

APPLICATION FOR CONTINUING REVIEW

**This form is to be used to request an annual review of an active research study. You may contact the Parker University Research Office for assistance completing this form.**

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| ADMINISTRATIVE STUDY INFORMATION |

**Form Date:**

**Study Title:**

**Principal Investigator Study Contact** *(if not PI)*

Name: Name:

Phone: Phone:

Email: Email:

**Expiration Date of Current Approval Period:**

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| STUDY INFORMATION |
| **1. Study Design.** Provide the study design, as stated in the protocol. |
| **2. Study Purpose & Objective(s).** List the purpose and objective(s) of the research, as stated in the protocol. |

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| STUDY STATUS |
| **3. Study Status:** Open to Enrollment |
| **4. Study Duration** |
| **4.1.** Date this study was initially approved by the GHS IRB: |
| **4.2.** Date this study was estimated to be done:  *(refer to the new project application)* |
| **5.** If this study is has been actively recruiting longer than expected; ***OR***, if the study has been open considerably longer than initially planned, please explain why and provide current plans to address the  issue(s) *(Enter n/a if not applicable)* |

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| STUDY STATUS |
| * + 1. Number of participants enrolled:     2. Total number of participants currently receiving study intervention:     3. Total number of participants who completed study intervention:     4. Total number of participants in follow-up:     5. Total number of participants whose study intervention was terminated early or who have chosen to withdraw from the study: 6 |

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| LOCAL PARTICIPANT INFORMATION |
| **6. Complete the following using local info only** |
| **6.1.** Estimated number of participants approved by the GHS IRB: |
| **6.2.** Actual number of participants consented to date:  *(include all participants that consented but were not enrolled)* |
| **7.** If this study is actively recruiting and enrollment has been slower than anticipated; ***OR***, if the consented screen failure rate is higher than expected, briefly explain why and identify any plans to address the issue(s). *(Enter n/a if not applicable)* |
| **Attention!** You must submit an amendment to enroll more subjects than what was approved by the IRB. Overenrolling is a reportable Unanticipated Problem. If you have consented & enrolled more than the number approved by the IRB, you must also submit an “Unanticipated Problem” package, and an “Amendment/Modification” package (if the study is actively  enrolling) to increase the approved number. |

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| PARTICIPANT STATUS |  |  |
| **8. Complete the following table by entering the number of participants that apply to each category.** | | |
| **8.1. Consented, but not Enrolled** *(i.e., dropped out or excluded before starting protocol)* | → | 2 |
| **8.2.** Actively **Receiving Research-Related Interventions**1 | → | 2 |
| **8.3.** In **Long-Term Follow-Up**2 (LTFU) | → |  |
| **8.4.** That have **Completed ALL** research-related interventions & LTFU | → | 2 |
| **8.5.** That have **Withdrew**, were **Withdrawn**, or **Lost to Follow-Up**, and not in LTFU | → | 2 |
| **8.6. Deaths** *(either during intervention or long-term follow-up)* | → | 2 |
| ***Attention!*** *The sum of this table must equal the number reported in* [*6.2*](#_bookmark0) | → |  |

1 **Research-Related Intervention** is any test, procedure, survey, etc., that would **NOT** have been performed or completed outside of the research study no matter the level of risk.

2 **Long-Term Follow-Up** is research interactions that involve no more than minimal risk to subjects *(e.g., quality of life surveys)*; and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical care to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

PARTICIPANT WITHDRAWALS

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**9. Summarize any participant withdrawals reported in** [**8.5**](#_bookmark1) **above** *(Enter n/a if not applicable).*

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| **Subject ID** | **Withdrawal Date** | **Reason for Withdrawal** |
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| PARTICIPANT COMPLAINTS |
| **10. Provide a summary of any complaints about the research from subjects enrolled at the local site during the last approval perio****d**3 *(Enter n/a if not applicable).* |

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| AMENDMENTS/MODIFICATIONS MADE DURING LAST APPROVAL PERIOD |
| **11. Have there been any changes to the research during the last approval period**[3](#_bookmark2) ? *(e.g., consent form or protocol changes [especially those involving risks to subjects], changes to research team, etc.*) |
| **Yes** → Provide a brief summary of the approved amendments during the last approval period[3.](#_bookmark2) |
| **No** amendments or modifications have been made to the research during the last approval period. |

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| ALLOWABLE MODIFICATIONS WITH CONTINUING REVIEW SUBMISSION |
| **12. Below are the only protocol or consent modifications allowed with continuing review. Select all that apply, explain, and upload the study document(s) with your submission.** |
| Location of research: |
| Grammatical or spelling errors corrected: |
| Boilerplate changes previously approved by the IRB: |
| None of the modifications listed above have been made. |
| **Attention!** All other modifications must be submitted separately as an Amendment/Modification. |

3 **Approval period** refers to the time since the initial approval *(if this Is the first continuing review for this protocol)* or since the last continuing review approval.

