



PAIR & CHIBE

Participant-Centeredness Guide

Ways to make your study more participant-centered

This guide covers a variety of participant-centeredness topics that researchers should consider as they plan for their **study budgets, protocols, and procedures**.

Some considerations are for **grant proposals & budget line items**



Other considerations are for **study design planning**

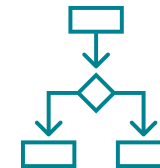


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Importance of being participant-centered

Be participant-centered from the start.

Consider the following...

- How will you facilitate transportation if your study requires that your participants go to a clinic, lab, or other location to complete a study activity?
- How will your study enroll non-English speaking participants?
- How will you recruit participants for this study?
- How will you retain participants throughout the study?

Importance of being participant-centered

Being participant-centered helps underserved groups.

- It can be more difficult for groups that are underserved by the medical establishment to participate in medical research
- Lack of representation of underserved groups in research exacerbates health inequities
- With intentional study design, we can enhance informed decision-making and reduce barriers for underserved communities to improve equitable representation in research

[Natale et al, 2021](#)

Importance of being participant-centered

Barriers to recruitment and retention include:

- Lack of understanding of the research
- Feeling unsupported in the decision-making
- Confusion due to language barriers
- Competing priorities with the added burdens of research participation

Participant-centered interventions can reduce or remove these barriers!

Transportation

If your study requires that your participants go to a clinic, lab, or other location to complete a study activity, how will you facilitate transportation?



Why offer transportation services?

- Transportation is a barrier to both research participation and clinical care
 - Transportation barriers can lead to postponement of care, which can result in poorer health outcomes
- Lower socioeconomic status communities encounter increased rates of transportation barriers

Transportation

Plan ahead

- Transportation can be a significant piece of your budget; make sure to include this during project development
- Provision of transportation services can be listed as a method for including underserved populations

Transportation

Offer reimbursement or pay upfront

- Provide cash to cover transit costs
- Build into participant payment structure a flat rate for travel costs
- Utilize [ClinCard](#) as an option for transportation reimbursement

Transportation

Offer a free ride

- Provide a [SEPTA pass](#)
- Or utilize [CCT connect](#), when applicable
- Utilize rideshare
 - [Lyft integration with ClinCard](#)
 - [Penn Transit & Indego bikeshare options](#)
- Open an account with a car service of your choosing

Transportation

Offer alternatives to traveling

- Mail study materials directly to participants
- Home visits (outside service or research staff)
- Labs at home or in their neighborhood (e.g., Quest/ExamOne)
- Telecommunication – note guidance for remote consent from [Penn IRB](#)
 - › Apple FaceTime
 - › Google Meet
 - › Skype
 - › Zoom
 - › Facebook Messenger video chat
 - › Other private video conferencing software

Transportation

Translation & Interpretation



How will your study recruit and enroll non-English speaking participants?

How will you ensure that they have the same access to the research as English-speaking participants?



Determine if your target population includes Limited English Proficient (LEP) individuals

- *Individuals who do not speak English as their primary language or have limited ability to read, speak, write, or understand English*

If your target population includes LEP individuals, translation and interpretation services should be utilized

**Translation &
Interpretation**

Know the difference between a *translator* and an *interpreter*

- **Translator:** A person who translates written texts
- **Interpreter:** A person who translates a message spoken in one language into a second language

**Translation &
Interpretation**

Ensure informed consent

- It is a requirement that the informed consent process be completed in a language that the participant understands
- Penn IRB recommends full translation of the consent form when target population includes LEP individuals (short informed consent forms are acceptable on an as-needed basis)

**Translation &
Interpretation**

Understand the importance of translation and interpretation

- “LEP individuals should not be systematically excluded from research without a sound scientific or ethical rationale to ensure equitable subject selection” (Penn IRB)
- “Increasing inclusivity in patient centered research begins with language”

**Translation &
Interpretation**

Consider language access beyond informed consent

- What other documents need to be translated? (e.g., recruitment fliers, outreach messages, surveys)
- How will staff communicate with participants throughout the study?
- Are medication instructions and drug labels translated?
- If document translation is not possible, consider using an interpreter

