# ANNEX 1

**AF/01-012/01** **Study assessment and report form**

**A. Particulars of the protocol**

|  |  |  |
| --- | --- | --- |
| **Sl. No** | **Items** | **Details** |
| **Protocol:**  |
| 1 | Protocol Number |  |
| 2 | Reviewer’s Name |  |
| 3 | Date of review |  |
| 4 | Status of review | New  Amended |
| 5 | Protocol Version Number |  |
| 6 | Date of protocol |  |
| 7 | Principal Investigator(s), Institute with contact numbers |  |
| 8 | Professional Registration Number (if applicable) |  |
| 9 | Co-Investigators with contact numbers |  |
| 10 | Total No. of participants |  |
| 11 | Number of study sites |  |
| 12 | Funding Agency |  |
| 13 | Contact No. of funding agency |  |
| 14 | Duration of study |  |
| **Informed Consent Form (ICF)**  Waiver  No Waiver |
| 15 | ICF version number |  |
| 16 | Date of ICF |  |

**B. Protocol Review Details**

|  |  |
| --- | --- |
| Type of the Study:  | Intervention  Epidemiology Observation Document based  Individual based GeneticSocial Survey  Others, specify |
|  Review Status: | Full board  Expedited  Emergency |
| Description of the Study in brief: Mark whatever applied to the study.  Randomized Stratified Randomized Open-labeled Double blinded Placebo controlled  Treatment controlled  Cross-over Parallel Interim Analysis Use of Tissue samples Use of Blood samples Use of genetic materials Multicenter study Screening Descriptive**Brief the study design and the statistic used:** **Study Objectives:** |
| **Mark and comment on whatever items applicable to the study.** |
| Study Protocol – Scientific issues |
| 1. 1
 | Objectives of the Study clear  unclear | What should be improved? |
| 1. 2
 | Need for Human Subjects.  Yes  No(Note: Refer SOP/007/01 for more details on the definition of human subject) |  |
| 1. 3
 | Methodology: (Study design, sampling methodology, Data collection and analysis plan) clear  unclear |  |
| 1. 4
 | Background Information and Data sufficient  insufficient |  |
| 1. 5
 | Sufficient number of participants? Yes  No(**Note:** For quantitative study, is sample size calculation details provided?) |  |
| 1. 6
 | Inclusion Criteria appropriate  inappropriate Not provided |  |
| 1. 7
 | Exclusion Criteriaappropriate  inappropriate Not provided |  |
| 1. 8
 | Discontinuation and Withdrawal Criteria appropriate  inappropriate Not provided(**Note:** The intervention(s) has to be discontinued and withdrawn if there is SAE/AE and there has to be clear criteria for such discontinuation and withdrawal of the intervention(s). |  |
| 1. 9
 | Data collection tools (such as Questionnaire, Guidelines, Manuals, Forms) appropriate  inappropriateNot provided |  |
| Qualifications of Investigators and study sites  |
| 1. 10
 | 1. Are Qualification and experience of the Participating Investigators appropriate?

Yes  No CV not attached |  |
| 1. For Clinical Trails only, does the PI and/or Co-PI has proof of GCP training

