

Control Number

**Meharry Medical College
Human Subjects Review Form for New Projects**

Principal Investigator:	Dept:	Phone:
Co-investigator:	Dept:	Phone:
Co-investigator:	Dept:	Phone:
Study Coordinator:	Dept:	Phone:

Study Title:

SUBMISSION CHECKLIST

Check all boxes that are applicable to your submission:

- Human Subject Review forms
- Research proposal(s) or protocol(s)
- Consent/Permission/Assent forms, if applicable
- HIPAA authorization forms, if applicable
- Research Instruments (Surveys, Questionnaires), if applicable
- Clinical Trial (required documents): Protocol Investigator's Brochure
- Approval letter from Radiation Safety Officer, if applicable
- Copy of Indemnification statement from contract, if applicable
- Waiver of Informed Consent
- Recruitment Material: Advertisements, letters, brochures, etc.
- Copy(s) of Human Subject Protection Training (CITI)
- Waiver of HIPAA Authorization
- IRB approval letters from other sites with IRBs
- Verification letter(s) from other sites without IRBs that research can be conducted at their site(s)
- Documentation of approval utilizing Departmental Funds
- Documentation of comment to fund IRB review, if applicable
- Additional information:

Answer all questions; use NA when necessary, and do not leave any items blank unless instructed to do so. Please type. Be sure that this document is consistent with your research proposal and consent form.

1. I agree to accept responsibility for protecting human subjects involved in this study. I also agree to submit any additions, corrections or modifications to the full protocol or the consent form(s) and any advertisements to the IRB for approval before implementing them. I agree to report immediately any serious adverse events or any complications (locally or at other sites) that may occur as a result of this study.

2. I have proofread the finished Human Subjects Review Form and consent form(s). All editorial corrections have been made. All typographical errors have been corrected. I am satisfied that this proposal and the consent form(s) are now ready for IRB review.

I agree not to start this study until final IRB approval has been obtained.

Date: Principal Investigator:

Date: Faculty Advisor:

(Required if P.I. is a trainee)

Answer all questions; use NA when necessary, and **do not leave any items blank** unless instructed to do so. Please type. Be sure that this document is consistent with your research proposal and consent form.

3. Do you believe your project can be reviewed by expedited procedure? Yes No
If yes, please check one of the following to explain why. [Expedited review requirements](#)

- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (45 CFR 110(f)(2))
- Prospective collection of biological specimens for research purposes by noninvasive means (e.g. hair, nail clippings, teeth, saliva) (45 CFR 110(f)(3))
- Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies (45 CFR 110(f)(7))
- Other (specify):

Request for:

- Waiver of Informed Consent
- Waiver of HIPAA authorization

PROJECT DESCRIPTION

4. The project will be funded by

- Federal grant or contract. Agency Grant #
- Other nonprofit sponsor (American Heart Association, etc.). Name Name
- Pharmaceutical company. Name Protocol#
 - A. Funding for IRB Yes No
- Investigator-initiated
- Meharry Departmental funding
- Other. Describe
- No funding identified (No Sponsor)

5. Performance Sites: Please indicate all sites where subjects will be recruited and/or studied:

- Meharry Medical College Clinical Research Center
- Other Meharry sites: Name
- Metro General
- Vanderbilt Medical Center
- Other Vanderbilt Sites: Name
- Murfreesboro Veteran's Admin. Hospital
- Foreign sites. Describe Does it have an IRB?
- Other. Describe Does it have an IRB?
- If approved by another IRB, provide name of IRB
and approval letter

6. CONFLICT OF INTEREST

- A) Do you and/or spouse or any of your key personnel have a conflict of interest with the funding source (i.e., stock or stock options, interest in technology, consultant to sponsor)? Yes No
If Yes, identify person
- B) If yes, please select the appropriate box or provide explanation:
 - i. 1. Compensation by sponsor for speeches, travel, grants, equipment, retainers for ongoing consultation, or honoraria
 - 2. Proprietary interest (not limited to patent, trademark copyright, royalties, or licensing agreements)
 - 3. Equity interest (stocks, stock options, or ownership interests) that exceeds \$10,000 or 5% ownership in a company

7. KEY PERSONNEL AND HUMAN PROTECTIONS TRAINING

List all individuals that have contact with human subjects during the duration of this project, including those who will be obtaining consent. (Note: Everyone listed below must provide a copy of Human Subject Protection training (i.e., CITI) before final approval is given).

