TOURO COLLEGE

 HEALTH SCIENCES

**Institutional Review Board for the Protection of Human Subjects (IRB)**

**REQUEST FOR IRB REVIEW**

**This form must be submitted with proof of completion of the Collaborative Institutional Training Initiative course on working with human subjects. The course is free. Instructions for this mandatory instructional training can also be accessed at this link:** [www.touro.edu/departments/osp/health-sciences-irb/training](http://www.touro.edu/departments/osp/health-sciences-irb/training)

|  |
| --- |
| Protocol and Study Information |
| Date Submitted to IRB: | HSIRB No. (office use only) | Campus: Brooklyn 23rd St. Manhattan Bay Shore  125th St. Manhattan Middletown □Other \_\_\_\_\_\_\_\_ |
| Principal Investigator: (Must be Full time faculty member) | Research Advisor: |
| Proposal Title: |
| Number of Subjects | Age Range |
| Total | Male | Female | From | To |
| Investigator Information |
|  | Name | Department |
| Principal Investigator |  |  |
| Co-Investigator |  |  |
| Co-Investigator |  |  |
| Co-Investigator |  |  |
| Co-Investigator |  |  |
| Co-Investigator |  |  |

IRB applications should be sent to the IRB committee via email, to the current chair of the committee, Dr. June Kume at HSIRB@touro.edu.

If email is impractical, the forms should be sent in triplicate by snail mail or in-house interoffice mail to: IRB office

Touro College School of Health Sciences

1700 Union Blvd., Bay Shore, NY 11701

For questions and additional information, please call 631- 665-1600 ext. 6243.

## **Part A**

## **APPLICATION STATUS**

**The final determination of application status will be made by the IRB committee.**

 Full Review

(Project involves invasive procedures or other medical or therapeutic interventions)

 Expedited Review

(Project does not involve invasive procedures or other medical or therapeutic interventions. Generally include interviews, review of existing data such as chart reviews or data collected in previous studies, or passive observations)

**Full or Expedited Reviews require annual recertification.**

 Exempt

(Project fits the Federal criteria outlined in the IRB instructions, or surveys)

**Exempt status can only be determined by the IRB committee. Exempt studies do not require annual recertification, unless changes are made to the research methods.**

## **CONCISE STATEMENT OF PROPOSED RESEARCH WITH DETAILS OF HUMAN SUBJECTS USE ASPECT**

Describe within the space below, **in layman’s terms**, what is to be done so that a realistic estimate of the risks to the subjects and the benefits of the project can be assessed. If, in addition to this concise statement, an extensive description of the project has been drafted, please attach.

The inclusion of females and members of minority groups and their sub-populations must be addressed in the development of the research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of gender and racial/ethnic group. Provide a rationale for each selection of such subjects. Your proposal should contain a description of the proposed outreach programs for recruiting females and minorities as participants.

**Part B**

**Answer the following questions:**

1. Are human subjects involved in the proposed study? Yes No

 If yes:

 a. Are the human subjects healthy volunteers? Yes No

b. Are the subjects under medical or therapeutic Yes No

treatment?

 c. What is the age range of the subjects? From: \_\_\_\_ To: \_\_\_\_

 d. How many subjects will be studied at this site? \_\_\_\_\_\_\_\_\_\_\_

 (approximate estimate if definite number is not known)

1. Of the subjects studied, how many will be females? \_\_\_\_\_\_\_\_\_\_
2. Of the subjects studied, how many will be from minority groups?

\_\_\_\_\_\_\_\_\_\_\_\_

 g. Are the subjects capable of understanding the Yes No

 nature of the study?

 h. What is the population source of the subjects to be studied?\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Are the subjects in-patients? Yes No

j. Are you the subjects’ attending physician and/or therapist? Yes No

k. How long will each subject be in the study? \_\_\_\_\_\_\_\_\_\_\_,

**If more than a year, study will have to be recertified in one year.**

l. At what intervals will each subject be seen?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Will any of the following classes of subjects be involved in the proposed study?

 Minors (if yes, assent form may be required) Yes No

 Incompetents Yes No

 Compromised Mental Status Yes No

 Females Yes No

 Pregnant Women Yes No

 Fetuses Yes No

 Fetal Tissue Yes No

 Minorities Yes No

 Prisoners Yes No

3. Are human tissues, biological fluids or products (feces, mucus, etc.) involved in the study? Yes No

 If yes,

1. What tissues, fluids or products are involved? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

b. Are the tissues, fluids or products being collected solely for the purpose of the study? Yes No

c. Are extra quantities (more than needed for routine tests) of the above being collected? Yes No

d. Are the above to be removed from a cadaver? Yes No

e. Are the above to be removed during a surgical Yes No procedure?

f. Are the above to be obtained during routine non- Yes No

 operative procedures?