Translation & Interpretation

Know the applicable laws and regulations – federal, state, local, institutional

US Department of Justice: [Title VI](#)

- LEP individuals are protected from national origin discrimination under Title VI
- Failure to provide meaningful access to LEP persons constitutes national origin discrimination
- This includes both intentional and unintentional discriminatory acts

**Translation &
Interpretation**

Ensure that services are provided by qualified personnel

- Assess research staff for language proficiency in the subject matter; consider specific regional vernacular
- Ideally, use professional translators & interpreters (use of non-professionals may lead to errors)
- Prepare staff to use interpretation services properly

[Regenstein et al, 2008](#)

[Joseph & Dohan, 2009](#)

[International Medical](#)

[Interpreters Association, 2007](#)

[Mann et al, 2005](#)

[Quantel service tips & tricks](#)

Translation & Interpretation

Utilize University resources

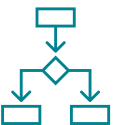
- Penn IRB [short informed consent forms](#) for non-English speakers
- PennGlobal offers [tips](#) on what to ask a language provider and links to translation and interpretation suppliers in the Penn Marketplace
- JRP offers a guide on how to use language services (translation and interpretation)

**Translation &
Interpretation**

Recruitment & Consent



**How will you recruit
participants for this
study?**



Recruitment strategies

- Consider LEP individuals: language barriers and lack of preparedness can prevent potential participants from enrolling
- Create recruitment materials that are culturally relevant and linguistically adapted
- Obtain assent from participant families and communities
- Use diverse methods: TV ads on local channels, educational videos, newsletters, personalized stories

**Recruitment
& Consent**

Consent

- Consult University IRB resources on health literacy and JRP resources on plain language and readability for further guidance

Penn IRB: [Health Literacy Guidance](#)

Decision aids

- Use of a decision or information aid allows potential participants to better decide if a particular study is right for them

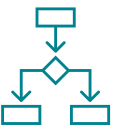
[Giles et al, 2019](#)

**Recruitment
& Consent**

Communication & Retention



**How will you retain
participants throughout
the study?**



Provide access to communication technologies

- Provide information about places to access free internet (e.g., libraries, community centers)
- Fund collect calls or provide phone cards
- Create a toll-free study hotline or 800 number

**Communication
& Retention**

[Dibartolo et al, 2003](#)

[Hasson Charles et al, 2022](#)

[Kurt et al, 2016](#)

[Mann et al, 2005](#)

Consider participants' schedules, preferences, and lifestyles

- Provide reminders about important dates, including physical reminders (e.g., calendars, magnets)
- Ask about preferences for communication (e.g., mail, phone, email, personal visit)
- Arrange childcare in the vicinity of study visits; acknowledge children during home visits
- Be flexible with timing; have availability beyond normal business hours

**Communication
& Retention**

Consider retention during study planning

- Hire research staff from the community that can relate to participants
- Ensure that materials are tailored to the participant population and pilot-tested
- Implement participant navigation programs that assist with research participation, and/or participant education for your study

**Communication
& Retention**

Summary

Putting it all together

Be participant-centered from the start

1. Plan strategically to ensure inclusion of a diverse participant population
2. Identify all your needs before preparing your budget
3. Engage leadership to champion these efforts on a larger scale

Summary

Importance of Being Participant-Centered

- Without proper representation, research continues to exacerbate inequities for communities that are underserved by the medical establishment
- Barriers to participation include lack of understanding of research, feeling unsupported, language barriers, and competing priorities
- With intentional study design, we can reduce barriers to research participation for underserved communities

Transportation

- Offer reimbursement or pay upfront for transportation (cash, ClinCard, SEPTA pass)
- Offer a free ride (Lyft, via Greenphire, Penn Business ride share, CCT Connect, car service)
- Offer alternatives to traveling (home visit, telecommunication, at-home labs, mailed materials)

