**Self-Assessment Form for PI**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Proposal No.  (for staff) | Research Topic (English): | | | | | | |
|  |
| PI Name | | | | | | Age | |
| Request for | | □ Exemption | □ Expedited review | | | □ Full board review | |
| **Assessment List** | | | |  |  |  |  |
| **I – Qualification of Researcher** | | | | **Have** | **Not have** | **NA** | **note\*** |
| Specialist of PI | | | |  |  |  |  |
| Ethics Certificate  (If in Clinical Trials, PI must have GCP Training certificate) | | | |  |  |  |  |
| **II - Protocol** | | | | **Have** | **Not have** | **NA** | **note\*** |
| 1. Research value/merit | | | |  |  |  |  |
| 2. Research validity | | | | **Have** | **Not have** | **NA** | **note\*** |
| 2.1 Rationale | | | |  |  |  |  |
| 2.2 Appropriate design and Methodology | | | |  |  |  |  |
| 2.3 Sample size calculation | | | |  |  |  |  |
| 2.4 Statistical analysis | | | |  |  |  |  |
| 3. Inclusion/exclusion criteria | | | | **Have** | **Not have** | **NA** | **note\*** |
| 3.1 Fair paricipant’s selection | | | |  |  |  |  |
| 3.2 Appropriated representatives of research participants | | | |  |  |  |  |
| 3.3 Concern about appropriateness of recruiting or excluding risk group | | | |  |  |  |  |
| 4. Risk (to.............................................................................) | | | |  |  |  |  |

**Note\* Please explain the reason**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **II - Protocol** | **Have** | **Not have** | **NA** | **note\*** |
| 5. Benefit (to ) |  |  |  |  |
| 6. Vulnerability |  |  |  |  |
| 7. Additional Safeguard | **Have** | **Not have** | **NA** | **note\*** |
| 7.1 Appropriate Recruitment |  |  |  |  |
| 7.2 Adequate informed consent process |  |  |  |  |
| 7.3 Acceptable treatment available |  |  |  |  |
| 8. Material Transfer Agreement/Clinical Trial Agreement: MTA/CTA |  |  |  |  |
| 9. Advertising, CRF, etc. |  |  |  |  |
| **III – Informed Consent Form (ICH GCP 4.8.10)** |  |  |  |  |
| 1. Documentation for explain information for research participants | **Have** | **Not have** | **NA** | **note\*** |
| 1.1 Topic of the research |  |  |  |  |
| 1.2 Understandable language |  |  |  |  |
| 1.3 Declaration of research |  |  |  |  |
| 1.4 Reasons for the invitation to take part in the research project |  |  |  |  |
| 1.5 Research objective |  |  |  |  |
| 1.6 Number of research subjects participating in the research project. |  |  |  |  |
| 1.7 Procedures for the treatment of research subjects. |  |  |  |  |
| 1.8 Duration of research subjects needs to remain in this research project. |  |  |  |  |
| 1.9 Expected directed benefit of the research for research subjects, and/or benefits to community/ society/ or new knowledge |  |  |  |  |
| 1.10 Potential Risk, discomfort, or inconvenience that may occur to research subjects in research project. |  |  |  |  |
| 1.11 Alternative treatment procedure if the research subjects do not participate in research project. |  |  |  |  |
| 1.12 Compensation for travel expenses, lost time, inconvenience, discomfort, and lost income as a result of participating in the research project, method and allocation time. |  |  |  |  |

**Note\* Please explain the reason**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **III - Informed Consent Form (ICH GCP 4.8.10)** | **Have** | **Not have** | **NA** | **note\*** |
| 1.13 Provide medical treatment or compensation in case of damages or risks related to the research. |  |  |  |  |
| 1.14 Funding Support Information |  |  |  |  |
| 1.15 Genetic research requires informed consent and genetic counseling |  |  |  |  |
| 1.16 Request for collecting the remaining samples from the research and the period of collecting for further usage. Informed consent is necessary for the collection of the remaining samples, but the use of this example must be examined by the Ethics committee. |  |  |  |  |
| 1.17 Contact person and phone number that may be contacted 24 hours a day in case of an adverse event. |  |  |  |  |
| 1.18 The telephone number of the human research ethics committee that the research subjects may contact in case of a complaint. |  |  |  |  |
| 1.19 Availability of information document suitable for children aged 7-12 years. |  |  |  |  |
| **IV - Consent Form** | **Have** | **Not have** | **NA** | **note\*** |
| 2.1 Including the statement of research subjects “I have the freedom to refuse or withdraw from the research project at any time without interfering with the usual treatment that I should be receiving, or losing any benefit.” |  |  |  |  |
| 2.2 Scope of Confidentiality of information |  |  |  |  |
| 2.3 Appropriateness of signature of the research subject, and/or legal representative. |  |  |  |  |
| 2.4 Appropriateness of informed consent for those who are unable to read or write. |  |  |  |  |
| 2.5 Appropriateness of requesting for assent and signature (for Children aged 7-18 year) |  |  |  |  |

**Note\* Please explain the reason**

Please check the following risk/benefit categories of your research project in the table below. Only select one type.

|  |
| --- |
| **Risk/Benefit Category of the Whole Protocol** |
| □Research involving not greater than minimal risk.  □Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants.  □ Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition.  □ Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of participants. |

Researcher Signature……………………………………………………………….

(……………………………………………………….)

Date……………./………………../……………….