**APPLICATION FOR FULL BOARD/EXPEDITED CONTINUING RENEWAL**

**OR STUDY CLOSURE**

**INSTRUCTIONS: This entire application must be completed whether you intend to renew this protocol or close your study. All questions must be answered and the application must be signed for it to be processed. This document will be reviewed and serve as the final closing documentation for this protocol.**

**Check which type of review is requested**:

***For guidance regarding IRB Continuing Review requirements See Standard Operation Procedure 015***

[***http://orip.syr.edu/files/SOP%20015%20-%20Continuing%20Review.pdf***](http://orip.syr.edu/files/SOP%20015%20-%20Continuing%20Review.pdf)

[ ]  **EXPEDITED Continuing Renewal**

Please submit:

* 1. **ONE** signed copy of the completed application for continuing renewal/study closure.
	2. A copy of the initial IRB protocol application *updated with all changes* since the initial approval.

 **AND if your study remains open to enrollment also include:**

* 1. Copies of the currently approved informed consent/assent document(s).
	2. Clean copies (unmarked/not date stamped) of the identical informed consent/assent document(s) for approval and date stamping for use during the next approval period, if applicable. Please consult <http://orip.syr.edu/human-research/human-research-irb.html> for guidance.

[ ]  **FULL BOARD Continuing Renewal**

 Please submit **FOURTEEN (14) copies of the following**:

1. The completed and signed application for continuing renewal/study closure.
2. The initial IRB protocol application *updated with all changes* since the initial approval.

 **AND if your study remains open to enrollment also include:**

1. Copies of the currently approved IRB date stamped informed consent/assent document(s).
2. Clean (unmarked/not date stamped) copies of the identical informed consent/assent document(s) for approval and date stamping for use during the next approval period, if applicable. Please consult <http://orip.syr.edu/human-research/human-research-irb.html> for guidance.

 [ ]  **Request to CLOSE**

 Please submit:

1. **ONE** signed copy of the completed continuing renewal/study closure application.

**I/We assure the IRB that the following statements are true:** All information provided in this application for full board/expedited continuing renewal or study closure is accurate and complete.

For full board/expedited continuing renewals: I understand that I must seek and obtain prior written approval from the IRB for ***any future modifications*** including changes in procedures, investigators/research staff, consent forms, questionnaires, surveys, etc. I will promptly report any unanticipated problems that may occur in the future course of this study. I will report any significant findings which may affect the risks and benefits to participation. I will comply with all IRB requests to report on the status of my study. I will maintain records of this research according to IRB standards. If any of the above conditions are not met, I understand that approval of this research may be suspended or terminated.

**Signature:** **Date:**

**Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 Principal Investigator (faculty advisor)

**Signature:       Date:**

**Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 Student (if applicable and available)

**To edit the content of the form -unprotect the document as follows:**

**For Office 2003 Users (or below)**

* **Browse to View->Toolbars->Forms. The Forms toolbar will pop up.**
* **Click on the padlock icon on the right side. This will unlock the form.**
* **Make sure to protect the document (click on padlock) again when you need to click on a checkbox.**

**For Office 2007 Users**

* **On the ribbon choose Review >Protect document>Restrict Formatting and Editing>Stop Protection.**
* **To protect the document again when you need to click on a checkbox, click on>Yes, Start Enforcing Protection>OK**

**Section 1 - General Information Relating to the Study**

**Principal Investigator /Faculty Member:**

**PI/Faculty Member email address:**

**PI/Faculty Member campus address:**

**Student/Research Staff (if applicable):**

**Student/Research Staff email address:**

**IRB #:**

**Protocol Title:**

**IRB Expiration Date:**

**Name of Person Preparing this Application:**

**Date of Application Preparation:**

**Current Status (Check one):**

**[ ]**  Active - still enrolling participants. This is a request for continuing review.

**[ ]** Closed to enrollment - but participants are still engaged in the research or follow-up continues. This is a request for continuing review.

**[ ]**  Closed to enrollment - data analysis\* continues, data have **not** been de-identified. This is a request for **expedited** continuing review. Please follow expedited continuing renewal instructions for submission.

**[ ]** Closed to enrollment - data analysis\* continues, data have been de-identified. This is a request for my protocol to be closed and archived. Please complete this entire form to close this protocol.

**[ ]**  All research related activities completed. This is a request for my protocol to be closed and archived. Please complete this entire form to close this protocol.

***\*Data Analysis***: *The Office for Human Research Protections (OHRP) has determined that no analysis of identifiable private information may be conducted without IRB review. As a result, researchers may only close studies that have completed enrollment and study interventions and are doing data analysis on de-identified/anonymous data.* ***If data analysis continues on identified data then the investigator must continue to obtain IRB approval for the research.*** *For Full Board studies-When research activities are limited to data analysis the protocol may be renewed through the expedited review process.*

**Brief Description of the Study:**

Include a brief description of the study restating the research purpose.

**Brief Progress Report:**

Provide a brief description of your progress toward completing the project’s purpose. This summary should: incorporate all amendments approved by the IRB since the last submission; include an overview of any major preliminary or final results, as well as any information (advances in knowledge or changes in the area) that may affect the IRB’s deliberations about the local conduct of this research; and include a summary of any interim findings since the last IRB review. *Use additional space as needed, but please limit your answer to a maximum of three short paragraphs.*

**Participant Enrollment:**

Enrolled participants are those who have signed a consent form. For studies where consent and /or documentation of consent has been waived, enrolled participants are those who have been studied per protocol. Participants enrolled for a study do not need to be re-consented annually.

