Australian Teletrial Program-Victoria (ATP-VIC)
Teletrials – Ethics, Site Governance and Startup

HREC expectations when reviewing teletrials & case studies

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HREC expectations when reviewing teletrials

- Specific guidance for ethics review and site specific assessment required to allow for consistency and review and documentation
- Alfred Hospital Ethics Committee experience
- Majority of teletrial model applications submitted as an amendment

HREC expectations when reviewing teletrials – Assessment of Associate Investigator and Satellite Site

The Reviewing HREC is required to make an assessment of:

- Associate Investigator of Satellite Site
  - Based on CV
- Each Participating Site:
  - Previous clinical trial experience
  - Facilities available
  - Depending on risks and phase of clinical trial, access to emergency services, ICU
  - Research governance oversight

HREC expectations when reviewing teletrials – Core clinical trial activities

The Reviewing HREC is required to have an understanding of:

- where the 'core' clinical trial activities are taking place and;
- who has responsibility for each activity

Core trial activities occurring at Primary and Satellite Site:

- Recruitment
- Consent
- Screening procedures – pathology, imaging, etc
- Administration of investigational product
- Follow-up

HREC expectations when reviewing teletrials – Core clinical trial activities

- **Why?:**
  - Assessment of the capabilities of each Site
  - Include information about the location(s) of the clinical trial activities, procedures, assessments in the PICF(s)
- **Initially requested the supervision plan for this purpose**
  - Requires resubmission to HREC of amended plan
  - Increasing reluctance as considered a governance document
  - Requirement to create a clinical trial activities schedule template and include details in the PICF when submitting to HREC

HREC expectations when reviewing teletrials – PICF

- Challenging if teletrial sites are added via an amendment application
- Currently two options for Main PICFs:

- **Master PICF approved for all Sites:**
  - usually does not include teletrial information
  - cannot amend to include teletrial information and build in options for locations of core trial activities as will need to re-consent all participants
  - Opportunity to incorporate teletrial options if PICF is amended for other reasons

HREC expectations when reviewing teletrials –PICF

- **Standalone Teletrial PICF:**
  - does not include site specific information about trial activities
  - provides information about data collection/use/disclosure by ATP
  - include data collection/use/disclosure by other teletrial groups
  - sponsors prefer data collection to be kept separate to Master PICF

HREC expectations when reviewing teletrials –PICF

- **Patients at Satellite Sites:**
  - Consented with Site-specific Master Main PICF of Primary Site and Standalone Teletrial PICF
  - Requirement for a tailored site-specific PICF which reflects the conduct of the trial at Satellite Sites
  - Introduction of a Master Teletrial PICF
  - Retention of separate PICF for teletrial data collection

HREC expectations when reviewing teletrials – Teletrial Protocol

- HREC requires details of the teletrial model in order to approve the conduct of the trial under this model

- Teletrial model not incorporated into international Protocols
  - Australian–specific teletrial protocol
  - Addendum to protocol

HREC expectations when reviewing teletrials – Adoption of processes from COVID-19 contingencies

- **Acceleration of adoption of COVID-19 contingencies into teletrial model:**
  - eConsent/telehealth consent (SOP on consent process)
  - Local pathology, imaging
  - Drug delivery to participants' homes
  - Home nursing services
  - Remote monitoring

HREC expectations when reviewing teletrials – Privacy

- **Consideration of access by Primary and Satellite Site**
  - Structure of EDC portal – segregated access or shared access
  - If shared, inclusion of statement in PICF regarding researchers at both or one Site(s) having access to re-identifiable data

HREC expectations when reviewing teletrials – Legal and regulatory documents

- **Legal and regulatory documents:**
  - Satellite Sites included in draft eCTN
  - Satellite Sites listed in HREC Review Only indemnity, if applicable
  - Medical Physics Report if radiation risk category exceeds previously approved level

HREC expectations when reviewing teletrials – Case Studies and observations

- **Delays in HREC approval due to <u>not</u> submitting:**
  - Sufficiently detailed amendment request form including details of teletrial model
  - CV and GCP certificate of Associate Investigators at Satellite Sites
  - Amended Protocol and/or teletrial Protocol addendum/country specific amendment (if available)
  - Table of core trial activities, locations and responsibilities (template to be drafted)

HREC expectations when reviewing teletrials – Case Studies and observations

- **Delays in HREC approval due to <u>not</u> submitting:**
  - National Master Standalone Teletrial PICF template and/or
  - Amended Master PICF including teletrial details with options to enable tailoring at Site level
  - eConsent/telehealth consent standard operating procedure
  - Draft amended eCTN listing Satellite Sites
  - Revised HREC Review Only indemnity listing Satellite Sites, if applicable
  - Medical Physics Report for Satellite Site if radiation risk category exceeds previously approved level

HREC expectations when reviewing teletrials – Conclusions

- Specific guidance on ethics and site specific assessment processes to be developed to ensure consistency in review processes and document requirements
- An ability for a tailored, site-specific PICF to be prepared for patients at Satellite Sites
- Inclusion of data collection by all teletrial groups in the Standalone Teletrial PICF and guidance on determining which apply for various Sites
- Development of a core clinical trial activities schedule template
- Work with Sponsors to find solutions to address absence of provision for teletrial model in Protocols
- Managing research other than clinical trials under teletrial model