Checklist for IRB/EC Oversight of Decentralized Clinical Trials

This document is a checklist of the issues that IRBs/ECs should consider when reviewing a decentralized clinical trial. The checklist is organized into three domains: people, data collection, and remote data oversight. Within each domain are relevant decentralized approaches that may be part of a DCT and the questions for IRB/EC review. For additional information on the ethical considerations of any particular element, please consult the full set of recommendations.

PEOPLE

eConsent

- Determine the risk level of the trial (minimal/no minimal risk).
- Ensure the consent includes appropriate descriptions of DCT modules used, the functionality of eConsent platform, method of obtaining signatures, and assistance available to potential participants.
- Verify the identification method for participant and site staff identities (should be included in consent).
- Ensure the platform is secure and acceptable (e)Signature methods are used per region.
- Consider special considerations for vulnerable populations, including pediatric populations.

Social Media Recruitment

- Review approach and consent plans
- Consider how research staff are identified on social media platforms
- Review PHI storage and ensure use is appropriate and secure
- Ensure
    - privacy of potential online participants is protected
    - Social media channels use for recruiting are compliant with applicable regulations
    - Management and communication plan is in place for social media actions of participants and consequences

Technology Use

- Ensure equitable digital access to the study.
- Review the device considerations and participant education materials, resources, and training.
- Consider privacy and confidentiality considerations.
- Consider special populations, such as prisoners and children.

Notifications and Reminder Checklist

- Is the implementation of notifications or reminders likely to create an undue burden or introduce risks to privacy or confidentiality?

- Does the communication contain potentially sensitive or identifiable information? Can the inclusion of that information be further minimized?
- Are there data security concerns introduced by these communications and, if so, can they be eliminated?
- What control does the participant have over the form, frequency, and content of the communication?
- What is the plan if the participant fails to respond to a safety-related notification?
- What are the consequences, risks, and potential harms:
    - If the communication fails?
    - If the communication is received by a third party?
- Is there a monitoring plan for the system of notifications and reminders?
- Does the study include participant feedback, and is it elective?

Direct to Participant Shipping Checklist

- Understand what is being shipped and associated shipping requirements
- Consider labeling and shipping
    - Rapid identification of trial shipment balanced with privacy concerns
    - Receipt verification procedures
    - Contingencies for shipping errors
    - Burden to participants
    - Real time assistance protocol and or technical
- Consider equity issues: Does DTP create unforeseen barriers for certain populations
- If investigational medical product is shipped, ensure
    - Compliance with good manufacturing & good distribution practices (GMP & GDP)
    - All materials are included for administration
    - Blinding can be maintained
    - Adherence to local, national and international shipping laws for IMP
    - A plan for receipt, storage, accountability and maintenance
    - Plan for documentation
    - Recipient training and readiness for receipt and administration of IMP
    - Participant monitoring including AE reporting and responsibilities
    - Rapid unblinding of IMP in medical emergencies procedures
- For devices and sensors, consider
    - training/cost or penalties in case of loss

Help Desk Checklist

Assess study complexity when considering

- Is there 24/7 Access for participant related to questions about participant safety or data quality
- Ensure
    - Appropriate Help Desk staffing and training (including training frequency)
    - Appropriate triage of helpdesk issues and questions to medical protocol and technology resolution

- Systems for using helpdesk trends as way to assess technical issues that may impact participation and retention
- Scripts for different situations
- Appropriate PHI recording, maintenance, and discarding
- Accommodations of underserved and underrepresented populations
- Languages / TTY assistance/assistive devices for people with disabilities.

Rewards Checklist

- Consider risks to privacy, confidentiality, data storage and transfer change if rewards are given
- Ask if using technology for rewards administration, changes the risk perception to privacy/confidentiality/data storage & transfer
- Understand if there are any rewards or features of a reward program engineered to inculcate addictive behavioral patterns or to provide sensitive information
- Consider if there is undue influence in the device disposition plans at end of trial or are proportionate to the burden, and will not influence voluntary nature of participation
- Understand costs and/or penalties associated with loss of provisioned devices or sensors
- Ensure appropriate "data and tracking cleaning procedures" in place before transfer to the participant of the provisioned devices or sensors
- Consider effects on persons with addictions or children

Remote Data Collection

Remote, In-home, and Local Visit Checklist

Considerations	Tele visit	In-home	Local provider
Consider whether access to internet, cellular data, devices, software, and technical support will be equitable across participants	•		
Ensure multiplicity of language availability of software and software programs	•		
Verify Modifications and accommodations for inclusion of people with disabilities exist	•		
Verify Methods of data validation and remote monitoring	•		
Shipment, receipt, administration and disposal of IMP and other research products	•		
Ensure Participant preferences for method of interaction with research study team	•	•	
Evaluate and Mitigate Risks to privacy and confidentiality of participant	•	•	
Ensure Data privacy and security in collection, transfer and storage	•	•	•

Ability of PI to provide adequate oversight of HCPs recruited for study activities	•	•	•
Verify status of healthcare provider: competencies, licensure, protocol familiarity, Form 1572		•	•
Verify Task log for providers and third-party vendors, consider if they are engaged in research		•	•
Ensure availability of emergency and other care if needed		•	•
The need for a face-to-face participant visit, laboratory tests, or imaging study			•

Devices in DCTs Checklist

Equity: Consider	BYOD	Provisioned
• Equity issues when minimum device requirements are not met.	•	
• What the options are for participation if data plan is insufficient	•	
• Security and confidentiality in data transfers	•	
Ensure Consent includes		
• Costs and use of device and whether replacements devices are available (at what cost)	•	•
• ensure Instructions and process are available if device lost, damaged, stolen		•
Consider disposition at end of study (keep or return)		•
Ensure Appropriate instructions and training		•
Ensure access to helpdesk troubleshooting		•

Connected Sensors Checklist

Consider

- Purpose of the sensor (critical vitals/at risk group)
- Regulatory status of sensors
- Frequency of monitoring of the sensor data
- Where sensor data is stored
- Burden of sensor to participants
- Clarity of where to get help for sensor issues
- Disposition of sensor

Real-Time Data Monitoring Checklist

Considerations for investigators and site staff

- What real time data is available to investigators?
- Are data unique in some way?
- Will real time data access unblind study?
- Issue related to confidentiality or privacy of data
- Are staff systems and resources in place to respond in real time
- Safety concerns related to real time monitoring expectations

Considerations for participants

- What real time data is available to participants?
- Will data unblind?
- Will access to data be understandable/ actionable?
- Will access to data impact participant behavior, safety, or study results?
- Is ICF language
    - clear about what data will be monitored in real time, and
    - clear about expectations for AE reporting to site staff?
- Participant burden on AE reporting
- Participant adherence to etasks (eCOAs)
- Resources to participants regarding staff availability and response times
- Data collection is fit for purpose and minimized
- Back-up systems are in place if technology fails to collect data

Study Close-Out Checklist

Data Considerations

- Consider completeness of source data and verification
- Ensure only required data retained in study records
- Ensure deactivation from provisioned devices/sensors/trial platforms and applications
- Verify Data storage privacy and security and all usual end-of-study activities

Investigational Medicinal Product and Direct-to-Participant Shipping :

- ensure accountability and documentation completed

BYOD

- Ensure BYOD Data transfer & removal (cookies, PHI, tracking) from participants BYOD/device

Provisioned device

- Ensure disposition of device is clear