8. SUMMARY

Two members of the IRB receive copies of your proposal; the other committee members rely on this form to understand and evaluate your project. Use the space provided. Do not use attachments.

In lay language, explain the rationale and the specific aims of the study.

PROTOCOL

9. A) Describe in sequence all procedures that will be carried out with each type of subject. If you are studying records or specimens, describe the sources, nature and format of the data and all procedures that will be carried out to collect and process this information. A person who has not read your research proposal should be able to visualize your experiment from reading this section. Use complete sentences. Do not use attachments.
- B) Which of the above procedures above is for research purposes only?

CONFIDENTIALITY OF DATA

10. Describe the information that will be collected for each patient. Check all that apply. Must match HIPAA authorization form, if applicable.
- Name
 - Geographic subdivision other than state or zip code
 - Any date (admission, discharge, birth, death) other than year for those under 89
 - Telephone number
 - Fax number
 - E-mail address
 - Social security number
 - Medical record number
 - Health plan beneficiary number
 - Bank account number
 - Certificate/license number
 - Vehicle identifier and serial number, including license plate
 - Device identifier and serial number
 - Website address
 - Internet protocol address
 - Biometric identifiers, including finger and voiceprints
 - Full-face photographic or comparable image
 - Any other unique identifying number, characteristic, or code
 - None of the above

11. A) Describe in detail measures you will take to disconnect subjects' identities from information about them.
- B) Will a key be prepared that links subjects' identities with code numbers at any time during this study?
Yes No
- C) If "yes" to "B", where will the link be kept? Identify both electronic and "hard" storage sites?
- D) Who will have access to the link? Who will have access to the data?
- E) Will all copies of the link be destroyed at any point? If yes, how and when? (Inform the IRB)
- F) What are the plans for final disposition and/or destruction of the data?
- G) Will any information listed in number 10 be shared with investigators at other institutions or shared with other organizations? Yes No
If yes, list the institutions and/or organizations:

SUBJECTS

12. How many subjects will be studied during the entire life of the project?
If Multi-site, total number for entire project _____ Local study site goal _____
- Is this a gender specific study? Yes No
If yes, what is the gender of the subjects? Male Female
Number of Males (local) _____ Number of Females (local) _____
- What is the age range of the subjects?
- Will blood be drawn from normal controls? Yes No

If yes, please submit a copy of the consent form to be used for normal subjects

13. Select the following **category** of subjects and the **number** that will be recruited for this study*:
- | | |
|---|---|
| <input type="checkbox"/> Pregnant women | <input type="checkbox"/> Inpatients |
| <input type="checkbox"/> Fetuses/abortuses | <input type="checkbox"/> Outpatients |
| <input type="checkbox"/> Children (Ages 0-1) | <input type="checkbox"/> Psychiatric patients (hospitalized) |
| <input type="checkbox"/> Children (Ages 2-6) | <input type="checkbox"/> Psychiatric patients (institutionalized) |
| <input type="checkbox"/> Children (Ages 7-17) | <input type="checkbox"/> Meharry Medical College employees |
| <input type="checkbox"/> Cognitively impaired | <input type="checkbox"/> Meharry Medical College students |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Other |

*Will any portion of the subject population be your own patients? Yes No
If yes, explain how coercion, resulting from doing research on your own patients, will be minimized.

If non-English speaking subjects, how will they be consented? Translated orally or written? Who will translate information? What are the qualifications of the translator?

BLOOD **Scale: (1 tsp= 5cc, 1 T. =15cc, 2T. =1 ou.)**

14. A) Will blood be drawn for this study? Yes No (If no, go to item 15.)
B) Amount of blood (single withdrawal in cc.):
C) Number of times blood will be drawn:

D) Total amount of blood to be drawn:
E) Over what interval of time will the total amount of blood be drawn?

F) Will the blood be stored during this study? Yes No If yes, where?
G) Will any portion of the blood be shared with other investigators or institutions?
 Yes No

H) If yes, describe in detail what will be done with the stored blood.

I) Will any portion of the blood be stored after the study ends? Yes No
J) If yes, where will the blood be stored?
K) How long will the blood be stored?
L) Why will the blood be stored? Be specific.

M) Will blood be used for genetic studies? Yes No
N) Who will have access to the blood?
O) Who will be able to connect each blood specimen with the identity of the donor?

TISSUE

15. A) Will tissues be used for this study? Yes No (If no, go to 16)
B) If yes, identify the tissue?
C) Identify the source of tissue specimens (including stored surgical samples):
 Meharry
 Commercial supplier
 Another institution
 Other
D) Where will the tissue be stored during this study?
E) Will any portion of the tissue be shared with other investigators or institutions?
 Yes No
F) If yes, describe in detail what the other party will do with the stored tissue.

