



Increasing Diverse Enrollment in Human Subjects Research

Welcome to the resource page designed to assist researchers in promoting and increasing diversity in human subjects research. Achieving diversity in research participation is crucial for ensuring equitable representation, enhancing the generalizability of study findings, and improving health equity. Effective January 2024, the University of Arizona IRB will actively promote and encourage investigators to prioritize the enhancement of diversity in research studies. The primary objective of this initiative is to achieve a 10 percent increase in overall enrollment numbers within the next three years. By fostering greater representation and inclusivity, the University aims to broaden the impact and applicability of research findings while addressing disparities in research participation.

RECRUITMENT STRATEGIES

Community Engagement: Engage with local communities and stakeholders to build trust, establish partnerships, and develop culturally competent recruitment strategies. Collaborate with community leaders, organizations, and institutions to ensure representation and inclusion.

Culturally Tailored Materials: Develop recruitment materials (e.g., brochures, posters, and advertisements) that are culturally sensitive, inclusive, and accessible. Ensure the representation of diverse populations in these materials.

Language Accessibility and Literacy: Provide materials and consent forms in multiple languages based on the demographics of the target population. Utilize professional translators to ensure accurate translations and cultural relevance.

OUTREACH AND ENGAGEMENT

Community Consultation: Community consultation is a process that involves engaging with a specific community or group of individuals to seek their input, feedback, and perspectives on a potential research project that may affect them. In research, community consultation may involve consulting with potential research participants or community representatives to ensure that the research design, methods, and objectives align with the community's values, interests, and needs.

Key aspects of community consultation typically include:

- **Inclusivity:** It involves reaching out to a diverse range of community members to ensure that various perspectives are heard, including those who may be directly affected by the research project.
- **Information Sharing:** Providing clear and understandable information about the research study to the community, ensuring transparency and openness.



- **Two-Way Communication:** Creating a dialogue where community members can express their views, ask questions, and provide feedback, while also receiving responses and clarifications from the researchers.
- **Respect and Empowerment:** Respecting the knowledge and expertise of community members and empowering them to actively participate in the decision-making process.
- **Collaboration:** Seeking opportunities for collaboration and partnership between the community and the organizers to make informed decisions.
- **Feedback Incorporation:** Taking the feedback received from the community into account when making decisions or shaping a research project.

Social Media and Online Platforms: Leverage social media platforms to reach diverse populations and promote research opportunities. Utilize tailored advertisements and engage with community groups and influencers to increase visibility and engagement.

Community Events and Health Fairs: With appropriate permission, participate in community events and health fairs to raise awareness about research studies. Offer opportunities for individuals to learn about the benefits of participation and address any concerns or questions they may have.

Patient Advocacy Groups: Collaborate with patient advocacy organizations and support groups to connect with individuals who may be interested in participating in research. These groups can provide valuable insights and connections within specific communities.

TRAINING AND EDUCATION

Community-Engaged and Community-Based Participatory Research CITI Training: Provide researchers and study staff with training on Community-Engaged Research (CEnR). CRnR refers to a cooperative approach to research that includes partnerships and collaboration among researchers and community organizations and agencies.

UArizona IRB Workshop: Exploring Ways to Foster Diversity, Equity, and Inclusion in Research [Recording](#).

REPORTING AND DISSEMINATION

Transparent Reporting: Clearly report and document the demographic characteristics of study participants in research publications and during yearly continuing reviews to the IRB (if applicable). This ensures transparency and provides information necessary for the evaluation of diversity and inclusion efforts. Please note, certain studies housed in OnCore are expected to include demographic data reporting as a standard requirement.

Dissemination in Diverse Channels: Disseminate study findings through diverse channels, including publications, conferences, and community forums. Reach out to community



organizations, local media outlets, and social media platforms to promote the findings and their implications.

