



Review Article

Climate Change and the IRB review Process of Protocols

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Abstract: Climate change is a global environmental threat that affects societies specially making the greatest health inequities, and disparities in the present day. Therefore, now a day, research is concentrated on understanding the extensive consequences of climate change on health and evaluating the effectiveness of interventions to adjust and alleviate these effects. The Institutional Ethical Review Board (IERB) is vital in maintaining ethical standards in research by safeguarding the rights, safety, and well-being of participants. They evaluate research protocols, examine potential risks and benefits, and offer researchers advice on ethical matters. Nevertheless, climate change justice is new to IERB specially in developing countries. To find out the gaps in the review process and possible solutions between climate change, health research, and IERB. This result may facilitate awareness among IERB members and provide an action guide to policy makers with the reflection of good ethical practice in climate health research.

Key words: Climate change, ethical consideration, potential risk, IERB, health research.

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Introduction: Climate change, an escalating global crisis stands as one of the most profound and pressing challenges of the 21st century. It has far-reaching implications for human health, well-being, and global equity¹. Impacts of climate change are not uniform throughout the world; it disproportionately affects vulnerable populations, exacerbates existing inequalities, and creates new forms of injustice¹. From extreme heat events and altered patterns of infectious diseases to food insecurity and displacement, the health consequences of a changing climate are increasingly evident and demand urgent action^{2,3,4}.

Climate change is unequivocally proven to have consequences of the greenhouse effect (global warming); mostly due to man-made emissions of greenhouse gases (mostly CO₂, CH₃ & NO₂) from ever rising fossil fuel burning and land use changes⁵. The IPCC Report gives detailed projections for the 21st century, and these show that global warming will continue and accelerate⁵. Rising global temperatures contribute to changes in precipitation patterns and extreme weather events, such as heat waves, floods, and droughts which ultimately impact water quality, food insecurity, and increase the risk of water-borne and vector-borne diseases like dengue fever and malaria. Air pollution, often exacerbated by fossil fuel combustion and wildfires, contributes to respiratory and cardiovascular diseases^{3,4}. Beyond direct physical health impacts, climate change also profoundly affects mental health through experiences of displacement, loss of livelihoods, and chronic environmental stress⁴⁻¹².

This escalating crisis of climate change has led a significant increase in research efforts aimed at understanding, mitigating, and adapting to climate change, particularly concerning its human health dimensions². However, as research protocols delve into sensitive areas involving human populations, often the vulnerable ones, the ethical complexities inherent in such studies become paramount. The researches involving human beings, animals, foods, or environments also have significant impact on climate, health and communities. This necessitates a rigorous and

thoughtful review process by Institutional Research Ethics Boards (IREBs), or Institutional Review Boards (IRBs) to ensure the protection of human subjects and the responsible conduct of research.

The current IERBs typically based on international ethical guidelines (e.g. Nuremberg Code and the Declaration of Helsinki), review research protocols to ensure scientific soundness, minimize risks to participants, maximize potential benefits, and uphold principles of justice, beneficence, and respect for persons^{14,15}. The current IRB system typically focuses on issues related to the individual, such as adequate informed consent, and may not be sensitive to the impact of the study on the community and environmental health^{15,16}. For climate change-related research, the IERB's role takes on additional layers of complexity, as the studies often involve diverse populations, transboundary implications, and long-term consequences that may not be immediately apparent¹³⁻¹⁶. New scientific discoveries and real-world experience are making people take a fresh look at the ethical issues in environmental health^{7,3}. This is based on the idea that individuals, communities, and businesses all have a shared responsibility to care for the environment and protect public health.

Climate change presents a profound ethical crisis, particularly due to its disproportionate impact on health, especially of the vulnerable group call for the urgent impartial responses. The ethical dimensions of climate change are multifaceted. Incorporating ethics into climate policy involves recognizing the value of all human lives equally, regardless of geography or economic status. The intersection of climate change, health, and ethics underscores the necessity for policies that are not only effective but also inclusive. Research in these areas, therefore, often involves studying populations already under significant duress, highlighting the need for enhanced ethical vigilance^{1,2,14,15,17,18}.

The unique ethical considerations in climate change research protocols are increasingly being recognized. These include, but are not limited to, issues of distributive justice,

intergenerational equity, and the potential for research itself to inadvertently exacerbate existing vulnerabilities or create new harms. The concept of "prevention of harm" is concerned not only with individual participants but also to the broader communities and ecosystems affected by climate change and the research undertaken in response¹. The UNESCO Universal Declaration on Bioethics and Human Rights (2005) emphasizes protecting future generations and the environment as essential ethical duties¹⁷. The Declaration of Ethical Principles in Relation to Climate Change¹ outlines key values, such as, stewardship, justice, precaution, solidarity, and transparency to guide climate-related decisions and policies. Together, these frameworks ensure climate research is both scientifically rigorous and ethically grounded.

