Satellite Site RGO Submission Document Checklist

Insert subtitle

*Documents to be uploaded against the Research Governance Application at the Satellite Site. This is only to be done after receiving approval from the Primary Site RGO.*

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| **In accordance with local processes** | |
| Cover letter from SS AI which includes:   * A statement: “*The study is to be conducted under the teletrial model with [enter PS name] as the Primary Site and (name of this site) as a Satellite Site.* * List of documents uploaded for SS RGO review * Information if ionising radiation is standard of care (SOC) or study specific or if study specific reporting is required additional to SOC *(where applicable)* |  |
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| **Mandatory** | |
| Site Specific Assessment (SSA) Application   * with PS PI listed as the PI, and AI at this SS listed as an AI * all relevant Heads of Department signatures completed |  |
| Copy of HREA submitted to HREC  HREC Approval Letter/s listing all current HREC approved documents  (For NT NMA studies only: NMA reciprocal approval letter from NT HREC) |  |
| Protocol |  |
| Participant Information Sheets and Consent Forms:   * HREC Approved Master PICF/s (clean) * Cluster PICF/s - tracked and clean, ensuring the agreed Teletrials Specific Wording has been approved by the HREC and is included in the relevant section of the Cluster PICF (e.g. Page 1)   Please consider using the following formatting:   * Jurisdictional or Institutional logo on page 1 of the PICF and on the Consent page * Consent page attached to the Information Sheet with matching version details. * Footer details:   [cluster name] PICF, ver x: dd/mmm/yyyy   BASED on Master PICF ver y: dd/mmm/yyyy  BASED on Global PICF ver z, dd/mmm/yyyy  *OR*  Stand Alone Teletrial PICF |  |
|  |
| All other recruitment documentation e.g. flyers etc. – where applicable  (provide Master documents – clean only and cluster specific documents – tracked and clean)  Copy of HREC Approval Letter(s) (when obtained) |  |
| Any other trial documentation to be provided to participants, which require cluster specific changes |  |
| Evidence of current Good Clinical Practice (GCP) Training for each investigator at this SS |  |
| Certificate of Insurance from Sponsor |  |
| Budget signed by relevant SS finance officer, which includes quotes and approvals from relevant SS supporting department(s) e.g. pharmacy; pathology; medical imaging |  |
| **Teletrials Specific Documentation** | |
| Evidence of Sponsor agreement to conduct the trial as a teletrial |  |
| Evidence of HREC acknowledgment that the trial may be conducted as a teletrial |  |
| Evidence of Sponsor approval of this site as a SS |  |
| Evidence of notification to HREC that this site will be included as a SS in the cluster (if not included in the initial HREC application) |  |
| Copy of RGO Authorisation Letter from PS RGO |  |
| Memo from PS RGO to SS RGO which identifies any potential SS considerations with this trial |  |
| Teletrials subcontract agreements signed by PS personnel |  |
| Signed supervision plan between PS and this SS |  |
| CVs for AI/s at this SS if not previously submitted |  |
| GCP Certificates for research team members at this SS - if not submitted in last 3 years (the expiry date of GCP training may be listed on the GCP Certificate and is generally 3 years) |  |
| **As applicable** | |
| Evidence of submission of eCTN/CTA form |  |
| Investigator’s Brochure |  |
| Assessment report by a Medical Physicist or District Radiation Safety Officer applicable to all cluster sites |  |
| Indemnity Form from Sponsor between Sponsor and SS - only required if Sponsor is providing indemnity to participating sites. |  |

If you consider there should be changes or updates to this template, please contact:

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