AFIC F -6125

Introductory Questionnaire

|  |  |
| --- | --- |
| Title of protocol: |  |

Principal Investigator and Co-Investigators:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| NAME |  | DESIGNATION | DEPARTMENT | SIGNATURE |
| NAME |  | DESIGNATION | DEPARTMENT | SIGNATURE |
| NAME |  | DESIGNATION | DEPARTMENT | SIGNATURE |
| NAME |  | DESIGNATION | DEPARTMENT | SIGNATURE |

1. Project involves the use of:

(Check all pertinent ones)

|  |  |  |
| --- | --- | --- |
|  |  | Experimental drug(s) |
|  |  | Radioactive agents |
|  |  | Non-therapeutic research |
|  |  | Non-approved use or non-approved dose for approved drugs |
|  |  | Experimental surgical procedures |
|  |  | Fetal research |
|  |  | Behavioral research |
|  |  | Gene molecular cloning |
|  |  | Other (please specify): |

Please provide details in case **a** or **d** is checked

1. What is the purpose of the study? (Please give a brief background of the study)

2. Enumerate the objectives of the study

1. Brief description of methods (sample size Calculation) used in protocol.

4. a) Expected duration of the study period (to completion).

b) Expected duration of study on each individual subject.

5. a) Please indicate source of funding.

b) Has funding been approved?

1. Subject information.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| a) Group: |  | Patients |  | Students |  | Others |
| b) Records: |  | | | | | |
| c) Age range: |  | | | | | |
|  |  | | | | | |
| d) Gender |  | Male |  | Female |  | Both |

1. If subjects are children, pregnant women, mentally retarded, or prisoners, or if it

includes foetal research, give brief explanation of need to use these particular individuals.

7. a) Compensation (to research subject):

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Monetary: | No | |  | Yes |  | Amount: |  | |
| Other: | No | |  | Yes |  | Specify: |  | |
| Reimbursement of expenses: | | No |  | Yes |  | Type & amount: | |  |
|  |  |  |

b) Compensation (to Investigators):

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

If yes then

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Monetary: |  | | Travel: |  | Gifts: |  | Amount: |  |
| Other Specify: | |  | | | | | | |

8. Adverse effects:

a) Describe adverse effects/risks expected to the subjects involved in the investigation during the study?

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1. What is the provision for managing these effects?

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1. Who will pay for them?

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9. Laboratory and Radiological studies:

1. Will any tests be performed which are not routinely included as part of the work-up for these types of patients?

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1. Who or what agency will pay for these tests?

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10. Location of study:

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| --- | --- | --- | --- | --- | --- |
| Outpatients units: |  | Inpatients units: |  | Community based: |  |

|  |  |  |
| --- | --- | --- |
|  | Please specify the location where research will take place |  |

11. What are actual potential benefits of this research, if any, to be obtained?

a) By participants.

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|  |

b) By the society ?

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1. By the funding agency or sponsors.

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1. Please specify benefit of the study to AFIC&NIHD where study is being conducted.

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12. How will the confidentiality of the subjects be ensured?

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13. How will the study findings be shared with?

a) Study subjects ( If applicable)

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| --- |
|  |

b) AFIC&NIHD (Compulsory)

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14. Discuss the **Ethical Issues** involved in the study.

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15. Any other information relevant to the study you would like to share with the committee?

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16. Has this study been conducted elsewhere earlier? If yes where? Please give references

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