Touro University Nevada

Touro University Nevada Institutional Review Board (IRB)

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**Continuing Review Form**

(For Renewal of IRB Approval)

|  |  |
| --- | --- |
| **Principal Investigator:** |  |
| **TUN IRB Number:** |  |
| **Study Title:** |  |

This form is strictly for **renewal of IRB approval** of Human Subjects Research. If the research has been revised since its most recent approval, or you intend to revise the research, submit a *Request for Amendment Form* to the IRB, in addition to the Continuing Review Form.

**SECTION A. Does the project need continuing review?**

Projects that have progressed to the point that only specific activities are still taking place no longer need continuing review. *Check all of the following that apply to your project*:

My project has progressed to the point that I’m **analyzing data** (including analysis of identifiable private information or identifiable biospecimens). I will not have any further interactions/interventions with the human subjects.

My project has progressed to the point that I’m only **accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care**. I will not have any further interactions/interventions with the human subjects.

**If you checked one or both boxes**, and these activities represent the **only** work on this project going forward (besides manuscript preparation or other dissemination), **submit this form filled out to this point to request that your project be removed from the Continuing Review list**.

**If the research involves other activities** (regardless of whether the boxes above are checked), **proceed to fill out this form**.

*Check current status below and complete the appropriate section for the appropriate option*.

This research is **still active** and being conducted according to the currently approved procedures. **I wish to renew IRB Approval for this study**.

Complete SECTION B and SECTION D and return this form.

The research has **never been initiated**, but will be conducted according to the currently approved procedures. **I wish to renew IRB Approval for this study**.

Complete SECTION C and SECTION D and return this form.

**SECTION B. Active studies still in progress**

1. Activity Status (choose only one)

New participant recruitment is still in progress.

Enrollment closed, but participants are still undergoing study procedures

Enrollment closed, participants have completed study procedures, but are still in follow-up

2. Describe any adverse events or participant complaints related to study procedures, and describe how you handled each.

3 Yes  No Were any of these events unexpected, or more serious than expected?

4. Describe any additional risks or benefits observed during the course of the study.

5. Participant/ Numbers

     # of participants actively enrolled or records/samples **being reviewed (at present).**

     # of participants enrolled, or records/samples reviewed **since most recent approval**.

     # of participants enrolled, or records/samples reviewed **since original approval (Total)**.

     # of additional participants **to be recruited**, or records/samples needed to complete the study.

6. Review the protocol that you submitted to the IRB, including any amendments. Report any differences between the IRB-reported protocol and the actual protocol you are using. Type ‘NA’ if there are no differences. If you find differences that have not been approved by the IRB, submit the ‘Amendment’ form and submit it with your continuing review.

7. Provide a summary of your progress to date.

8. When do you expect the research to be completed?

**SECTION C. Studies that have not yet been initiated**

1. Provide an explanation of why the research was never initiated.

2. List any additional risks that have been identified since the most recent approval.

**SECTION D. All studies**

1. If any investigators’ situation and qualifications have substantially changed since the last IRB review (for example, change in medical license status, increase in number of studies overseen by investigator, suspension of hospital privileges, etc.), explain below. Write ‘NA’ if no changes have occurred.

2. If any investigators’ conflicts of interest relative to this project have changed, explain below. Write ‘NA’ if no changes have occurred.

3. If institutional commitments (personnel, financial support, facilities) or applicable regulations relevant to this project have substantially changed since the last IRB review, explain below. Write ‘NA’ if no changes have occurred.

4. Informed Consent Procedures

You are responsible for keeping abreast of new findings in this study or others which may affect a subject’s willingness to participate (for example, risk is higher than expected or an alternative treatment is now available). Relevant information should be incorporated into the consent forms.

*Choose only one*:

I will **continue to use the IRB approved consent/permission/assent form(s) and/or HIPAA or FERPA Authorization** to recruit participants without revision. Attach an electronic copy of the consent/permission/assent form(s) and/or HIPAA Authorization you are currently using.

I will be **revising the consent/permission/assent form(s) and/or HIPAA or FERPA Authorization** to recruit participants. Send an electronic copy of the revised consent/permission/assent form(s) and/or HIPAA Authorization, and attach (MS Word format) to tun.irb@tun.touro.edu (Be advised that these revisions may also require Request for Amendment Form).

Explain why a revision is necessary

**Checklist for submission:**

Form is complete

Consent/Assent/HIPAA/FERPA forms to be used in the upcoming interval are attached, as appropriate

Amendment form to approve changes to protocol or consent procedures, as appropriate.

Submit this form and supporting documents to [tun.irb@tun.touro.edu](mailto:tun.irb@tun.touro.edu). **Subject line: “Continuing review TUNIRB #**. If someone else (example: graduate student, post doc, Co-PI, or staff) is submitting the continuing review request on behalf of PI, the **submission should be copied to the PI**.