Position of the
European Network of Research Ethics Committees (EUREC) on vulnerability and responsible inclusion in research

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Background

Ensuring ethical and inclusive research is a fundamental principle instilled by research ethics committees (RECs). While the protection of participants from harm remains a core focus of RECs, there is growing acknowledgement that excluding certain groups from research can also constitute harm. Recent revisions to international ethical guidelines, including the updated Declaration of Helsinki (DoH), reflect a shift toward responsible inclusion (RI), building on principles already outlined in the CIOMS International ethical guidelines for health-related research involving humans (2016).

EUREC supports responsible inclusion as a central principle of contemporary research ethics and encourages RECs to adopt a context-sensitive and dynamic understanding of vulnerability. Responsible inclusion requires that participation in research be both ethically justified and socially meaningful, with attention to the broader contexts that shape who can participate and under what conditions.

The Clinical Trials Regulation N° 536/2014 (CTR), the Medical Devices Regulation N° 745/2017 (MDR) and In Vitro Diagnostic Regulation N° 746/2017 (IVDR) are generally compatible with the paradigm of responsible inclusion articulated in the updated Declaration of Helsinki (2024) and the CIOMS (2016) guidelines. EUREC encourages RECs, research sponsors and investigators, and regulators to interpret EU regulations in a way that reflects a dynamic and contextual understanding of vulnerability and to promote the application of these regulations in ways that support responsible inclusion. This position paper advocates for greater alignment of European regulatory frameworks with responsible inclusion.

Position

1. The Declaration of Helsinki (Article 19) states that “some individuals, groups, and communities are in a situation of greater vulnerability as research participants due to factors that may be fixed or contextual and dynamic, putting them at greater risk of being wronged or incurring harm.” EUREC supports the view that vulnerability is not a fixed category but can fluctuate depending on specific circumstances. Since all individuals may experience vulnerability in certain contexts, ethics review should acknowledge this complexity rather than rely on static classifications.

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2. RECs have the responsibility to protect the respect, well-being and safety of participants. People in situations of vulnerability are generally at higher risk in clinical trials due to their reduced ability to protect their own interests, and they require special and/or additional protections, such as enhanced informed-consent procedures, risk minimisation, and a strong justification for their inclusion. EUREC also recognises that research involving populations in vulnerable situations is, in many cases, necessary. Exclusion can constitute harm, as it may prevent groups with distinct health needs from benefiting from research, thereby exacerbating situations of vulnerability. It may also lead to exacerbating potential inequalities across certain vulnerable populations. Enabling the participation of groups in vulnerable situations helps ensure that research findings are relevant and applicable to diverse populations, supporting interventions and policies that, for example, address specific health needs and improve overall health outcomes. Ethics review should ensure that (a) inclusion is proportionate to the potential direct or indirect benefits for participants or their communities, (b) participants are provided with appropriate support throughout the study, and (c) clear and well-defined protective measures are in place.

3. EUREC recognises that the primary responsibility for implementing responsible inclusion lies with research sponsors and investigators, who design and conduct studies. The role of RECs is to promote, assess, and support such inclusion through ethics review. During the ethics review, RECs should be able to identify whether groups in vulnerable situations should be or are participating in research, then define the specific vulnerabilities present in the study context – considering situational, social, or health-related factors – and finally ensure that protective measures adequately safeguard participants.

4. According to the Declaration of Helsinki (Article 19), responsible inclusion necessitates "specifically considered support and protections" for research participants in vulnerable situations. RECs must identify the needs that inform the development of these supports and protections and ensure that such measures enable participation rather than create barriers to it. Respect for participants, including recognition of their autonomy, values, preferences and lived experiences, should guide all such efforts.

5. Meaningful engagement with research participants, patient advocacy groups, and the public can help RECs as well as research sponsors and investigators better understand the needs of groups in vulnerable situations and thus further responsible inclusion. EUREC encourages RECs to actively support patient and public involvement (PPI) initiatives and committee membership, particularly those that represent groups in vulnerable situations, as part of a broader commitment to inclusive and participatory ethics review processes. Such engagement ensures that inclusion efforts are grounded in the lived experiences, perspectives, and priorities of those most affected by the situation. Furthermore, responsible inclusion is shaped by broader societal, economic, and political contexts. These contextual realities must be acknowledged when assessing inclusion efforts.

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