Research Design Considerations from a DEIJ Perspective

(Diversity, Equity, Inclusion, and Justice)

The Institutional Review Board (IRB) Office emphasizes the importance of including participants of all backgrounds into research and ensuring that recruitment methods and studies are designed to be intentionally outreaching and inclusive.

Why?

The regulations and ethical principles that inform the conduct of human research indicate that research participants should not be excluded based on characteristics secondary to the study design. Participant selection should be equitable, as should the risk/benefit ratio regarding the distribution of burdens and potential benefits to specific populations.

Researchers and the IRB Office should be cognizant to identify and work to mitigate the possibility of inequitable inclusion criteria, recruitment strategies, study design, and coercion of research participants. Researchers and the IRB should also consider if a research project benefits one group at the disproportionate cost of another. As studies have varied levels of fiscal support, some of the recommendations will be harder to implement for projects with fewer resources.

Community Engaged Methods and Approaches

The IRB Office recommends that study teams consider using community-engaged methods to make their research more inclusive for the participant population and community. Learn more about Community Based Participatory Research methods, including information on Consultation Support and a document highlighting the key considerations in community-engaged research on the Center for Community Health (CCH) page. The FAIR Workgroup recommends that research teams consider using inclusive language that adheres to the Northwestern University Marketing Standards guidelines. Please see the FAIR website for more information.

Enrolling Non-English Speakers/Translating Documents

If you expect to enroll participants with limited English proficiency, or if you or your designee will conduct the study internationally, the IRB expects you to translate your approved consent document into the appropriate language for your research. The IRB Office recommends that you first obtain IRB approval for your English-language consent document to reduce translation costs. After you receive approval, translate your document, and submit that document in eIRB+ as a modification, including a Certificate of Translation. Please see the Certificate of Translation template and the non-exclusive list of translation service providers. Please note that with certain minimal risk studies and when appropriate, the IRB Office does accept translations by a fluent speaker provided that the person has the appropriate language fluency in English and the other language to provide an accurate translation. You must provide documentation equivalent to the Certificate of Translation.

Considerations for Researchers and the IRB:

1. How is the population most affected by this condition being included in the study design? What gaps in the literature/data can you address regarding underrepresented populations?

   a. For example, per National Cancer Institute Cancer Disparities, Black/African American people have the highest prostate cancer mortality rates among all US racial/ethnic groups; Asian Americans and Pacific Islanders experience higher rates of gastric cancer; and Hispanic and American Indian/Alaska Natives experience higher rates of cervical cancer, yet these participant populations and communities are underrepresented as participants in clinical trials.
2. Consider whether any potential participants might require additional support from the research team over the course of their participation due to a disability or marginalized group status.
   a. For example, is your research study location accessible to wheelchair users? Or, do your recruitment, consent, and data collection methods account for people who may not have access to or ability to navigate digital landscapes?
3. Is the research study designed in a way that may unnecessarily burden or impact a specific population?
   a. For example, if your research requires in-person visits, do you have the option for study visits after 9-5 working hours or on weekends for participants who are unable to take time off during the day or who do not have transportation to come to in-person visits?
   b. For example, a research study that requires the participants to have a computer that is not supplied.
4. 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?
   a. Is the location of your research going to prohibit participation of some populations?
   b. For example, queer individuals might feel disenfranchised from participating in research studies because recruitment materials do not ask questions that are reflective of queer identity.
5. Does the research team have the appropriate qualifications and experience/knowledge with any specifically affected populations related to the research question?
   a. For example, if your research focuses on sexual and gender minority youth, do members of your research team have experience working with/in this community?
   b. Do you ask questions that affirm participant identities?
6. In addition to the above, to what extent are community members/the intended study population part of forming the research questions, study design, study start-up and implementation?
7. Does the recruitment plan have the potential to effectively engage a diverse, representative, and equitable population?
   a. For example, will recruitment activities take place in spaces that are primarily occupied or utilized by a single homogeneous group, or will recruitment activities take place in a variety of spaces that are occupied or utilized by diverse groups of people?
8. How does the study identify their recruitment population? What resources is the study team using to decide who should be included and excluded in the study population? A few resources for consideration may include:
   - FAIR Workgroup Selection of Participants page,
   - Consultation Support & ShARPs: Center for Community Health: Feinberg School of Medicine, and the

- CCH's Community, Patient, and Clinician Engagement in Research: Key Considerations and Frequently Asked Questions.

9. Are there specific and justified limitations to including additional study populations?
    a. For example, if the research does not include non-English speaking participants, has a study-specific justification been provided for the exclusion of non-English speaking participants? Are potential participants excluded from participating based solely on their English proficiency?
        i. Unless there is sufficient justification for excluding certain populations, we encourage researchers to design inclusion criteria so that the study design enhances diversity, equity, inclusion, and justice in research.
        ii. The IRB Office website has resources for using a Short Form consent process (used when you cannot predict whether non-English speakers may enroll), and Northwestern Medicine offers interpreter services (log in to NMI first for link to work) that can be used for consent discussion and ongoing visit communication.
10. Certain populations are frequently excluded from research initiatives (e.g., pregnant persons, transgender and gender-diverse people, non-English speakers, individuals living in rural areas, etc.). Has the study team considered if targeted inclusion of these people would be beneficial to the research? How is the targeted exclusion justified?
11. For sexual and gender minority individuals, has the study team researched and included gender-affirming language?
    - See the FAIR Workgroup's page on gender-affirming language.
12. Has the researcher described how they will share knowledge, benefits, and resources with their communities of focus?
        a. Sharing results with interested participants demonstrates the ethical principle of respect for persons, as it respects their integral role in research and the generation of the data.

Considerations for IRB Members

Use of Consultants or Subject Experts During IRB Review:

One of the questions the IRB Office considers during the review process is whether the IRB membership has specific expertise to assess the adequate protection of the population that may be studied. While the IRB Office maintains a diverse roster of IRB Panel members, we also recognize that it is challenging to have expertise or adequate representation for every field of study and research participant. To address this, the IRB Office may reach out to experts in a specific subject matter or representatives of a specific participant group so that perspectives from individuals with these backgrounds are included during the review and approval of research protocols.