

Considerations from a DEIJ Perspective

The regulations and ethical principles that dictate the Institutional Review Board (IRB) process and inform the conduct of human subjects research imply that research participants should not be excluded based on characteristics irrelevant to the study design. Participant selection should be equitable, as should the risk/benefit ratio with regard to the distribution of burdens and potential benefits to specific populations.

IRB Panel members should be cognizant to identify and work with research teams to mitigate the possibility of inequitable inclusion criteria, recruitment strategies, or coercion of research participants.

The IRB should also consider if a research project benefits one group at the disproportionate cost of another.

The IRB recommends that in some cases, research personnel consider the need to include certain elements that would make their research more inclusive for the subject population and/or community they are in. One example is the use of a community-engaged approach. Human research protections are not just about individuals but also the respect, beneficence, and justice for the community. Learn more about Community Based Participatory Research [here](#).

Use of Consultants:

While the IRB Office maintains a diverse roster of IRB Panel members, we also recognize that it is not possible to have expertise or adequate representation for all elements that could be involved in a research protocol. To address this, the IRB Office may actively reach out to include experts in a specific subject matter or representatives of a specific participant group in the review and approval of research protocols.

Questions to consider:

1. Does the IRB membership have specific expertise to assess the adequate protection of the population that may be studied?
2. Does the protocol include sufficient background information and references regarding the population that is to be included in the research?
3. Is there a population that is most affected by the condition being studied?
4. Consider whether any potential participants might be particularly vulnerable (in need of special care, support, or protection due to their condition or marginalized group status) and how the research may account for or mitigate this status.
5. Consider whether the research study is designed in a way that may unnecessarily burden or impact a specific population.
6. Are there disparities between populations for the condition being studied? Is the research designed in a way that addresses or might further drive such disparities?
7. Does the research team have the appropriate qualifications and experience/knowledge with any specifically affected populations related to the research question?
8. Does the recruitment plan have the potential to effectively engage a diverse, representative, and equitable population?
9. How does the study identify their recruitment population? What resources is the study team using to make a decision on who should be included in the study population?

10. To what extent are community members/the study population a part of study start-up and implementation?
11. When drafting the research proposal or protocol, what DEI considerations has the study team taken into account?
12. Are their specific and justified limitations to including additional study populations?
13. Certain populations are frequently left out of research initiatives (e.g., prisoners, transgender and gender diverse people, non-English speakers, etc.) Has the study team considered if the targeted inclusion of these people would be beneficial to the research?