**Checklist of Required Documents – Sponsored Clinical Trials**

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| **Submitted**  | **Documents Required for the SSA Form**  | **Notes**  |
| ☐  | SSA Application Form  | Required.  |
| 1. The proposed study  |
| ☐  | Most Recent HREC Approval Letter – with the specific site listed  | Ensure that the Ramsay Site is listed on the Approval.  |
| ☐  | Study Protocol – clean version  | Required.  |
| ☐  | Study Protocol – tracked version (if applicable)  | If any changes from the previously approved version.  |
| ☐  | Study Protocol – administrative memo (if any)  | If available.  |
| ☐  | Participant Information Consent Form - Approved Master Version  | Required. Unless: ☐ Waiver of consent is sought.  |
| 2. The research project (**Required for:** ☐**multi-site study using site specific forms**)  |
| ☐  | Participant Information Consent Form- Site Specific – Clean Version  | Please ensure that the DCS of the specific Ramsay Facility (or equivalent individual) or the Ramsay National Research Office is listed as contact for any complaints relating to the research.  |
| ☐  | Participant Information Consent Form – Site Specific – Tracked Version  | Tracked changes from the approved master version.  |
| 3. Experimental product (**Only required when:** ☐ **unapproved products/ unapproved indication**)  |
| ☐  | Investigator’s Brochure – Clean Version  | Required.  |
| ☐  | Investigator’s Brochure – Tracked version (if applicable)  | If any changes from the Previous approved version.  |
| ☐  | CTN/ CTX Acknowledgement – with Specific Site listed  | Ensure that the Ramsay Site is listed on the Acknowledgement.  |
| 4. Resources demanded at Facility (No mandatory documents are required)  |
| Please ensure that any resources required from Ramsay Health Care to support the research are outlined in the SSA form. Please provide sufficient detail to allow assessment of the application.  |
| 5. Legal considerations  |
| ☐  | CTRA and/or MTAA - Ramsay Approved Version  | For any enquiries, Please contact the NRU.  |
| ☐  | Memorandum of Understanding, Service Level Agreement, or equivalent document (if required)  | For any enquiries, Please contact the NRU.  |
| Indemnity and Insurance  |
| ☐  | MTAA standard Indemnity - indemnifying Ramsay Health Care  | For any enquiries, please contact the NRU.  |
| ☐  | MTAA Standard Indemnity - Indemnifying the Principal Investigator  | For any enquiries, please contact the NRU.  |
| ☐  | Proof of the current insurance cover (e.g. a Certificate of Currency) | Insurance policy for the specific study or Medical Malpractice Policy that covers relevant research activities. |
| 6. Conflict of Interest (no mandatory documents are required)  |
| 7. Merits and Reputation of the Research Team  |
| ☐  | CV of each member of the research team  | Required unless current version previously provided. |
| ☐  | GCP Certificate of each member of the research team  | Required unless current version previously provided. |

**Checklist of Required Documents – Research Projects other than Sponsored Clinical Trials** (e.g. Investigator-initiated Research Projects)

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| **Submitted**  | **Documents Required for the SSA Form**  | **Notes**  |
| ☐  | SSA Application Form  |   |
| 1. The proposed study  |
| ☐  | Most Recent HREC Approval Letter – with the specific site listed  | Please ensure that the Ramsay Site where research will be conducted is listed on the Approval Letter  |
| ☐  | Study Protocol  | Required.  |
| ☐  | Participant Information & Consent Form- Approved Master Version  | Required, unless: ☐ waiver of consent is sought.  |
| 2. The research project (**Required for:** ☐ **multi-site study using site specific forms**)  |
| ☐  | Participant Information & Consent Form- Site Specific – Clean Version (if applicable)  | Please ensure that the DCS of the Ramsay Facility (or similar individual) or the Ramsay National Research Office is listed as contact for any complaints relating to the research.  |
| ☐  | Participant Information & Consent Form – Site Specific – Tracked Version (if applicable)  | Tracked changes from the approved master version.  |
| 3. Investigational product (**only required when:** ☐ **unapproved products/unapproved indication**)  |
| ☐  | CTN/ CTX Acknowledgement – with Specific Site listed (if applicable)  | Ensure that the Ramsay Site is listed on the Acknowledgement.  |
| 4. Resources demanded at Facility (No mandatory documents required)  |
| Please ensure that any resources required from Ramsay Health Care to support the research are outlined in the SSA submission. Please provide sufficient detail to allow assessment of the application.  |
| 5. Legal Considerations: Indemnity and Insurance  |
| ☐  | Proof of the current insurance cover for the proposed study (e.g. a Certificate of Currency)  | Insurance policy for the specific study or Medical Malpractice Policy that covers relevant research activities.  |
| ☐  | Proof of insurance for any students wishing to undertake the research (if required)  | For any enquiries, Please contact the NRU.  |
| ☐  | Letter of support from academic supervisor for the study  | Required unless: ☐ the study is not a student project.  |
| ☐  | Research agreement (if applicable)  | May be required if payments to Ramsay Health Care come from the funding of the project. For any enquiries, Please contact the NRU.  |
| 6. Conflict of Interest (no mandatory documents is required)  |
| 7. Merits and Reputation of the Research Team  |
| ☐  | CV of each member of the research team  | Required unless current version previously provided.  |
| ☐  | GCP Certificate of each member of the research team (if there is participant contact)  | Required unless current version previously provided.  |