Translation & Interpretation

- Determine if target population includes Limited English Proficient individuals: those who do not speak English as their primary language or have limited ability to read, speak, write, or understand English
- Identify language services for translation of written texts and interpretation of spoken messages
- Translate necessary materials: informed consent, recruitment fliers, outreach messages, surveys, drug labels
- Prepare staff to communicate with participants throughout the study, using qualified interpreters
- Consult University resources (IRB and PennGlobal) and JRP Interpretation & Translation Guide

Recruitment & Consent

- Use diverse recruitment methods: TV ads, educational videos, newsletters, personalized stories
- Consider language accessibility
- Ensure materials are culturally relevant and linguistically adapted
- Obtain assent from participants' communities
- Use decision or information aids to assist patients in deciding if the research is right for them
- Consult University IRB resources on health literacy and JRP Readability Guide and Plain Language Guide

Communication & Retention

- Ask about communication preferences
- Provide participants with access to communication technologies (places to access free internet, funding for collect calls or a phone card, toll-free hotline)
- Provide reminders about important dates, including physical reminders (e.g., calendars)
- Arrange for childcare in the vicinity of study visits
- Be flexible with timing and availability beyond business hours
- Implement patient-navigation programs and/or education about the research
- Ensure that research staff and materials are relevant to the community (including hiring staff from the community)

References & Resources

References

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Resources – Transportation

Greenphire / ClinCard

- Providing Transportation for Participants: <https://benhelps.upenn.edu/support/solutions/articles/15000069193>
- ClinCard & Lyft Rideshare: <https://greenphire.com/rideshare/>

SEPTA

- Fare Products: <https://www.septakey.org/info/fare-products>
- CCT Connect: <https://www5.septa.org/travel/cct/>

Penn Sustainability

- Transportation Options: <https://sustainability.upenn.edu/campus-initiatives/transportation>

Penn IRB

- Guidance on remote consent: https://irb.upenn.edu/wp-content/uploads/2023/02/Guidance-on-Remote-Consent-Procedures_Non-Penn-Medicine.pdf

Resources – Translation & Interpretation

Penn IRB

- Penn IRB Standard Operating Policies, V.13, February 2023: <https://irb.upenn.edu/wp-content/uploads/2023/02/Standard-Operating-Procedures-2023.pdf>
- Enrolling participants with Limited English Proficiency: <https://irb.upenn.edu/homepage/biomedical-homepage/guidance/recruitment-and-consent/participants-not-fluent-in-english/>
- Short form consent: <https://upenn.app.box.com/s/xxl0ea9s8p0imzp1juh836rfcx0sjama>

Penn Global: Translation services information: <https://global.upenn.edu/sites/default/files/global-support-services/Translation%20and%20Interpeter%20Resources.pdf>

Quantel: Tips for using interpreters:

<https://upenn.app.box.com/file/983777666308?s=9pi10zgej8pipoehv1xuv8my74xw06pe>

Joint Research Practices Working Group: Language Interpretation Guide:

<https://chibe.upenn.edu/research/joint-research-practices/>

Resources – Recruitment & Consent

Penn IRB

- Healthy Literacy Guidance: <https://irb.upenn.edu/wp-content/uploads/2023/02/Health-Literacy-Guidance.pdf>

Joint Research Practices Working Group

- Readability Guide & Plain Language: <https://chibe.upenn.edu/research/joint-research-practices/>

Additional Literature

Transportation

- [Attitudinal barriers to participation in oncology clinical trials: factor analysis and correlates of barriers](#)
- [Barriers to recruiting underrepresented populations to cancer clinical trials: A systematic review](#)
- [A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders](#)
- [Barriers to Clinical Trial Enrollment in Racial and Ethnic Minority Patients with Cancer](#)

Additional Literature

Translation & Interpretation

- [Health Consumer Alliance, Language Access Responsibilities under Federal Civil Rights Laws](#)

Recruitment & Consent

- [Improving Informed Consent with Minority Participants: Results from Researcher and Community Surveys](#)

Miscellaneous

- [Research Participation in Marginalized Communities — Overcoming Barriers](#)