

8. ANNEX

ANNEX 1 AF/01-009/01: Application Form for Initial Review (2 pages)

ANNEX 1
Form AF/01-009/01

APPLICATION FORM for INITIAL REVIEW

| | |
|------------------|------------------------------------|
| Protocol Title: | |
| Protocol number: | Total participants to be included: |

STUDY TYPE: (Mark "✓" whichever apply to the study)

- Survey
- Retrospective
- Prospective
- Social
- Behavioral research
- Community based
- Individual based
- Screening study
- Observational
- Epidemiology
- Intervention
- Medical
- Research on stored biological samples
- Clinical Trial: Phase I
- Phase II
- Phase III
- Phase IV
- Genetic Study
- Others.....

STUDY POPULATION: Healthy Patient
Vulnerable groups

CHARACTERISTICS of PARTICIPANTS:

- Age Range: 0 -17 yrs 18 - 44 yrs 45 - 65 yrs ≥ 66 yrs
- Pediatric None < 1 yr 1-3 yrs 4 -14 yrs
- Impaired Limitation None Physically Cognitively Mentally
- illiteracy Prisoners Hospitalized in Nursing home
- Pregnancy Poor/uninsured Employees of study site
- Students or staff of the PI Military personnel
- Others vulnerable to coercion, specify.....

REQUESTED EXCLUSION OF PARTICIPANTS:

- None Male Female Children Other (specify)_____)

SPECIAL RESOURCE REQUIREMENTS (check all that apply):

- Intensive Care Isolation unit Surgery
- Psychiatric institution Paediatric Intensive Care Transfusion
- CAT scan EKG scam
- Gene therapy Controlled substances (Narcotics / Psychotropics)
- Prosthetics Gynecological services
- Others, specify.....
- Organ transplantation, specify.....

IONIZING RADIATION USE (X-rays, radioisotopes, etc):

- None Medically indicated only

INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE):

None

IND

IDE

DRA No.:.....

DRA No.:.....

Name:.....

Name:.....

Sponsor:.....

Sponsor:.....

Holder:.....

Holder:.....

PROCEDURE USE:

Invasive

Non-invasive

MULTI-SITE COLLABORATION:

YES, number of sites.....

NO

FINANCIAL DISCLOSURE:

YES

NO, why

not.....

PARTICIPATING INVESTIGATORS:

| Name/ Institution | License No. | Title and Role | Telephone / Fax No. |
|-------------------|-------------|----------------|---------------------|
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |
| 7. | | | |
| 8. | | | |

Has the principal investigator ever been involved in or convicted of a crime, disciplined by a public or private medical organization, or by a licensing authority?

No

Yes, explain.....

Does the PI, the study colleagues or their families have any financial relationship with the sponsor other than payment for the conduct of the study?

No

Yes, describe the relationship.....

For this study, how many of the following will the PI supervise?

Sub-investigators..... Study sites.....

How many (in total) of the following does the PI currently supervise?

Open studies..... Location..... Sub-investigators..... Study staff.....

Has the research study been disapproved or terminated by any other Research Board?

No

Yes, explain.....

SIGNATURES:

_____ Date:
Principal Investigator

_____ Date:.....
Protocol Chairperson (if applicable)

COMPLETION:

_____ Date:.....
Member-Secretary, REBH

APPLICATION NUMBER : / -