 (6.2)
Sexual reproductive and maternal newborn health	99 (19.9)
Water, sanitation and hygiene	14 (2.8)
Multiple health areas	65 (13.1)
<b>Location of authors</b>	
National study	31 (6.2)
International study	467 (93.8)

Reporting of ethics approval was low, with only 45.8% of articles reporting that ethics approval was received and 2.4% of articles reporting that an ethics waiver was obtained. In almost half (47.3%) of the articles, the authors did not report whether they had sought ethics approval or a waiver for their study. In an additional 2.0% of articles, the authors reported that they had not sought ethics approval or a waiver exemption for their study, and in 2.4% of articles, the authors reported that they did not seek ethics approval but did not report if they had sought a waiver. No articles reported seeking ethics approval and not receiving it.

Of the 22 studies for which the authors reported that they did not seek ethics approval or a waiver or reported that they did not seek ethics approval but did not report if they sought a waiver, the stated reasons included that the study was a monitoring and evaluation study (54.5%) or used chart or secondary data (31.8%) or that there was no

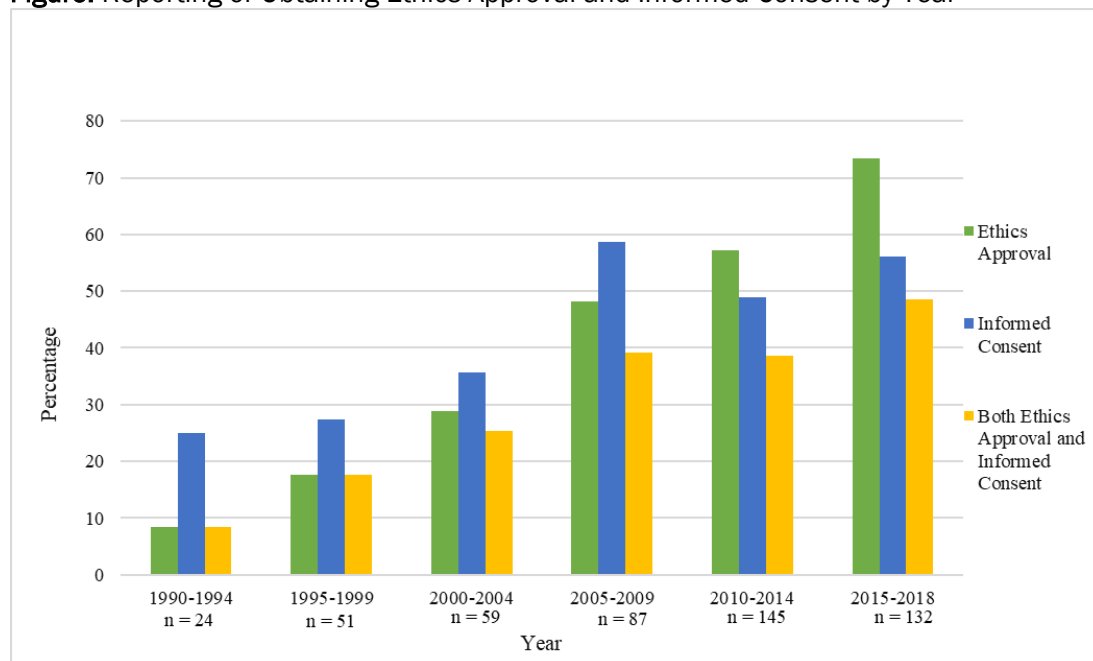
active IRB (4.5%). For the remaining 9.1% of articles, it was unclear why researchers did not seek ethics approval or a waiver.

Reporting rates of ethics approval differed greatly between international and national studies, with lower reporting of IRB approval in the subset of international studies (43.0%) than national studies (87.1%). Among international studies, in only 38.8% did the authors report receiving ethics approval from both their home institution's ethics board and the ethics board in the country of study; in 28.4%, the authors reported receiving ethics approval only from an international institution; and in 31.8%, the authors reported receiving ethics approval only from an institution in the country of study. Interestingly, 88.5% of the articles for which the authors did not report obtaining ethics approval were published in journals that required reporting of ethics approval. Of the 236 studies that did not report ethics approval, only one was published in a journal listed in the 2016 Beall's List of Predatory Publishers.<sup>26</sup>

Reporting of informed consent was also low, with only 46.6% of all research studies reporting that informed consent was obtained. In almost half (49.0%) of the studies, the authors did not report whether they obtained informed consent from their study participants, and in 4.4% of studies, the authors reported that they did not obtain informed consent. Of the 232 studies for which informed consent was obtained, the most common types of informed consent were written consent (34.9%) and verbal consent (33.2%), and a small proportion of the studies reported other types of consent, such as implied consent or a combination of written and verbal consent (3.0%). An additional 28.9% of studies did not report how informed consent was obtained.

