

Procedural and Logistical Checklist

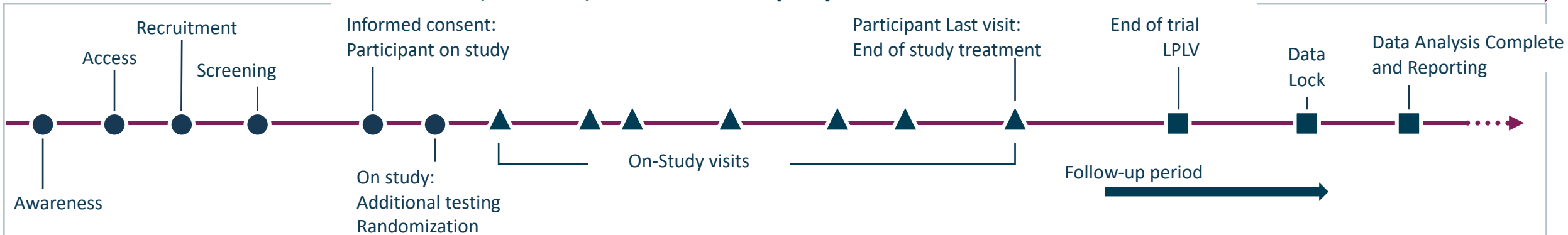
Audience: Investigators and their research teams, Sponsors, CROs, Research Sites, IRBs, QA/QI Teams

Purpose: This checklist is for investigators, their research teams, sponsors, and others to use when considering Diversity, Equity and Inclusion (DEI) in a clinical trial. At each stage of a research study, there are logistical and procedural considerations to help lower the barriers for inclusion of underrepresented populations. This is a non-exhaustive list, intended to prompt attention to affirmative steps to address DEI.

Considerations for Use: This checklist maybe a useful educational and ‘best-practices’ guide:

- For HRPPs and their IRBs to review and distribute
- For investigators and their study teams to have and consult
- For institutional quality assurance/quality improvement (QA/QI) programs to use in monitoring
- For sponsors to plan, conduct, and report trials
- For CROs to consider to plan site engagement strategies.

DIVERSITY, EQUITY, & INCLUSION (DEI) STUDY LEVEL CONSIDERATIONS



Pre-Study Considerations

- ❑ Form and nurture partnerships with underserved communities. Engage with community physicians, patients, and others (e.g., cultural ambassadors) to inform the study question, design, and conduct.
- ❑ Develop health-literate communications and support educational activities to enhance diverse participant awareness, access, recruitment and retention (e.g., translation of study materials, participation in local health fairs, engage with community health centers).
- ❑ Establish processes to minimize burden (e.g., protocols for payment, flexible appointments, accommodations, translation services). Consider if decentralized/hybrid trials would be an appropriate option to reduce burden.
- ❑ Create/adapt a standard mechanism to collect, record, and track demographic and non-demographic variables of participants screened, offered, and consented into study.
- ❑ Develop objective screening approaches and systematically collect and record reasons for screen failure.
- ❑ Periodically analyze/evaluate screen failure data.

On-Study Considerations

- ❑ Document the basis of the decision for excluding participants from a trial.
- ❑ Devise a simple, honest, and clear informed consent process for participants that is conducted in a health-literate, culturally- and linguistically-appropriate manner.
- ❑ Provide translation services of the informed consent form and/or interpreter services for individuals with limited or no English proficiency, as applicable.
- ❑ Apply accessibility principles to study documents and provide accommodations for people with disabilities as required.
- ❑ Allow flexible strategies that enable participants and their caregivers to adhere to the expectations of the study (e.g., amenable clinic hours, locations, virtual visits; provision of childcare, eldercare, and food during study visits; transportation assistance; appropriate reimbursement and compensation).
- ❑ Offer regular, open, and respectful communication through the platform of participant preference (i.e., phone, text, email, virtual meeting, etc.) to foster participant understanding.
- ❑ Establish a monitoring and evaluation system to ensure timely interventions if actual enrollment does not meet expected enrollment or if the actual enrollment does not reflect the expected demographic(s) intended for the study.
- ❑ Monitor retention to study by demographic and non-demographic factors.
- ❑ Put practices in place that provide continuous education, support, and outreach to participants and their communities.
- ❑ Train all staff interacting with participants and their caregivers in principles of respectful communications, bias, and cultural humility.

Post Study Considerations

- ❑ Plan for data analyses that includes sub-group analysis and examination for heterogeneity of treatment effects as applicable to the study.
- ❑ Provide clear communication around end-of-study expectations, including transitions of care, potential later outreach, timing of further communications.
- ❑ If the study involved an investigational product, anticipate continued access to the investigational product for participants who are benefitting from the treatment and have no other equivalent options for treatment
- ❑ Return aggregate and, to the extent possible, individual study results in health literate and understandable language to study participants.
- ❑ Return aggregate results, if applicable, to the community in a culturally- and linguistically-appropriate manner to the community.
- ❑ Conduct post-study survey of participants to learn what worked well and areas for improvement.
- ❑ Review study performance for lessons learned and to help plan future studies.