4. Does the study involve a drug? Yes No

 If yes:

 a. Is this a marketed drug? Yes No

 If yes, is the study being initiated by a physician or a drug company?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 b. Is this an investigational drug\* or is the study

 intended to support an application for marketing permit?

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*If study involves an investigational drug/agent, the sponsor’s investigator drug brochure must accompany this form.

c. In what phase of the study is the drug? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. What is the dose range of the drug to be used? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

e. Have there been untoward reactions to the drug? Yes No

 If yes, what tissues or organ systems were involved in these reactions?

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 f. Will a placebo be used in this study? Yes No

 g. Is this a double blind study? Yes No

 h. Will the subject be denied other drugs customarily Yes No employed for this disease?

 i. I am familiar with the “Formulary and Regulations Yes No

 Governing Drugs” at the Division at which the study is being conducted.

5. Does the study involve a device? Yes No

If yes,

 a. Is the device FDA- approved? Yes No

1. If yes, please provide documentation.

c. If no, is this a significant risk device? Yes No

d. If yes, please provide IDE # \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

 or

 Has the 30-day waiting period expired? Yes No

 or

 Has the FDA waived requirement for an IDE? Yes No

If either Numbers 4 or 5 have been answered yes, then the investigator must attach a specific list of parameters to be monitored and the frequency of monitoring. This may be a copy of a list supplied by the sponsor.

The Investigator must also report any untoward reaction to the IRB or its Officers after its occurrence within two working days.

6. Does the study involve a diagnostic or therapeutic Yes No procedure?

If yes:

a. Is the procedure entirely new, new to thisinstitution, or routine? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 b. Have there been untoward reactions to this Yes No procedure?

 If yes, what tissues or organ systems were involved in these reactions? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 c. Will placebo procedures be used in the study? Yes No

 d. Will routine procedures customarily employed Yes No for this disease be denied the subject?

All applicants must answer the following questions:

7. Will the subjects personally benefit from the study? Yes No

 a. May the study contribute directly to the subject’s Yes No health or welfare?

 b. May the study provide health benefits for mankind? Yes No

 c. Are the subjects paid for entering the study? Yes No

 What is the amount and source of the $\_\_\_\_\_\_\_\_\_ funds? Source \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 d. Are other inducements going to be made to Yes No recruit subjects?

 If yes, explain:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. Are all parties in the project protected? Yes No

 a. Are consent forms to be used? Yes No

 b. Does the investigator have the needed insurance Yes No coverage?

 c. Is Touro College covered by its insurance under Yes No the conditions of the project?

 d. Have provisions been made for the subjects’ care Yes No in case of an untoward reaction?

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\*\*IMPORTANT\*\*

Protocols will be delayed if the following items are not submitted along with this form:

 1. Consent Form

 2. IND Form – If applicable

3. Indemnification Letter – If Drug Company sponsored protocol

4. Contractual Agreement – If Protocol is sponsored by an external source

9. FINANCIAL COMPENSATION FOR SERVICES

 a. Are the services and/or tests associated with this Yes No study billable to the patient or third party payers?

 If no, please describe below how these costs will be recovered.

**Part C:**

**All applicants must carefully answer the following eight questions.**

**Please address the following questions regarding your project. Answer as briefly as possible, but in detail. Refer to the IRB Instructions for further detail.**

**Remember that some reviewers are not specialists in your field. Word your answer so that an educated layperson will be able to understand your study.**

1. Who will the subjects be and how will they be selected?

Include copies of all recruitment material such as flyers. All recruitment material must include the College’s name, the purpose of the study, and contact information for the IRB office.

2. Where will the research be performed? Who will be your approved supervisor?

3. What precisely will be done with the subjects? Describe in reasonable detail. If a questionnaire will be used, please enclose a copy.

4. How will subject anonymity and confidentiality be guaranteed?

5. Will the project require subjects to be uninformed, misled or misinformed in any way (e.g. sham treatment, placebo effects)?

If yes, discuss the rationale for this approach and what measures are being taken to remove the deception at the earliest possible moment.

6. In your judgment, what will project’s cost be to subjects involving discomfort, stress, time and/or risk to the subject?

7. If a written consent form will be obtained from the subjects, please attach a copy. If your project is a survey, please attach the cover letter and questionnaire. Generally, surveys will not require a separate consent form.

All consent forms are required to include the name and address of the **Touro College Health Science Institutional Review Board, 1700 Union Blvd., Bay Shore, NY 11706. tel. 631 665 1600 ext 6243.**

8. What benefits may there be to the subject(s) and/or society? If there are risks involved, do the benefits outweigh the risks? Please explain.