

MEDICAL APPENDIX: RESEARCH INVOLVING MEDICAL PROCEDURES

Instructions:

- Complete this form according to the following outline. **(Hand written forms will not be accepted.)**
- Submit the signed form to the Office of Academic Affairs.

1. List the site(s) where research will be conducted:

2. Have you contacted the IRB at the aforementioned sites? Yes No
You will need to provide approval documentation from the external site's IRB.

3. Is the research investigating an experimental drug or procedure? Yes No

4. If an experimental drug is involved, submit an Investigational Drug Data Form and complete the following information.

a. Name of Drug/Device:

b. IND/IDE Number:

c. Sponsor/Manufacturer:

d. Number of Subjects:

5. Does submission involve the administration of radioactive drug(s)? Yes No

Name of radioactive drug(s):

6. Does submission involve recombinant DNA under NIH regulations? Yes No

7. Does submission involve a Phase IV antibiotic? Yes No

8. Describe the qualifications of the person(s) administering drugs, alcohol, or nutritional supplements, drawing blood, taking tissue samples, or giving injections.

Consent

9. Participants should not be distracted, coerced or pressured during the consent process. Please state when and where the informed consent process will take place and who will be responsible for obtaining initial and ongoing consent. Specify how much time participants will have to make their decision. Please reference and append a copy of the consent script if applicable.

10. If applicable, state how the recruitment and the consent process will differ if a potential subject's ability to give informed consent is in question (e.g., when acutely ill, demented or may become demented while participating in the research study).

Risks/Costs

11. Detail the potential medical risks associated with your research. What is the likelihood of these risks occurring? Do NOT simply append a drug product information sheet to the application. You must summarize the contents.

12. Describe procedures for protecting against or minimizing potential medical risks and arrangements for the provision of medical treatment if needed.

13. Address any additional monetary costs to the participant or insurance provider that are a direct result of participation in the research. Address additional costs in the consent form.

NOTE: If the research requires HIV testing, initial the following paragraph to document that you are informed of and will comply with, the IRB guidelines for safeguarding the confidentiality of these subjects.

The Code of State Regulations (Title 19) requires that test results be reported to the Department of Health within seven days of receipt. Subjects' names and addresses, however, should not be reported when the test is a direct result of participation in the research. In such cases, the consent form must be signed before the HIV test is performed. Use only a unique patient identifier when you send the blood specimen to the laboratory and when positive test results are reported to the Department of Health to protect research subjects' confidentiality

Investigator's initials _____ Date _____