DOCUMENT REQUIREMENTS FOR INITIAL REVIEW

Basic Documents (must submit):

- RIHS ERC FORM 2B: Review Checklist
- RIHS ERC FORM 2C: Registration and Application
- RIHS ERC FORM 2D: Study Protocol Assessment
- Study Protocol
  - Brief Background and Justification.
  - Objective/Purpose of the Study and a Brief Statement as to why the research question(s) is relevant.
  - A schematic diagram of the study.
  - Methodology (including sampling methodology and sample size).
  - Ethical Considerations of the study which shall include, but not limited to, the possible risk and benefit to the participants; compensation if any for the participants; a description of the arrangements for indemnity.
  - Limitations, if any.
  - Significance of study with a careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
  - Plans for dissemination of research results to the relevant stakeholders.
  - Budget and timelines.
  - References.
- Study Protocol Synopsis not more than 300 words
- Data Collection Forms including Case Report Forms and Patient Recruitment Forms
- Curriculum Vitae of Principal Investigator and Study Team Members
- Electronic copy of study protocol and RIHS ERC Forms 2B, 2C, 2D and 2E

Study-specific Documents (submit as needed):

- Investigator's Brochure (for clinical trials phase I, II & III) (an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product together with a summary of clinical experience with the study product to date) or Product Insert (for clinical trials phase IV)
- RIHS ERC Form 2E: Informed Consent Assessment Form (for studies with human participants)
- Informed Consent Form in English and Local language (for studies with human participants)
- Assent Form in English and Local language (for studies involving minors)
- Good Clinical Practice (GCP) Training Certificate of Principal Investigator, Co-investigator and the rest of the study team (for clinical trials)
- Disclosure of previous ethical and/or scientific board reviews
- Regulatory clearance for all types of studies from appropriate regulatory authorities, if necessary
- Insurance/Indemnity policies, indicating who are covered
- Disclosure of funding sources, sponsors, institutional affiliations and other possible sources of conflicts of interest