

NEW PROJECT APPLICATION CHANGES

MARCH 28, 2005

The sections with altered text appear below with the 'track changes' feature showing what has been added or deleted.

7. EXPERIMENTAL TREATMENTS AND PROCEDURES INVOLVING HUMAN SUBJECTS

Completion of this section is required for all types of projects with direct involvement of human subjects.
If there is no direct involvement of subjects, please delete this section.

7.1 Please submit a Study Protocol for approval by IRBMED.

Submission of a separate Study Protocol document is mandatory.

The protocol document should bear a date, and a title matching the title shown in this application. It may have been prepared by the investigators or by the research sponsor. It should include goals of study, background information, specific aims, experimental design, statistical analysis of results, subjects of the research, risks and benefits of treatments or procedures, and significance of the outcomes.

Please indicate below, that it is appended.

7.2 Will the research subjects receive payments or other compensation for participating in the research? Please provide a description of the compensation.

(Payments and other compensation offered to subjects may be considered coercive. Payments in excessive amounts of , or bonus payments for completing a study would be considered coercive.)

Please answer "Yes" or "No". If yes, please provide justification for offering payments or compensation, the amounts, and the manner in which any prorated amounts will be distributed for visits, sessions, encounters or experiments.

7.3 Where will the subjects undergo the research-related treatments or procedures?

(*e.g.* University of Michigan General Clinical Research Center; University of Michigan Hospitals Cardiac Catheterization Laboratory; Computer Laboratory at the Mental Health Research InstituteÉ)

7.4 Will the investigators carry out the research-related treatments or procedures themselves?

Please answer "Yes" or "No". If yes, for each treatment or intervention that requires special skills (*e.g.* cancer chemotherapy, arterial cannulation, tissue biopsyÉ), please identify the responsible qualified Investigator. If no, please indicate the arrangements for implementation by qualified personnel.

7.5 What treatments or procedures will the subjects undergo solely for the purposes of this research?

Please provide precise information in reference to what will be done or will happen to the subjects, that would not have been done or happened, if they did not participate in this research.

7.6 If the research is to take place while the subjects are undergoing treatments or procedures for health care reasons, will these health care-related treatments or procedures be modified for the purposes of this research?

Please answer “Yes” or “No”. If yes, please provide precise information in reference to what will be done differently.

7.7 Does the research require withholding or postponing any medically-indicated customary health care?

Please answer “Yes” or “No”. If yes, please provide precise information in reference to what procedure or treatment will not be done or postponed, that would have been done for medical reasons, if the subjects did not participate in this research.

7.8 Will the subjects complete any interviews or survey instruments, or attend group meetings for the purposes of this research?

Please answer “Yes” or “No”. **If yes, please complete Section 11.**

7.9 Will blood be removed from the subjects for the purposes of this research?

Please answer “Yes” or “No”. **If yes, please complete Section 12.**

7.10 Will any biological specimens (other than blood) be removed from the subjects for the purposes of this research?

Please answer “Yes” or “No”. **If yes, please complete Section 13.**

7.11 Will any investigational, FDA-exempted drugs, biologics or devices be administered or applied to the subjects?

[Investigational drugs are defined as chemicals or drugs that are not FDA-approved for use in humans; a commercial product or an FDA-approved drug, provided at no charge by the study sponsor for use in a comparative trial with other drugs or placebo; or an FDA-approved drug, supplied at no charge to the subject, to be used for a non-FDA-approved indication for the purpose of a study. As defined by JCAHO, medication or drug includes prescription medications, sample medications, herbal remedies, vitamins, nutraceuticals, over the counter drugs, vaccines, diagnostic and contrast agents, and any product designated by the Food and Drug Administration \(FDA\) as a drug that is used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions.](#)

Please answer “Yes” or “No”. **If yes, please complete Section 14.**

7.12 Will FDA-approved (non-investigational, commercially available) drugs, biologics or devices be administered or applied to the subjects for the purposes of this research?

Please answer “Yes” or “No”. **If yes, please complete Section 15.**

7.13 Will the subjects be exposed to any ionizing radiation during the course of this research?

Please answer “Yes” or “No”. **If yes, please complete Section 16.**

7.14 Will any organs, tissues or cells from other humans be administered to the subjects for the purposes of this research?

Please answer “Yes” or “No”. **If yes, please complete Section 17.**

7.15 Will any genetic material be transferred to the subjects?
Please answer “Yes” or “No”. **If yes, please complete Section 18.**

7.16 Will genetic analysis be performed on any biological specimen to be acquired in conjunction with this research?
Please answer “Yes” or “No”. **If yes, please complete Section 19.**

***** End of Section *****

14. INFORMATION ON INVESTIGATIONAL, FDA-EXEMPTED DRUGS, BIOLOGICS OR DEVICES TO BE ADMINISTERED OR APPLIED TO THE SUBJECTS

Please complete this section, if answer to Question 7.11 was “Yes”.
If not relevant, please delete this section.

14.1 What are the generic names and/or code names of the drugs, biologics or devices (test articles)?
If more than one test article is involved, sequentially number them, and use respective number also in responding to the subsequent questions in this section.

