**INITIAL PROTOCOL PACKAGE CHECKLIST**

Protocol No.: \_\_\_\_\_\_ Date Documents Received: \_\_\_\_\_\_\_\_\_\_\_\_

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **REQUIRED DOCUMENTS** | **REMARKS** |
| 1. Application Form for Ethical Evaluation of Proposed Study |  |
| 1. Results of technical/ethical review from other ERCs (if applicable) |  |
| 1. Research protocol |  |
| 1. Written Information for the participants of the study |  |
| 1. Informed Consent/assent documents- These must be both in English and in language appropriate to the level of understanding of the research participant |  |
| 1. Study Tools (questionnaires, case report form, posters/advertisements for recruitment, etc.) |  |
| 1. Curriculum vitae of principal investigators and co-investigators which will also include relevant training and proof of ethics training |  |
| 1. Information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, compensation for the study participants/subjects |  |
| 1. Contracts and approval of relevant offices |  |
| 1. Study/Protocol Budget |  |

All required documents complete for FULL BOARD REVIEW \_\_\_\_

for EXPEDITED REVIEW \_\_\_\_

Required documents incomplete

Checked by: Noted by:

**<Name and Signature of Secretariat Staff> <Name and Signature of CLHRDC-ERC Chair>**