Primary Site RGO Submission Document Checklist

Insert subtitle

*Documents to be uploaded against the Research Governance Application at the Primary Site*

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| **In accordance with local processes** | |
| Cover letter from PS PI which includes:   * A statement: “*The study is to be conducted under the teletrial model with [enter PS name] as the Primary Site and [insert sites] as the Satellite Sites.* * List of documents uploaded for PS RGO review * Clarification of whether 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 and all relevant Head 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, where applicable e.g. flyers   * Master documents – clean only * Cluster specific documents – tracked and clean   (ensure version details are included) |  |
| 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 PS |  |
| CTRA between Sponsor and PS (signed in relevant section by PS PI) |  |
| Certificate of Insurance from Sponsor |  |
| Form of Indemnity naming this PS (may also include any known SS/s in this cluster) |  |
| Budget signed by relevant PS finance officer, which includes quotes and approvals from relevant PS supporting department(s) e.g. pharmacy; pathology; medical imaging |  |
| **Teletrials Specific Documentation** | |
| Evidence of Sponsor agreement to conduct the trial as a Teletrial (eg formal letter, email or signed statement from PI) |  |
| Evidence of HREC acknowledgment that the trial may be conducted as a Teletrial |  |
| Evidence of Sponsor approval of proposed SS/s |  |
| CTRA amendment to add SS as location (Sched 1) and amendments to budget (if applicable) (Sched 2) |  |
| Teletrials subcontract agreements between PS and SS/s |  |
| Signed supervision plan(s) between PS and SS/s |  |
| GCP Certificates for research team members at SS/s - 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 Brochure |  |
| Assessment report by a Medical Physicist or District Radiation Safety Officer applicable to all cluster sites |  |
| Indemnity Form from Sponsor between Sponsor and PS - only required if Clinical Trial Research Agreement – Medicines Australia Standard Form has been used. |  |

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

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