 Yes  No Proof not attached  NA(**Note:** Usually the GCP training certificates are valid for only 2-3 years. Check the validity of the certificate) |  |
| 1. 11
 | Facilities and infrastructure of Participating SitesAppropriate  Inappropriate Site not mentioned |  |
| 1. 12
 | Disclosure or Declaration of Potential Conflicts of Interest Yes  No(**Note:** Refer serial number 17 of the “AF/01-009/01 APPLICATION FORM for INITIAL REVIEW”) |  |
| 1. 13
 | Is there a Physician if the PI is non Physician?Yes No Not applicable |  |
| Study Participation- Ethical Issues |
| 1. 14
 | Risks and Benefits Assessment acceptable  unacceptable(**Note:** The reviewers shall assess the risks and benefits of the study. Comment on how to protect vulnerable subjects, level of risks, identification of types of risks (e.g. placebo, clinical or social risk, etc.), benefits: benefits to participants, benefits to society, risk/benefit ratio) |  |
| 1. 15
 | Involvement of Vulnerable Participants  Yes  No(**Note:** Refer Glossary in the SOP (Chapter 11) for the definition of vulnerable participants.) |  |
| 1. 16
 | Voluntary, Non-Coercive Recruitment of Participants  Yes  No |  |
| 1. 17
 | Are blood/tissue samples sent abroad? Yes No(Note: If ‘Yes’, review the Material Transport Agreement. For details refer SOP/) |  |
| 1. 19
 | Privacy & ConfidentialityYes  No(Note: Privacy refers to persons and their interest in controlling access to themselves. Confidentiality refers to agreements with the participant about how data are to be handled.) |  |
| 1. 20
 | Inducement for ParticipationUnlikely  Likely (**Note:** Among other things like information sheet and examine the budget details) |  |
| 1. 21
 | Provision for Medical / Psychosocial Supportappropriate  inappropriateNot mentioned  NA |  |
| 1. 22
 | Provision for Treatment of Study-Related Injuries appropriate  inappropriate Not mentioned NA |  |
| 1. 23
 | Provision for Compensation appropriate  inappropriate NA |  |
| Community involvement and Impact |
| 1. 24
 | Community Consultation Yes  NoNA(Note: Community is a group of people living in the same place or having a particular characteristic in common. E.g., epilepsy population, Bhutanese community in Australia, etc.  |   |
| 1. 25
 | Involvement of Local Researchers and Institution in the Protocol Design, Analysis and Publication of Results Yes  No |  |
| 1. 26
 | Contribution to Development of Local Capacity for Research and Treatment Yes  No |  |
| 1. 27
 | Benefit to Local Communities Yes  No |  |
| 1. 28
 | Availability of similar Study / Results Yes  No(**Note:** Refer the list of protocols approved by IRB besides doing literature search online) |  |

 **C. Consent form review details:**  Applicable  Not applicable

|  |  |  |
| --- | --- | --- |
| Sl.No | Informed Consent Information | Comments |
|  | Are procedures for obtaining Informed Consent appropriate?Yes  No |  |
|  | Is there an informed consent information to be provided for the participantsYes  No |  |
|  | Contents of the Informed Consent clearclear  unclear |  |
|  | Language of the Informed Consent  clear  unclear |  |
|  | Information contents for the informed consent adequate Adequate  Inadequate |  |
|  | Is the informed consent information translated into local language?Yes  No  NA |  |
|  | Form for signature to ensure the administration of informed consent form, witness and person conducting informed consent formappropriate  inappropriate Not available  NA |  |
|  | Contact Persons for Participants Yes No(**Note:** Name and contact number of the investigator(s) and IRB shall be there in the information sheet) |  |

**D. Assessment Report**

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| --- | --- |
| Elements Reviewed (AF/01-012/01)  | Attached  Not attached |
| Review of Revised Application  Yes  No | Date of Previous review:  |
| DECISION :(**Note:** Refer “ANNEX 9 of SOP/012/06” for the criteria) | Protocol (Version No.: ....................... dated: dd/mm/yyyy):Approved Approved with Recommendation Solicited for Resubmission (Expedited  Full Board ) DisapprovedIf approved, the frequency for continuing review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Informed Consent Form (Version No.\_\_\_\_Not mentioned\_\_\_\_\_\_\_\_\_\_\_):  Approved Approved with Recommendation Solicited for Resubmission (Expedited  Full Board )  Disapproved  Not Applicable |
| Tools (Version No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_):  Approved  Approved with Recommendation  Solicited for Resubmission (Expedited Full Board ) Disapproved |
| Other related documents (ex. Advertisement), Yes  No If Yes, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approved  Approved with Recommendation  Solicited for Resubmission (Expedited  Full Board )  Disapproved |
| Comment (**Note:** Mention recommendations/clarification to be sought from the assessment form AF/01or2-012/01 and any other additional comments here): |
| Signature:  |  | Date: |