14.2 What is the source (supplier or manufacturer) of the test articles?

14.3 What is the proposed mechanisms of action of the test articles?

14.4 Will a placebo be used in the study, as a control to a test article?
Please answer “Yes” or “No”.

14.5 What is the dosage, route of administration or application, and frequency & total duration of use of each test article?

14.6 If women with reproductive potential are involved, what measures will be taken to avoid the possibility that a test article may harm a potential fetus or off-spring?
(*e.g.* Screening subjects with pregnancy tests; use of various types of contraception; excluding subjects who are pregnant or are nursing an infantÉ)

14.7 Please submit manufacturer’s “Investigator’s Brochure” for approval by IRBMED.
Please indicate below, that it is appended.

14.8 If a test article is a drug or biologic ([as defined in section 7.11](#)), please submit the University of Michigan Hospitals Pharmacy Investigational Drug Service (IDS) acknowledgment document, or evidence of exemption from this requirement.

[All University of Michigan Hospitals require that investigational drugs/biologics be dispensed through the IDS.](#)

[Investigational drug or biologic studies conducted by Medical School faculty or using UMHHC facilities must be reviewed by the Investigational Drug Service \(IDS\) prior to submission to the IRBMED.](#)

Please indicate below, that it is appended. If review by IDS is taking place concurrently, indicate so below; make sure that the document is sent to the IRBMED by telefacsimile (763 9603).

- 14.9 If a device is being used for the first time at the University of Michigan Hospitals, please submit the University of Michigan Hospitals Biomedical Engineering Unit (BEU) (Plant Support Service) approval document, or evidence of exemption from this requirement.**

University of Michigan Hospitals require that any approved or investigational device to be used at the Hospitals for the first time, be inspected and approved by the BEU.

Please indicate below, that it is appended. If review by BEU is taking place concurrently, indicate so below; make sure that the document is sent to the IRBMED by telefacsimile (763 9603).

***** End of Section *****

15. INFORMATION ON FDA-APPROVED (NON-INVESTIGATIONAL), DRUGS, BIOLOGICS OR DEVICES TO BE ADMINISTERED OR APPLIED TO THE SUBJECTS FOR RESEARCH PURPOSES

Please complete this section, if answer to Question 7.12 was "Yes".

If not relevant, please delete this section.

- 15.1 What are the generic and trade names of the drugs, biologics or devices (articles)?
If more than one article is involved, sequentially number them, and use respective number also in responding to the subsequent questions in this section.**

- 15.2 What are the sources (supplier or manufacturer) of the articles?**

[15.21 If the article is a drug or biologic, will the article be provided at no cost to the subject \(if yes, complete section 14 with regards to this article\).](#)

[15.22 If the article is an approved drug or biologic, will a placebo be used as a control to the article, and will the drug or biologic be dispensed in a "blinded" or "masked" manner? \(if yes, complete section 14 with regards to this article\).](#)

- 15.3 What are the proposed mechanisms of action of the articles?**

- 15.4 Will the articles be used for an indication not approved by the FDA?**

Please answer "Yes" or "No". If yes, please indicate what the to-be-validated indication is.

- 15.5 If a drug is to be tested for an unapproved indication, what is the drug trial phase status, as assigned by the FDA?**

(i.e. Phases 1 through 4; please consult "Specific Information" section preceding this template. In addition, you may wish to consult "Test Article Use Guidelines" document, or 21 CFR 312 & 314, available on IRBMED Internet Web site).

15.6 **What is the dosage, route of administration or application, and frequency & total duration of use of each article?**

15.7 **If women with reproductive potential are involved, what measures will be taken to avoid that an article may harm a potential fetus or off-spring?**

(e.g. Screening subjects with pregnancy tests; use of various types of contraception; excluding subjects who are pregnant or are nursing an infantÉ)

15.8 ~~**If the article is a drug, will a placebo be used as a control to the article, and will the drug be dispensed in a “blinded” or “masked” manner?**~~

~~Please answer “Yes” or “No”.~~

15.9 ~~**If the approved drugs or biologics will be used in conjunction with a placebo, or will be dispensed in a blinded manner, please submit University of Michigan Hospitals Pharmacy Investigational Drug Service (IDS) acknowledgment document, or evidence of exemption from this requirement.**~~

~~Please indicate below, that it is appended. If review by IDS is taking place concurrently, indicate so below; make sure that the document is sent to the IRBMED by telefacsimile (763-9603).~~

15.10 **If a device is being used for the first time at the University of Michigan Hospitals, please append Biomedical Engineering Unit (BEU) (Plant Support Service) approval document, or evidence of exemption from this requirement.**

University of Michigan Hospitals require that any approved or investigational device to be used at the Hospitals for the first time, be inspected and approved by the BEU. **Please obtain and append the approval document of the BEU.**

Please indicate below, that it is appended. If review by BEU is taking place concurrently, indicate so below; make sure that the document is sent to the IRBMED by telefacsimile (763 9603).

***** End of Section *****