Despite low overall rates of reporting ethics approval and informed consent, our findings demonstrated that reporting has increased with time (see Figure). Reporting of ethics approval and informed consent followed a linear trend with the exception of articles published between 2005 and 2009, which had the highest percentage of studies reporting informed consent. Interestingly, reporting of ethics approval and informed consent was discordant, with some studies reporting either ethics approval or informed consent.

**Figure.** Reporting of Obtaining Ethics Approval and Informed Consent by Year



## Discussion

Overwhelmingly, our study demonstrated that ethics guidelines from national government organizations and UN agencies and grant regulations from funding agencies do not include details about the ethical conduct of research with conflict-affected populations. The majority of guidelines and granting regulations reviewed (87.5%) did not mention conflict-affected populations, and only one (3.1%) described any of the complexities related to conducting research with conflict-affected populations. These findings support critiques that many institutional ethics committees are inadequately prepared to provide **ethical oversight of research** that is conducted with conflict-affected populations.<sup>13</sup> Although it should be noted that the lack of guidance does not imply that unethical research practices are occurring, it highlights a gap that must be addressed. There is a need to integrate guidance for research with conflict-affected populations into national, UN agency, and donor guidelines.<sup>1,21,22</sup> We contend that such guidance should describe how to navigate ethical tensions that might arise in the conduct of research with conflict-affected populations, including how to negotiate conflicting ethical principles and how to operate in settings where there is a nonfunctional ethics review board. Further research is also needed to understand how the lack of detailed guidance is shaping research practices.

Our study also identified poor ethics reporting practices, with 47.3% of articles not reporting ethics approval or a waiver. These findings align with similar studies, including a recent scoping review by Makhoul et al on ethical research practice in studies with refugees and war-affected populations in the Arab world, which found that 52% of studies did not report receiving ethics approval.<sup>23</sup> Similar to Makhoul et al, our findings suggest that the reporting of ethics approval and informed consent has improved from the 1990s to the present, which might reflect changes in reporting requirements of journals.<sup>23</sup> Importantly, our study identified a large disparity between the subset of national studies and the subset of international studies reporting ethics approval. This



finding is particularly concerning, given the history of ethical violations by foreign scholars.<sup>15</sup>

Among the studies for which the authors did not report whether they received or did not receive ethics approval or a waiver, 88.5% were published in peer-reviewed journals that required the reporting of ethics approval. This inconsistency highlights the need for stricter enforcement of reporting requirements. Although poor reporting of ethics approval reflects a wider systemic issue,<sup>27,28,29</sup> the potential for ethical violations in research with conflict-affected populations requires greater ethical oversight of research practices.<sup>13</sup> Journals have a responsibility to ensure that all published articles contain details on ethical procedures, including, at a minimum, informed consent and institutional ethics approval. Some journal editors might contend that our request places additional burdens on authors and editorial staff. We agree that such requests place extra demands; however, we argue that the increased potential for ethical violations with conflict-affected populations requires stricter reporting standards. We would further argue that reporting should extend to a discussion of the ethical tensions that arose during the research process and how the researchers navigated those challenges. These discussions not only would be insightful for others working in similarly complex environments, but also would help make the research process more transparent and prevent any intentional or unintentional ethical violations.

Our study had several limitations. We relied on information that was reported by authors in the articles and were unable to do any additional follow-up. Our study was also limited to articles published in peer-reviewed journals. Moreover, given that the focus of our study was guidelines shared by decision-making bodies, such as governments, donors, and UN agencies, we did not extract guidelines from any nongovernmental or independent organizations. We were also limited to guidelines and granting regulations that were available online, and we excluded non-English literature and guidelines. We must also acknowledge that we only extracted current journal reporting requirements, which might have changed since when the article was published. Lastly, to identify articles, we used a database limited to articles on the delivery of reproductive, maternal, newborn, child, and adolescent health and nutrition interventions in conflict settings. However, we believe that using this database might actually have led to the inclusion of a wide set of studies capturing a range of health conditions and contexts.

These limitations are coupled with several strengths. To the authors' knowledge, this is the only study evaluating the reporting of ethical research practices with research on conflict-affected populations globally. Additionally, our review comprehensively looks at different stages of the research process from guidance to practice.

Overall, our work echoes the calls made by others—namely, that generating ethical research extends beyond the role of the researcher to include funders, journals, and other policy decision makers.<sup>22,23</sup> Partnerships between institutional ethics committees, donor agencies, and journals could ensure that guidelines are adhered to by researchers and that conflict-affected populations are protected. Through critical reflection and multidisciplinary collaboration, we can begin to shift the conversation of ethics from one of harm minimization to one of reciprocal benefit for researchers and conflict-affected populations.

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