Therefore, it is apparent that, the bridge between climate change, health research, and ethics is a burning issue. Moreover, the consideration of ethical issues related to research, and specifically research related to environmental health, is a much more recent concept. In Bangladesh, the ethical practice related to health research and climate change is not yet practiced routinely¹⁸. So, IERB can play a crucial role during the review process of the protocol.

Methodology: This systematic review involved identifying the climate change and the IRB review process of a protocol. To find suitable articles multiple databases were chosen. These were Lancet, PubMed, Google scholar. These databases were accessed through the internet. At first PubMed was selected for advanced search. "Climate change" was included for outlining findings up to last 10 years from the time of search. After clicking "search" we got descriptors for climate change. Then we clicked "Health" click "search" and got a search history. We repeated the same procedure with other keywords such as "research" and "ethics". Eventually, we combined all these search histories and got the result of 27 articles which address climate change and ethical aspects of research

Results:¹⁻³⁰. The relationship between health, climate change, and ethics is technically and theoretically complex. The existing work in this area remains fragmented, lacks a clear focus, and is still underdeveloped. In addition, barriers including lack of awareness, trained resources, financial capacity, and interdisciplinary collaboration, the following are the limitations of IERB.

1. Limited awareness of the ethical dimensions underpinning policy responses to climate change³⁰.
2. Insufficient action-guiding ethical frameworks tailored for health practitioners involved in climate-related decision-making³⁰.
3. Neglect of mental health and general well-being in assessments of climate change's health impacts.
4. Scarcity of ethical analysis in core areas of environmental health, such as population, pollution, transport, energy, food systems, and water use.
5. Lack of interdisciplinary ethical discourse, bridging public health, environmental science, policy, and philosophy³⁰.

What is needed:

1. Researchers should integrate ethical considerations of climate vulnerability, health equity, and sustainability into protocol design.
2. Health Equity: Climate change disproportionately affects vulnerable populations, with low-HDI (Human Development Index) countries underrepresented in research and policy discussions. Ethical concerns include inequalities in contributions to and harm from climate change.
3. IRB's Response: The IRB should implement strategies for the Climate Change Policy to address health risks.
4. Call to Action: Upstream solutions, such as structural and policy changes, are essential for primary prevention and promoting sustainable communities.

The 2015 Lancet Commission on Health and climate change emphasized that climate change is the global health threat of the 21st century, but also identified it as the greatest global health opportunity¹⁹. The scope of ethical considerations of climate and health

research may therefore need to be expanded to include more-than-human interests, acknowledge the value of ecosystems, and consider possible trade-offs between human and non-human health in research.

It stresses the importance of integrating diverse worldviews, specially indigenous understandings of health, which often link well-being with land, environment, and place into the normative frameworks that guide climate and health research.^{9,10}

Discussion: This section covers the role of IRBs in the protocol review process in climate change research. This part discusses why and how traditional methods can be changed toward climate health research to protect the rights and well-being of the climate-vulnerable population.

The Traditional IRBs and its role in protocol review^{13,15,16,21}: The foundation of the current IRB was built on acknowledging individual human rights. The current IERB mandate, typically rooted in international ethical guidelines such as the Nuremberg Code and the Declaration of Helsinki, involves reviewing research protocols to ensure scientific soundness, minimize risks to participants, maximize potential benefits, and uphold principles of justice, beneficence, and respect for persons¹⁵. The Nuremberg Code and the Declaration of Helsinki^{4,13,15,16} mandated a need for voluntary consent of participants free of coercion to any involvement in research and the participant's right to withdraw at any time from the study. Participant's consent must be based on a thorough understanding of the proposed research, and the benefits of the study must outweigh any risks or harm involved. Investigators must be fully qualified and must have through knowledge of all aspects of the study.

The Belmont Report and others^{6,13} also focus on the rights of individual participant by defining four elements: respect for autonomy, beneficence, non-maleficence, and justice. Justice is usually characterized as being fair, but it demands consideration of broader

societal issues of equity and distribution of services.

The U.S. Federal Policy for the Protection of Human Subjects (DHHS 2005, 45 CFR 46)¹³ defines a human subject as "a living individual about whom an investigator obtains data through intervention or interaction with the individual, or identifiable private information." This definition again focuses on protecting the safety and ensuring the rights of the individual, conversely, ignores issues related to tissue from deceased individuals and concerns for vulnerable populations and those unable to give informed consent because of a lack of capacity.