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| NEW & RELEVANT INFORMATION |
| One of the most important considerations for the IRB at the time of continuing review is whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB’s previous conclusion that (1) the risks to subjects are minimized, and (2) the risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result (45 CFR 46.111(a)(1) and (2)). |
| **13. Has there been any new and relevant information that has been received since the IRB last reviewed the study, especially information about risks associated with the research?** *(e.g., data analysis by the sponsor, relevant publications, changes in the investigator’s situation or qualifications)* |
| **Yes** → Provide a brief summary of new and relevant information published or unpublished since the last approval period[3](#_bookmark2) |
| **No** |

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| UNANTICIPATED PROBLEMS & ADVERSE EVENTS |
| **14. Have there been any Unanticipated Problems Involving Risks to Subjects or Others**? |
| **Yes** → Answer the following and upload a summary of **all local & non-local UPIRSOs** identified with this submission. The summary should include the date of the event(s) and a description of the event/outcome. |
| **14.1. Number of local & non-local UPIRSOs during the last approval period**: |
| **14.2. Total number of local & non-Local UPIRSOs since the start of this study**: |
| **No** |
| **15. Have there been any Adverse Events for local participants** in this study? |
| **Yes** → Answer the following and upload a summary of **all local AEs** identified with this submission. The summary should include the date of the event(s) and a description of the event/outcome. |
| **15.1. Number of local AEs during last approval period**: |
| **15.2. Total number of local AEs since the start of this study**: |
| **No** |

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| RISK ASSESSMENT & MONITORING |
| **16. Data and Safety Monitoring Board** *(or Similar Oversight Committee)* **Report.** *Select one.* |
| The most recent DSMB report has been uploaded to IRBNet. |
| Text from the most recent DSMB report is included below. |
| The DSMB for this study has not yet convened ↓ |
| → Enter the anticipated convene date *(month & year)*: |
| The DSMB for this study no longer convenes. |
| This study does not have a DSMB. |

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| INFORMED CONSENT PROCESS |
| **17.** Are you requesting informed consent review with this continuing review? |
| **Yes** → Upload the current, unstamped version of all consent(s) and enter the dates as they appear on the most recent informed consent approved by the IRB: |
| Current Approval: |
| Do Not Sign This Consent After: |
| **No**, informed consent review not requested. *(e.g., study is closed, informed consent was waived)* |



**IRB Number:**

**SUBMISSION TYPE: STUDY TITLE:**

PRINCIPAL INVESTIGATOR ASSURANCE STATEMENT

I certify that the information provided in this application is complete and accurate.

I understand that as the Principal Investigator I have ultimate responsibility for the conduct and ethical performance of the study, the protection of the rights and welfare of human participants, and strict adherence to the study protocol and institutional, federal, state and local policies.

I have read and agree to comply with Genesis’ policies concerning research involving human subjects and the IRB’s policies for protection of human subjects, including, but not limited to:

1. Developing and conducting research that is in accordance with the ethical principles in the Belmont Report;
2. Assuring all authorized study personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based;
3. Obtaining and documenting informed consent as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent;
4. Protecting the privacy of subjects and maintaining the confidentiality of data;
5. Complying with all applicable FDA regulations, including the Good Clinical Practices Guidelines, and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 & 812;
6. Ensuring that protocols receive continuing IRB review and approval prior to the expiration date of IRB approval;
7. Obtaining IRB review and approval in writing before changes are made to approved protocols or consent forms; and
8. Reporting unanticipated problems involving risk to subjects or others and any other reportable events to the IRB, based on the time frames outlined in the Genesis IRB Standard Operating Procedures

To obtain a copy of the Genesis IRB Standard Operating Procedures and Genesis research policies please contact the Research office at 563-421-7955

X

Principal Investigator's Signature & Date

CONTINUING REVIEW SUBMISSION CHECKLIST

Please review your amendment application and supporting documents for neatness and completeness. Your final "Amendment/Modification" submission package should include the following.

**REQUIRED:**

Application for Continuing Review *(this form)*

The latest version of the protocol in use at the site

Signed copy of the [Principal Investigator Assurance Statement.](#_bookmark3)

**IF APPLICABLE:**

Most recent data monitoring committee report(s)

Relevant regulator action letters occurring since the last review that could affect safety and risk assessments *(e.g., withdrawal or suspension from marketing in any country on the basis of safety, reports of recalls and device disposition required by 21 CFR 812.150(b)(6)).*

Questionnaires, payment schedules, recruitment materials, and scripts that are still being used.

For FDA-regulated research, the current Investigator’s Brochure, if available, including any modifications

Two (2) copies of the Informed Consent Form(s) currently in use at the site *(include separate consents for any optional aspects of the study [such as blood and tissue banking for future research])* and formatted as follows:

**ONE (1)** “clean” **WORD VERSION.** Clean means that the document does not contain any line numbers, visible track changes, or an IRB stamp with the previously approved dates.

Word version formatting rules:

* + 1” top, left, and right margins *(preferable)*
  + 1” (or greater) bottom margin (REQUIRED)
  + No text located in the bottom left footer (REQUIRED *[this is where the IRB stamp is placed upon approval]*)

**ONE (1) PDF VERSION**. To do this, with the Word document open, (1) click **Save As**, (2) choose the file location, (3) select **PDF (\*.pdf)** from the **Save as type:** dropdown, and (4) click **Save.**

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