Checklist of Required Documents for Ethics

You must complete your HREA in REGGS in order to apply to a Ramsay HREC

Supporting Documents are outlined in the table below and are dependent upon trial type and specifics.

The following information will also be required to be submitted in conjunction with your application:

- All research studies, including Low and Negligible Risk (LNR) studies, require a protocol. It is also advisable that all clinical audits should have a formal written project plan.
- A copy of your study protocol or project summary is required to be uploaded when completing your "Project Registration" form.
- If a researcher is ***a student***, we require confirmation from the educational institution in question that students are both adequately experienced and qualified or will be supervised.

Document Type	Data only	Lower risk	Higher risk	Clinical Trials	Database
Human Research Ethics Application (HREA) Completed in REGGS	X	X	X	X	X
Research Protocol/Project Description	X	X	X	X	X
Participant Information and Consent Forms *	X	X	X	X	X
• *Note this may also include Telephone script if Consent over phone or E-Consent (including all information available on electronic devices – screenshots or other).* • *For* **Data Only** *applications, a copy of previous consent form demonstrating consent for future use of data, together with a letter from the Data Custodian confirming that the data is available should also accompany your application.* • *Where a* **Waiver of Consent** *is sought, this MUST be accompanied by a RHC Waiver of Consent form available from the Helpful resources section on our Website.* *Where* **Opt-Out consent** *is sought, this should comprise a Participant Information sheet and Opt- Out or Withdrawal Form.*					
Abbreviated CV for each researcher	X	X	X	X	X
GCP certificate				X	
Data Collection Tools (eg data forms, questionnaires, surveys, interview questions, psychological scales or inventories; PREMS, PROMS etc)		X	X	X	X
Study advertisements and other recruitment materials (eg fliers, Letter of Invitation/ Letter to GP)		X	X	X	X

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Document Type	Data only	Lower risk	Higher risk	Clinical Trials	Database
Data Management Plan (may complete separate plan or incorporate into protocol)		X	X	X	X
Radiation Frequency Declaration Form or Radiation Safety Report (as applicable)		X	X	X	X
Investigator Brochure (IB) or Product/Procedure Information **OR** ARTG Certificate for study drugs and/or devices				X	
HREC Only Indemnity (commercially sponsored clinical trials) -				X	
Approval letter from Lead HRECs (if applicable)		X	X	X	X
Evidence of Peer or Scientific review and support for Research			X	X	