The FDA monitors drug and device development, requiring adequate demonstration of safety and efficacy before marketing a new product or device. FDA approval process initiates with and requires extensive animal testing to evaluate efficacy and safety before proceeding to human trials. The FDA requires a similar IRB approval process for human research with some minor differences with 45 CFR 46^{20,21}.

The current IRB system is still evolving as new biomedical treatments such as gene therapy develop. The IRB system also needs to evolve to support research designed to evaluate community-based issues, often referred to as community-based research or community-based participatory research (CBPR), and climate change related issues.

Community-Based Participatory Research (CBPR)^{13,22}: Community-based Research is a collaborative approach that fosters reciprocal partnerships between researchers and community members. It emphasizes building trust, fostering collaboration, and engaging in negotiation to pinpoint and tackle health challenges. CBPR is best characterized as doing research "with" the community, not "to" the community. It requires community involvement in all phases of the research from conception and planning to gathering data, interpreting results, and finally developing reports and action plans.

CBPR is based on the following six principles¹³.

1. Promotes active collaboration and participation of all parties at every stage of research.
2. Fosters co-learning and sharing of knowledge of researchers and participants.
3. Ensures that projects are community driven i.e., address questions and concerns of the community, not just of the researchers.
4. Disseminates results in useful terms and results are communicated to the participants in an appropriate and sensitive format.
5. Ensures that research and intervention strategies are culturally appropriate.
6. Defines community as a unit of identity (community to be defined) for collaboration in the project.

The workplace may also be considered a defined community, and the workplace varies from the traditional manufacturing area or fields in an agricultural area, and each of which requires thoughtful consideration of unique community issues¹³. As the ethical principles that support and guide the traditional IRB are focused on the individual, to address the broader constituency of the community and workplace, a new ethical construct is required to support and guide an Environmental Health and Community Review Board (EHCRB).

Are traditional IRBs capable enough in addressing climate change?¹³⁻¹⁶

The existing CIOMS & WHO ethical guidelines⁴ are comprehensive for biomedical and public health research, but have notable gaps when addressing the ethics of climate change and health. Some important noticeable gaps are-

1. Limited explicit focus on climate change: Current guidelines mention environmental considerations only tangentially. There is no dedicated section on how ethical review process should handle the climate Health Nexus.
2. Insufficient guidance on intergenerational justice: Climate change raises issue of protecting future populations. Guideline largely focus on current human subjects not long-term ecological and health impacts.
3. Neglect of ecological and planetary health ethics: Guidelines do not integrate planetary health principles, which is the independence of human and environmental health. Ethical guidance treat the environment as background not as an active concern.

4. Weak framework for climate vulnerability: Guidelines do not provide specific tools for assessing or protecting the groups vulnerable to climate change.

5. Lack of mandate for climate related ethical impact assessments: There is no structured requirement to evaluate how a study contribute to or mitigate climate change or related health impacts.

Why is Climate Change Relevant to IRB Review?

Climate change is not merely an environmental phenomenon; it is a profound determinant of health, well-being, and social stability^{2,4}. Research conducted in the context of climate change, or on populations affected by it, introduces unique ethical challenges that align directly with the IRB's mandate:

1. Exacerbated Vulnerabilities: Climate change disproportionately affects already vulnerable populations. Research involving these groups requires heightened ethical scrutiny.
2. Novel Risks and Harms: Climate impacts can introduce new physical, psychological, social, and economic risks to research participants and communities.
3. Justice and Equity: The unequal distribution of climate change impacts raises questions about who benefits from research and who bears its burdens.
4. Urgency vs. Ethics: The pressing need for climate-related research must be balanced with rigorous ethical oversight to prevent exploitation.

How IRB Review Can Address Climate Change Issues^{18,24,25,26}

The Institutional Review Board (IRB) plays a critical role in safeguarding the rights and welfare of human subjects participating in research. As climate change increasingly impacts human populations and ecosystems, its implications for research ethics are becoming more pronounced, necessitating a proactive approach by IRBs to address these complex issues within protocol review. IRBs can integrate climate change considerations into their review process by focusing on several key areas:

1. Prioritizing Ethical Review of Climate-Health Research: IERB can give special attention to research proposals focus on climate-related

disease patterns, vulnerable populations, and climate adaptation strategies in public health.

2. Identifying and Protecting Vulnerable Populations ^{2,4,5,20,26}

Expanded definition of vulnerability: IRBs should recognize that climate change creates or exacerbates vulnerabilities, which include individuals displaced by climate events, the population of climate-vulnerable areas (e.g., coastal areas, drought-prone regions), and communities whose livelihoods are directly threatened by environmental shifts.

Targeted safeguards: Protocols involving climate-vulnerable groups should detail specific measures to protect their rights and welfare, such as culturally appropriate consent processes, community-led engagement, and strategies to prevent coercion or undue influence.