TRANSLATION REQUIREMENTS

The IRB does not require the translation of research materials into languages other than English, but it strongly encourages it. However, if a protocol involves enrolling non-English speakers, the following provides specific guidelines outlining which documents must undergo certified translation.

- For studies that are no greater than minimal risk, or studies conducting research in a foreign language for which there is no certification exam, translations can be done by a non-certified, but qualified professional translator. Translation by the study team is not recommended unless a team member is a qualified, professional translator.
- For studies that are greater than minimal risk, or using Banner Health as a recruitment site, certified translated documents are required.

BANNER TRANSLATION CONSIDERATIONS

For projects occurring at a Banner Health location that will enroll non-English speaking individuals, all study-related documents seen or utilized by non-English speaking subjects require certified translation.

Use of Cyracom, Banner's approved translation service, is preferred for:

- Non-sponsored studies; or
- Sponsored studies where the Sponsor or central IRB will not provide translation of the study documents themselves.

Once English versions of study documents have been approved by the IRB, translation requests can be sent directly through Cyracom's portal <https://portal.cyracom.com/customers/#/sign-in/> or to doctrans@cyracom.com. Please review the [Language Translation Process](#) document for detailed instructions on how to obtain translations through Cyracom.

Researchers at the University of Arizona can also use alternative translation services as long as they issue a Certificate of Translation.

UA researchers may also utilize the University of Arizona's [National Center for Interpretation](#) to provide translated participant material and consent forms for use in studies occurring at Banner.

SHORT FORM USE

- A short form consent is a document used to obtain informed consent from individuals who may have difficulty understanding the full written consent form due to language



barriers. The short form supplements the full informed consent but is presented in the subject's language. It is designed to ensure that individuals are still adequately informed about the study and can provide voluntary consent.

- Use of a short form must be reviewed by the IRB prior to use. The IRB will approve the use of a short form up to five times for any one language. A Modification should be submitted in eIRB to document its planned use.
- The short form process and templates can be found on the [HSPP website](#).

SPONSOR CONSIDERATIONS

- Plan translation and interpretation costs early! Write expected costs as line items in the budget.

TRANSLATION RESOURCES AND RATES

- [The University of Arizona's National Center for Interpretation \(NCI\)](#) is a resource which UArizona investigators can use to translate study documentation or provide interpretation services. Typical cost averages about \$30/page. Rates start between \$0.25-0.27/word based upon language, word count, volume, and technical language with a minimum charge of \$160.00.
 - See: [Translation and Research: What researchers need to know](#)
- [Cyracom](#) is a nation-wide interpretation & translation service provider. Typical cost averages about \$30/page. Minimum cost is \$100.

INTERPRETER EXPECTATIONS AND RESOURCES

- An interpreter should be utilized in the participant's preferred language during research conversations.
- Members of the participant's family or friends should not be used as interpreters for ethical reasons. The study team should not provide interpretation unless trained and/or qualified for the job.
- If research will take place at a Banner Health facility, all Banner hospitals, clinics and ambulatory facilities have interpreter [resources](#) available.
- Commonly used interpreter services include, but are not limited to:
 - UArizona Interpretation Services: <https://nci.arizona.edu/hire-interpreter>
 - [American Translators Association \(ATA\)](#)
 - [National Council on Interpreting in Health Care](#)
 - [Language Line Solutions](#)



ADDITIONAL RESOURCES

- **National Institutes of Health (NIH) Guidelines:** The NIH provides guidelines on inclusion and diversity in clinical research, including strategies for recruitment, retention, and reporting.
- **CITI Program:** [What Does Diversity Mean in Clinical Trials?](#)
- **FDA Guidance:** [Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs](#)
- **OHRP- Promoting Research Representation and Engagement Opportunities under the Common Rule Recording:**
<https://www.youtube.com/watch?v=XIGbdZfoRVA>
- **UArizona National Center for Interpretation:** The NCI is available for consultation and to help researchers plan the language services portion of their proposals
<https://nci.arizona.edu/>.