## 1

PARKER UNIVERSITY INSTITUTIONAL REVIEW BOARD

**STUDY AMENDMENT APPLICATION**

### Instructions:

* Please use this locked form when preparing your Study Amendment Application. Use this form to submit all modifications, revisions, amendments, changes in investigators and research team, or re-activations of the research protocol and/or consent form for research currently approved by the PU-IRB Answer each question as indicated below. If a question does not apply to your research protocol, please indicate “not applicable.” Do not leave a question blank.
* REMEMBER: Amendments to the protocol and/or consent form cannot be instituted prior to receiving approval by the IRB, unless patient safety demands immediate action.
* Some amendments can be approved by expedited review. The IRB Chair will determine whether an amendment will be expedited. Amendments that are not expedited will be reviewed by the full IRB.
* Remember that all protocols must be submitted for Continuing Review. All protocols must be approved by Continuing Review every 12 months, unless the IRB has specified a shorter approval period. Approval of this amendment does not change the previously determined date for continuing review.
* This document will be provided to all IRB members. Please use language that can be understood by both scientific and non-scientific members.
* Please limit posted documents to those requested or suggested.
* If you have questions about how to answer any particular question, please call the HPA (214-902-7365)
* When submitting, please be sure to list the IRB Assurance number your project was assigned when initially submitted.
* The Amendment Package should include:
	+ The Amendment Application form
	+ A copy of the modified Informed Consent document with line numbers and tracked changes, if applicable.
	+ A copy of the modified Informed Consent, without line numbers or tracking, ready for patients to sign, if approved.
	+ A sponsor document that clearly outlines the amendment changes, if applicable.
	+ Amended protocol with tracked changes, if available.

### Please delete this instruction section from your submission copy.

1. **Form Date**
2. **Complete Project Title:**
3. **Amendment/Modification #, if applicable:**
4. **List the purpose and objectives of the research as stated in the protocol.**
5. **Does the sponsor, if applicable, require FULL Board review of this amendment?**

Yes No

### Principal Investigator Information:

Name:

Telephone:

Email:

### Research Coordinator or Administrator Information:

Name:

Telephone:

Email:

1. **Project Status** (please check the appropriate description)

|  |  |
| --- | --- |
|  | Project Status |
|  | Enrollment still active |
|  | Enrollment permanently closed |
|  | Study has been temporarily suspended but not closed.Date GHS-IRB Approved Study Suspension: |

1. **Participant enrollment information** (please use local data)

For “Total” report the status of all patients from original approval until now.

|  |  |  |
| --- | --- | --- |
|  |  | Total sinceoriginal approval |
| 1 | Goal or anticipated participant enrollment |  |
| 2 | Total participants consented |  |
| 3 | Total participants consented not enrolled (dropped out or excluded beforebeginning the protocol) |  |
| 4 | Total participants completed protocol & all follow-up |  |
| 5 | Participants still receiving research related interventions\* |  |
| 6 | Participants remaining in long term follow up |  |
| 7 | Participants enrolled but off study before completing all research relatedinterventions\*. Exclude deaths (see line 8) |  |
| 8 | Deaths during protocol or follow-up phase |  |
|  | Sum of rows 3-8 must equal the number in row 2. | 0 |

\*What are research-related interventions? Research related interventions are defined as anything that is not standard medical care being performed for clinical purposed no matter the level of risk. This may include participants who discontinued interventions early but are still being followed.

### Amendments submitted in this application include the following (place a "X", in the gray area, next to all that apply). For each checkmark, complete the section below that applies.

|  |  |
| --- | --- |
|  | Changes in local investigators or research coordinators (9a) |
|  | Administrative changes (contact information, processes in protocol management, etc) (9b) |
|  | Protocol changes: inclusion/exclusion criteria, methodology, interventions, risks, subject numbers,etc. (9c) |
|  | Consent form changes (9d) |
|  | Reactivation of suspended study (9e) |
|  | Other (9f) |

9a. **Changes in investigators or research coordinators.**

List any changes (additions or deletions) to the list of investigators or research coordinators. All new principal investigators and coordinators must complete the NIH on-line course [“Protecting Human Research Participants”,](http://phrp.nihtraining.com/users/login.php) or similar, if not previously done.

**Additions: Provide the names of those added to the research team (since last approval).**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Telephone | Email | Educ+ |

**Deletions: Provide the names of those no longer on the research team (since last approval).**

 Name

### 9b. Administrative changes

9c. **Protocol modifications/revisions**

9d. **Consent Form Changes (Please use bullet list, and provide corresponding line number of the consent form)** Note: Please submit a copy of the current consent form with the deletions shown as ~~strikeouts~~ and the additions underlined. Please add line-numbers to the consent form (for Word documents, see Page Set-up). Also include a clean copy of the new Consent Form. This form will be stamped and returned for your use.



### 9e. Reactivation of suspended study.

Please indicate date of suspension and the reason for suspension. State what changes have been implemented to justify the reactivation. If the study is being reactivated without changes, please provide information to justify this decision.

### 9f.. Other, please specify.

1. **What are your plans, if any, to inform currently enrolled study participants about the changes in this amendment?**

Verbal explanation to the subject New consent form

Research content addendum Patient letter

No action

Other. **Please specify:**

### What are your plans, if any, to inform study participants who have completed the protocol about the changes in this amendment?

Verbal explanation to the subject New consent form

Research content addendum Patient letter

No action

Other. **Please specify:**

**Principal Investigator Assurance Statement**

My electronic signature that will accompany the submission of this application and all supporting documents to the PU Institutional Review Board certifies that the research described in this application and all supporting materials will be conducted in full compliance with the Genesis Health System Institutional Review Board Guidelines and Federal regulations governing human subject research.

Furthermore, I will:

* + accept responsibility for the scientific and ethical conduct of this research study and for the conduct of my research team.
	+ obtain prior approval from the IRB before amending or altering the research protocol or implementing changes in the approved informed consent form.
	+ report to the IRB any serious adverse and/or unanticipated events on study participants that may occur as a result of this study.
	+ complete Continuing Review documentation at least annually, unless requested sooner by the IRB.
	+ use only PU Institutional Review Board approved, stamped consent forms for studies in which consent forms have been approved for the research activity.

**X** SIGNATURE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. DATE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# PARKER UNIVERSITY INSTITUTIONAL REVIEW BOARD GUIDENCE ON PREPARING A STUDY AMENDMENT FORM

9. The general intent of this application is to allow IRB members to review amendments without having to refer to secondary documents, except the informed consent. However, sponsors, when involved, often provide a concise summary of changes. The HPA will allow you to post these summary documents from the sponsor. In the section below, you would refer the reader to these specific documents – document and page numbers. Providing some general comments about the changes would helpful. For example: "changes made to inclusion criteria; side effect list altered, follow-up testing, etc." or "Arm C is being eliminated (or added)".

Sometimes these sponsor changes are buried in larger documents (protocols) and are not tracked. These will not be acceptable. In these cases, using a bullet list, please document each change providing the committee sufficient information to understand the change without referring to secondary documents.