3. Comprehensive Risk Assessment and Mitigation ^{20,21, 25,26}

Environmental risks during data collection: Potential physical risks related to climate conditions during fieldwork (e.g., extreme heat, air pollution, exposure to vector borne diseases etc.) are to be explicitly addressed. Protocols should outline safety measures, emergency plans, and adequate resources for participant well-being.

Psychological and emotional risks: Research on climate impacts can evoke distress, anxiety, or re-traumatization (e.g., discussing loss, displacement, or future uncertainties). IRBs should ensure protocols include psychological support mechanisms, referral services, and sensitive interview techniques.

Social and economic risks: Consider risks of stigmatization, discrimination, or economic disruption resulting from participation or the dissemination of findings, especially for communities reliant on climate-sensitive resources.

4. Robust Informed Consent Processes ^{1,13,14,17}. Transparency of climate-related risks: The consent form should clearly explain any climate-related risks associated with participation, including potential environmental

hazards during data collection or the emotional impact of discussing climate change.

Contextual understanding: For communities deeply affected by climate change, consent processes must be adapted to their specific cultural norms, literacy levels, and current circumstances (e.g., during or after a disaster, when basic needs might be paramount).

Addressing coercion: IRBs must scrutinize protocols to ensure that incentives for participation do not constitute undue inducement or coercion.

5. Promoting Environmental Justice and Equitable Benefits ^{1,24,25}. Fair participant selection: Evaluate whether research disproportionately affects or neglects marginalized populations.

Community-level benefits: Push for fair distribution of resources and benefits in climate-related studies, such as contributing to local adaptation strategies, informing policy, or building local capacity.

Benefit-risk ratio evaluation: IRBs must carefully weigh the potential benefits of the research (e.g., informing climate policy, developing resilience strategies) against the risks to participants, ensuring a favorable balance.

6. Ensuring Community Engagement and Participatory Approaches ^{13,23}.

Meaningful involvement: IRBs should encourage and ensure that the researchers engage affected communities in the design, implementation, and dissemination of climate change research in a meaningful & useful way.

Capacity building: Protocols could include plans for building local research capacity or empowering communities to conduct their own climate-related assessments.

7. Data Management and Sharing Ethics

Data security in unstable environments: Protocols should detail how data will be securely collected, stored, and protected in areas potentially affected by climate disasters or instability.

Sensitive data handling: IRBs should ensure robust data protection measures, including anonymization or de-identification where

appropriate, during handling sensitive personal data (e.g., health status, migration experiences, and economic hardship).

Data ownership and access: For research involving indigenous or local communities, protocols should address principles of data sovereignty and ensure equitable agreements for data ownership, access, and future use.

8. Supporting Interdisciplinary Approaches: IERB should encourage: Collaboration across public health, environmental science, and social disciplines. Integrated methods that address both health and ecological sustainability.

9. Sustainability and Societal Impact Considerations ^{1,27}

Sustainability of interventions: IRBs might consider long-term sustainability of an intervention, which contributes to community resilience beyond the research period.

Ethical dissemination: IRB should be vigilant whether protocols outline plans or not for disseminating findings in a way that respects participants, avoids sensationalism, and effectively informs policy and action without causing further harm or distress.

By integrating these considerations, IRBs can ensure that research addressing the critical challenges of climate change is conducted ethically, responsibly, and with due regard for the rights and welfare of all human participants, especially those most affected by environmental shifts.

Conclusion: The global climate crisis threatens most people and their human rights. The adverse consequences of climate change will continue to worsen. Addressing climate change is both a health and human rights priority, and urgent action is essential. Mitigation and adaptation measures must be equitable, protecting and promoting human rights. Climate change responses must be informed by the needs of affected communities and developed in partnership with them to ensure ethical integrity, social responsibility, and alignment with guidance from IERBs in routine policy and practice.

The Institutional Review Board (IRB) should shift its typical focuses on safeguarding the rights and welfare of human subjects participating in research. IRBs should be to more sensitive to issues related to the effects of climate change with related health hazards and participatory community involvement in research. To maximize this effort, IRB process involving environmental scientists in IRB, updating knowledge of IRB members by arranging regular training &, workshop on ethical issues.

Recommendation: Developed countries can play a crucial role in helping the IRBs of developing countries to address climate change and related health hazards from research by, i) capacity building and training ii) funding ethical infrastructure, iii) promoting equitable research partnerships, iv) sharing ethical tools and frameworks, v) supporting policy advocacy, vi) encouraging transparency and accountability. The new construct of IERB should incorporate climate change while emphasizing social responsibility along with the traditional principles of autonomy, beneficence, non-maleficence, and justice.

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