HIMS Hassan

**IEC SUMMARY SHEET**

|  |  |
| --- | --- |
| Title of Proposal: |  |
| Name of PI |  | Dept |  |
| Name & Designation of Guide in case PI is a student |  |

|  |  |
| --- | --- |
| Need for the study |  |
| Objective |  |
| Study Design |  |  | Site of study |  |
| Sample size |  |  | Study duration |  |
| **Study Process Flow Chart:** |
|  |

Above details shall not be beyond page 1

**HIMS IEC CHECK LIST**

|  |  |  |
| --- | --- | --- |
| **SlNo** | **Check list** | **Tick** |
| 1# | Have the corrections suggested by IRC (If any) been incorporated? | Yes / No |
| 2 | Does your research follow 12 general principles of research? (as per Section 1.1; pg:3-4)\* | Yes / No |
| 3 | What is the risk category your research proposal falls into: ***Less than minimal Risk/ Minimal Risk/ Low Risk / High risk*** (as per Table 2.1; pg:6)\* |  |
| 4 | Has the Informed consent form (as per Box 5.1; pg:50\*) submitted to IEC  | Yes / No |
| 5 | Is the study being undertaken on vulnerable population? (Refer to Box:6.1 & 6.2; pg: 56-57)\* | Yes / No |
| 6 | If yes, a justification statement is submitted to IEC? (Table 6.1;pg:59)\* | Yes / No / NA |
| 7 | Does the study involve participants of age group 0-18 years? | Yes / No |
| 8 | If Yes, Will the assent forms be obtained (as per Box: 6.6; pg-64)\* along with LAR/Parental consent | Yes/ No / NA |
| 9# | Does the study include any extra procedure / workup / investigation / Treatment beyond Routine clinical care? (Section: 2.5.2; pg:8)\* | Yes/ No / NA |
| 10 | If Yes, who will bear these costs **(Investigator / Institute / participant / Sponsor)** |  |
| 11 | Any payments to participants are provided? (Section: 2.5.2; pg:8)\* | Yes/ No |
|  | If Yes, provide details in separate document |  |
| 12 | Does proposal have any provision for Compensation for research related harm (Section: 2.6; pg:8)\* | Yes / No |
| 13 | Does the proposal comply with SAE reporting (Section: 2.6.1; pg:9)\* | Yes / No |
| 14 | Have the researchers taken appropriate measures to uphold the privacy and confidentiality of participants (as per Section 2.3; pg:7)\* | Yes / No |
| 15 | Will the participants berecruited as per distributive justice? i.e. Risks and benefits of research are equitably distributed among participants. (As per Section 2.4; pg:8)\* | Yes / No |
| 16 | Has the proposal been checked for plagiarism? | Yes / No |
| 17 | Is the authorship as per ICMJE criteria? \*\* | Yes / No |
| We the authors declare that all the details are true to best of our knowledge and belief. There is no conflict of interest, and we take full responsibility of ethical conduct of research from inception to publication. |
|  | Name of the author | Role | Signature with date |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |

\*<https://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf>

\*\*<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two>

# Sl No 1 has to be signed by IRC chairman, and Sl No 9 has to be signed by Subject expert.