What is the approximate number of participants listed on your initial application?

Did any participants withdraw from the study during the past approval period?

[ ]  No.

[ ]  Yes. If yes, please explain:

Has there been a significant change in the number of participants from the original application?

**[ ]** No.

**[ ]** Yes. If yes, please explain:

Was the increase in participant enrollment over 20%?

**[ ]** No.

**[ ]** Yes. If yes, an amendment form must be submitted with this renewal application to justify the increase. Amendment forms are located on our website at: <http://researchintegrity.syr.edu/wp-content/uploads/2018/09/IRB-Amendment-Request-Form.doc>.

 Your renewal application will not be approved without submission of this form.

Complete the table below as follows:

1. Number of participants enrolled/consented per approval period: For each approval period of your study, provide the number of new participants enrolled. The numbers reported should be for the most recent approval periods of your project and should not include projected numbers for future project renewal periods.
2. Number of participants that have withdrawn per approval period: For each approval period of your study, provide the number of participants who began your study, but have since withdrawn. If no participants have withdrawn, please report “0”.
3. The numbers reported should correspond to answers provided in the participant enrollment section above.
4. The “Total to Date” column must be tallied and should include the total number of participants from each project period.

**[ ]  N/A. No participants have been enrolled. Please explain:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Approval****period 1** | **Approval** **period 2** | **Approval period 3** | **Approval period 4** | **Approval period 5** | **Approval period 6** | **Approval period 7** | **Total to Date** |
| Number of participants enrolled/consented per approval period: |       |       |       |       |       |       |       |       |
| Number of participants that have withdrawn per approval period: |       |       |       |       |       |       |       |       |

**Section 2 - Events or Problems:**

Since the last review, have there been any events or problems for which IRB policies and procedures require prompt reporting to the IRB?

**[ ]** No.

**[ ]** Yes**.** If yes, please explain:

Were all applicable events reported to the IRB?

**[ ]** No. If no, please explain:

**[ ]** Yes.

**[ ]** N/A.

Were there any complaints about the research during the past approval period?

**[ ]** No.

**[ ]** Yes. If yes, please explain:

**Section 3 - Risks/Benefits:**

Has any relevant literature become available since the last IRB review that may affect its deliberations about the risks or benefits associated with the research?

**[ ]** No.

**[ ]**  Yes. If yes, please explain and provide or reference any relevant documentation, e.g., publications, abstracts, etc.

Have there been any harms to the participants since the last IRB review?

[ ]  No.

[ ]  Yes. If yes, please provide a summary of the harms that participants have experienced:

Please provide a summary of the benefits that participants have experienced since the last IRB Review:

Do you believe the relationship of the risks and benefits has changed since the last IRB review?

[ ]  No.

 [ ]  Yes. If yes, please provide a description of the changes:

Have there been any relevant multi-center trial reports since the last IRB review?

[ ]  No.

 [ ]  Yes. If yes, please provide a summary or attach the report:

[ ]  N/A.

**Section 4 – Amendments:**

List all amendments that have been approved by the IRB since the last submission:

 [ ]  N/A.

Were all modifications/amendments reviewed and approved by the IRB prior to implementation?

**[ ]** No. If no, please explain:

**[ ]** Yes.

**[ ]** N/A.

**Section 5 : Informed Consent**

Did the IRB require use of a written informed consent/assent document for this study?

**[ ]** No.

**[ ]** Yes.

Do you have a signed and dated Informed Consent Document on file for each participant?

**[ ]** No. If no, please explain:

**[ ]** Yes.

**[ ]** N/A. (Consent or documentation of informed consent waived by IRB)

Did the IRB approve use of an oral informed consent/assent script document for this study?

**[ ]**  No.

**[ ]**  Yes.

Are you continuing to enroll participants?

**[ ]** No. If “No”, **do not include consent/assent forms with your renewal application.**

 **[ ]** Yes. If “Yes”:

 Number of consent documents (including electronic and oral scripts) included with application:

Number of assent documents included with application (if applicable):

NOTE: If more than one consent/assent document will be included with your renewal application you must ensure that form numbers have been assigned to each individual form and added to the footer of the document. A separate log which identifies each document should be included with the renewal application.

**ALL QUESTIONS MUST BE ANSWERED AND THE APPLICATION MUST BE SIGNED FOR IT TO BE PROCESSED.**

**All required materials should be submitted at least FOUR WEEKS prior to the expiration date. Please submit your renewal application to:**

The Office of Research Integrity and Protections

214 Lyman Hall

Syracuse University

Syracuse, NY 13244-1200

**Questions? Call the IRB office at (315) 443.3013. Please refer to your protocol’s IRB number whenever calling or writing for information regarding the status of your protocol renewal submission.**

**Please send IRB notifications by:**

**[ ]  Hard copy campus mail. All correspondence mailed to the PI/faculty member’s address.**

**[ ]  Email notification (Only the original hard copies of date stamped consent/assent documents will be returned.)**