|  |
| --- |
| **Touro College Health Sciences IRB** |
| **Institutional Review Board for the Protection of Human Subjects (IRB)**  **1700 Union Boulevard  Bay Shore , New York , 11706  631-665-1600 x 6243 **  **email: HSIRB@touro.edu** | |

**Request for Recertification of an Ongoing Research Project**

**Instructions:**

Please fill out regarding the experiences in the past year with the approved study. Please submit at least one month before the annual anniversary date of the approval of the study. Researchers are requested to inform the committee when their research is completed. The committee also requests a copy of any paper or presentation made based upon this research.

|  |  |  |
| --- | --- | --- |
| **Date:** | | |
| **Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Faculty Mentor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Campus:**  **Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |
| **Full Title of Research Protocol:** | | |
| **Date of Initial IRB Approval:** | **Date of Most Recent IRB Approval:** | **IRB Approval Number:** |
| **Funding:**  **□ Federal □Non-Federal Award Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Agency Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Funding period: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |
|  | | |

1. Summary of progress
   1. Provide a summary of the progress to date.
2. Current Status of Human Subjects
   1. When did you first start working with human subjects. \_\_\_\_\_\_\_\_\_\_\_\_\_\_

If no participants enrolled to date, indicate why, and when do you plan to begin enrollment.

* 1. Describe the participants:
     1. Number
     2. Gender
     3. Ethnicity
     4. Age

c. Do you plan to continue enrolling new participants:

□ Yes. How many? \_\_\_\_\_\_\_\_

□ No – Study will continue with current participants only.

d. Have there been any untoward incidents involving human subjects?

□ NO □YES. If yes, please explain.

Please note that while the committee requests information on untoward incidents every year at time of recertification, researchers must report any untoward incidents to the committee at a reasonable time following the incident, no more than72 hours.

e. Have participants self-withdrawn from the study in the past year?

□ NO □YES. If yes, please explain how many and reasons for withdrawal.

f. Have there been participant complaints about the research project during the past year?

□ NO □YES. If yes, please explain how many and what type of complaints were received. What measures were taken to address these complaints?

3. Methodology:

a. How long do you estimate this research to continue? \_\_\_\_\_\_\_\_\_\_

b. Have there been any significant changes in methodology?

□ NO □YES. If yes, please explain. Indicate whether these changes result in increased risks to the participants.

Any significant changes in methodology should be reported to the committee before they are in use, unless it involves providing emergency protection to the subject. Then the intervention should be made and reported to the committee immediately after.

c. Were any changes made to the consent form(s)? Please submit a copy of the current consent form.

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

Signature of Principal Investigator Date

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

Signature of Faculty Mentor, if different Date