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:
  o If the communication fails?
  o 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
  o Rapid identification of trial shipment balanced with privacy concerns
  o Receipt verification procedures
  o Contingencies for shipping errors
  o Burden to participants
  o 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
  o Compliance with good manufacturing & good distribution practices (GMP & GDP)
  o All materials are included for administration
  o Blinding can be maintained
  o Adherence to local, national and international shipping laws for IMP
  o A plan for receipt, storage, accountability and maintenance
  o Plan for documentation
  o Recipient training and readiness for receipt and administration of IMP
  o Participant monitoring including AE reporting and responsibilities
  o Rapid unblinding of IMP in medical emergencies procedures
• For devices and sensors, consider
  o 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
  o Appropriate Help Desk staffing and training (including training frequency)
  o 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**

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

<table>
<thead>
<tr>
<th>Equity: Consider</th>
<th>BYOD</th>
<th>Provisioned</th>
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<tbody>
<tr>
<td>• Equity issues when minimum device requirements are not met.</td>
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<tr>
<td>• What the options are for participation if data plan is insufficient</td>
<td>•</td>
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<tr>
<td>• Security and confidentiality in data transfers</td>
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Ensure Consent includes

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<tr>
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<th>BYOD</th>
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<tr>
<td>• Costs and use of device and whether replacements devices are available (at what cost)</td>
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<tr>
<td>• ensure Instructions and process are available if device lost, damaged, stolen</td>
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Consider disposition at end of study (keep or return)

Ensure Appropriate instructions and training

Ensure access to helpdesk troubleshooting
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