**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. |