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

<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 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 exist</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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<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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<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>
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<tr>
<td>• Security and confidentiality in data transfers</td>
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| 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