Philadelphia FIGHT
INSTITUTIONAL REVIEW BOARD

Application for Approval of Investigation Involving Human Subjects in Which There Is More than Minimal Risk

IRB Protocol Number _____Date
IND Number_____

1. Date:

2. Principal Investigator:

3. Primary Institutional Affiliation:

4. Telephone No.:

5. Co-investigators and degrees / Primary Institutional Affiliation

a)

b)

c)

d) _____

6. Title of Proposed Investigation:

7. Average length of proposed research:_____

8. FIGHT affiliated site(s):

9. Funding Source:

NONTECHNICAL RESEARCH PLAN

Federal regulations require that the composition of the Institutional Review board (IRB) include individuals with varied background and education. Therefore, this section is to be written in terminology that is understandable across disciplines.

10. a) Describe <u>briefly</u> the background of the study, and state reasons for conducting it.

b) State objectives of the study.

c) Explain how the study will be performed. List all research procedures and/or interventions involving human subjects.

d) Outline criteria for selection and exclusion of subjects. *Please note that, in accordance with FDA guidance, participants must be able to provide informed consent using a) consent documents available at the time of the initial study visit when a language other than English is anticipated [for example: when conducting research at Clinica Bienestar] or b) in the case of an unexpectedly encountered non-English speaking subject, an oral translation of available documents by a 3rd party in the subject's preferred language.*

11. a) Characteristics of the research subjects to be included:

a) Sex: <u>All</u>
b) Race: <u>All</u>
c) Ethnic Group: <u>All</u>
d) *Target number at FIGHT and/or FIGHT related site:
e) Overall National Total:
f) Ages:_____

* After initial approval is granted the target number cannot be exceeded without prior approval.

b) Subject's state of physical health. Indicate if seriously or terminally ill.

c) Special populations:

□ minors	□ fetuses,
□ abortuses	□ pregnant women,
□ prisoners	□ none of thee above
□ people living with cognitive impairment	

d) If subjects are from one of the above special populations (11c), explain the necessity for including them.

12. Specify source of participating subjects, e.g. hospitals, clinics, institutions, prisons, industry, unions, schools, general population, etc. ***NOTE: If you plan to advertise for patients, the ad must be submitted to the IRB for review and approval <u>prior</u> to its publication and/or posting.***

13. **a) Will subjects receive any compensation, (monetary or other)? Yes □ No □**

If monetary, how much? _____ If other, specify _____

b) Will subjects be asked to assume any out-of-pocket costs for participating in the research? Yes □ No □.

If yes, what? Identify expenses such as additional transportation, laboratory tests, supplies, cost of study drug if it becomes commercially available**,** etc.

14) **Will isotopes be used? Yes □ No □. If yes, what isotope?**

15. **Will new drugs or biologic agents be administered to the subjects, or will previously used agents be used in a new manner? Yes □ No □**

If **yes**, please attach a copy of the Investigator's Brochure for the study drug(s) with this application.

RISKS TO SUBJECTS

16. Describe in detail any potential risks - physical, psychological, social, legal, ethical (e.g. confidentiality), or other and assess the likelihood and seriousness of such risks (none, low, moderate, and high). Include the incidence of complications if known.

INFORMED CONSENT

17. Attach a copy of the consent form. Indicate how (verbal or written) informed consent will be obtained (please see guidelines for completing informed consent).

18. **If subjects are minors or mentally disabled, describe how and by whom permission will be granted.**

Minors are excluded from this study by way of Philadelphia FIGHT's exclusion criteria. If FIGHT personnel should recruit a mentally disabled individual, the subject will only be enrolled after obtaining the consent form from the mentally disabled individual's guardian.

19. Where will the record of consent be stored? (Consent forms must be kept for three years after the completion of the investigation, unless otherwise stipulated by the IRB).

20. Describe any means by which the subject's personal privacy is to be protected and confidentiality of data maintained.

A subject's participation in this research study will remain confidential. However, it will be necessary for certain groups to inspect the study records and the subject's medical records. Representatives of **XXXX (the study sponsor)** and their designees, the U.S. Food and Drug Administration (FDA), the Philadelphia FIGHT Institutional Review Board (IRB), and representatives of other health authorities may review the trial data. The subjects will not be identified by name in any publication of information from this study.

21. **Assess potential benefits to be gained by the individual subject and explain why the benefits outweigh the risks.**

22. **Assess benefits which may accrue to society in general as a result of the planned work.**

23. **Do the investigators have any economic incentive other than the scholarly (e.g., publications) benefits? If yes, please specify and explain.**

REAL OR APPARENT CONFLICT OF INTEREST

24. **Other than the normal scholarly gains, are there any other gains you might receive from taking part in this study?**

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25. **Other information:**

Signature and Assurance Sheet

Principal Investigator's Assurance Statement:

I understand FIGHT's policy concerning research involving human subjects and I agree:

1. to accept responsibility for the scientific and ethical conduct of this research study;

2. to obtain prior approval from the Institutional Review board before amending or altering the research protocol or implementing changes in the approved consent form;

3. to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study;

4. to submit protocol progress reports as specified by the IRB.

Signature: _____ Date: _____

Typed Name:_____

Philadelphia FIGHT Administrative Authorization:

I have reviewed this application for approval and authorize the Principal Investigator to proceed with IRB review of this protocol for the conducting of research at Philadelphia FIGHT.

Signature: _____ Date: _____

Typed Name:_____