G) Will any portion of the tissue be stored after the study ends? Yes No
H) If yes, where will the tissue be stored?
I) How long will the tissue be stored?
J) Why will tissue be stored? Be specific.

K) Will tissue be used for genetic studies? Yes No
L) Who will have access to the tissue?

M) Who will be able to connect each tissue specimen with the identity of the donor?

N) Will a tissue bank or repository be used? Yes No

- O) If yes, who will receive the samples?
- P) Describe all tissue/data that will be given to repository
- Q) Where is the location of the repository?
- R) What security measures are in place to protect the samples?
- S) How will it be used?

DRUGS

16. Will this study involve the use of any drugs? Yes No (If no, go to item 22)
17. Identify all FDA-approved drugs to be used in this study.

<u>Drug Name</u>	<u>Dose</u>	<u>Route of Administration</u> <u>Approved Use</u>
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18. Is any drug listed in item 16 to be used for a purpose, or in a manner, not approved by the FDA? This includes: different route of administration, new formulation, or used in a subject population not approved for the drug, such as normal subjects? Yes No
19. If yes, identify the FDA-approved drug and the new investigational use.

<u>Drug Name</u>	<u>Investigational Use</u>
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20. Identify all investigational drugs to be used in this study.

<u>Drug Name</u>	<u>IND Number</u>	<u>Dose</u>	<u>Route of Administration</u>
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21. Drug will be obtained from:
- Company
 - Name of Contact Person
 - Other source (please specify)

X-RAYS

22. Will subjects be exposed to X-rays as part of routine care? Yes No
23. Will subjects be exposed to X-rays as part of research? Yes No (If No, go to item 27)
24. Will this study involve radioactive drugs? Yes No (If no, go to item 27)

25. Identify any radioactive drugs or other radionuclides subjects will be exposed to.

Drug Name	IND Number	Source
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26. Do you have approval to use this drug by the Radiation Safety Office? Yes No

MEDICAL DEVICES

27. Will this study involve the use of any medical device(s)? Yes No (If no, go to item 30)

28. Identify all investigational medical device(s) to be used in this study.

Device	FDA Status	IDE Number	IDE Holder
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A. Describe device(s):

29. Is medical device(s) approved for other uses? Yes No (If Yes, describe)

RECRUITMENT PROCEDURES

30. Describe how and where subjects will be recruited. **Include a copy of any recruitment letters or advertisements.**

31. Will participant incentives be used?

No Yes If yes, what kind? (Amount in dollars, if applicable)

32. Describe the criteria for selecting subjects.

33. Describe the criteria for excluding subjects from the study.

BENEFITS

34. Describe the benefits to the individual.

35. Describe the benefits to mankind.

RISKS

36. Summarize the major risks and/or discomforts to the subject for participation in this study. The concept of risk goes beyond physical risks and includes psychological and social risk.

37. What precautions will be taken to minimize potential risks to subjects in this study? Will a Data Safety Monitoring Board (DSMB) be used? If yes, describe composition.

38. Describe your plans for monitoring serious adverse events that may occur as a result of this research and who will conduct the monitoring and how often?

CONSENT

Attach a copy of the consent form(s), assent form(s), statements to be read, or informational letters directed to the subject. Be sure that these forms are consistent with information in the research proposal and Human Subjects Review Form.

39. Who will obtain consent? Name all persons.

40. Where will consent be obtained? List all locations.

41. When and how will consent be obtained?

42. From whom will consent be obtained? Check all that apply.

- | | |
|--|--|
| <input type="checkbox"/> Subject | <input type="checkbox"/> Closest Relative |
| <input type="checkbox"/> Parent or guardian of the subject | <input type="checkbox"/> Emancipated minor |
| <input type="checkbox"/> Court appointed representative | <input type="checkbox"/> Other |

43. If children are subjects, how will assent be obtained?

44. Explain the procedures to be used to obtain consent when subjects cannot consent for themselves.

ALTERNATIVE PROCEDURES

45. Describe any alternative procedure(s) or treatments available to the subject.

RESEARCH RELATED COSTS

46. List any costs to the subject that will be involved as a result of the research procedures or treatments, including costs that would normally be incurred by standard treatment. Indicate what costs the subject will be responsible for paying and what costs will be paid by the study. If clinical trial, it must be consistent with the Clinical trial agreement.