**Checklist: Considerations for Genetic Research**

1. **Need for the checklist**

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| Genetic research is still poorly understood and there is much to be learned by the scientific community, for a fuller and more comprehensive understanding of the genetic functions of the human body. Potential participants may have difficulty in understanding the research details and thus give informed consent on less-than-optimal understanding. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.Instructions for the PI: 1. *Please download the checklist, type the details, and email the signed copy to* *ethcom@yenepoya.edu.in**).*
2. *Please do not delete any of the questions/ sections/options provided by YEC-1 in the checklist.*
3. *Please note that all the details provided here are also reflected in the protocol and informed consent document.*
4. *Do not leave any question without a response. If not applicable, write not applicable*
 |

1. **Details of the protocol:**

|  |  |
| --- | --- |
| **Protocol Number:**  |  |
| **Title of the protocol** |  |
| **Principal investigator**  |  |
| **Department** |  |
| **List of Co-investigators/ Guides/ Co-guides** |  |

1. **Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)**:

|  |  |  |
| --- | --- | --- |
| **Sl No** | **Checklist item** | **Yes/ No/ Not applicable**  |
|  | Will the samples be made **anonymous** to maintain confidentiality? |  |
| Please mention the page numbers of the protocol in which these details are described.  |
|  | Will the **results be disclosed** to the participant or legally authorized representative? |  |
| 1. If yes, has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?
 |  |
| Please mention the page numbers of the protocol in which these justifications are described. |  |
| 1. If yes, will the results be used in management of current condition of patient?
 |  |
|  | Has the appropriateness of the various strategies for recruiting participants and their family members been considered? |  |
| Please mention the page numbers of the protocol in which these details are described. |  |
|  | Does the proposed study population comprise family members of the participants? |  |
|  | Will family members be implicated in the studies without consent? |  |
|  | Will the samples be destroyed immediately after research? |  |
|  | Will the samples be stored for future use? |  |
|  | Will the samples be shared with the third parties? |  |
|  | Will the samples be used for future research? |  |
|  | Will the data associated with it, be shared with other researchers? |  |
|  | Will genetic counselling be offered? |  |

Signature of the Principal Investigator: Date:

|  |
| --- |
| **YEC-1 Office use only** |
| Comments of Primary Reviewer |  |
| Primary Reviewer Signature and Date |

Instructions for the PI:

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4. *Do not leave any question without a response. If not applicable, write not applicable*