

Genesys Health Park
IRB APPLICATION FOR CONTINUING REVIEW
OF THERAPEUTIC RESEARCH

Instructions: The Institutional Review Board (IRB) approves research for a maximum period of one year. In order to determine whether continuance of IRB approval is warranted, it is the investigator's responsibility to submit this application for continuing review which must contain the following information pursuant to the IRB's charge by OHRP Regulations 45CFR46.109(e) and FDA regulations 21CFR56.109(e). Information should be provided according to the specific instructions in each subpart. Additional pages can be used as necessary. If questions are non-applicable to your study, please indicate N/A. – Any questions, please call Office of Research – 810 606-7722

SECTION I

A. APPLICATION DATA

Protocol # _____ Title of Protocol: _____

Principal Investigator: _____

Co-Investigator(s): _____

B. STATUS OF THE STUDY. Mark the status of the study (1-7) and note the specific section information that must be completed.

1. _____ **Termination requested - no subject accrual.** Submit Section I only.
2. _____ **Inactive with no accrual of subjects to date.** Submit Section I and Section II B5, C2, D2 and an unstamped original consent form(s).
3. _____ **Active with ongoing recruitment of subjects.** Submit both Section I and Section II and copies of the consent form (refer to Section II E.2).
4. _____ **Active with subject accrual completed.** Submit Section I, II, and copies of the consent form used to enroll the last subject.
5. _____ **Active with subject accrual completed after the last IRB Continuing Review with follow-up of subjects only.** Submit Section I and Section II. A, B, C1, D1, E1.
6. _____ **Active with subject accrual completed before the last IRB Continuing Review with follow-up of subjects only.** Submit Section I only.
7. _____ **Completed.** Date of completion: _____. Submit Section I and Section II (A, B, C.1, D.1, and E.1) as a final progress report.

C. CERTIFICATION OF PRINCIPAL INVESTIGATOR

Signature certifies that the above titled research has been/will be conducted in full compliance with the DHHS/FDA regulations and the Genesys Regional Medical Center governing human subject research as stated in the IRB policies. It is understood that IRB continuing review is required in order to maintain approval and any changes in the study/methodology which affect the subjects must be approved by the IRB prior to implementation. Alternatively, if the study has never been initiated or no enrollment and you are requesting termination (B.1 above), your signature verifies this request. If the study is completed (B7 above), the information provided on this form represents an accurate final progress report.

Signature of Principal Investigator Date

Submitting via IRBnet.org – an electronic signature is required.

(Residents – must also have Program Director or Research Faculty electronic signature)

SECTION II

A. DEMOGRAPHIC INFORMATION. Specify the demographic characteristics of the subject accrual using the following categories identified by the Office of Management and Budget (OMB) for Federal reporting:

1. **Total number of subjects accrued.** What is the total number of subjects accrued to date since activation of the study?

Total: _____ Male _____ Female _____

2. **Number of subjects accrued by ethnic origin.** How many of the subjects accrued to date since activation of the study are in the following ethnic categories?

_____ Caucasian	_____ Black, not of Hispanic origin
_____ Hispanic	_____ Asian/Pacific Islander
_____ American Indian	_____ Other or unknown
_____ Alaska native	

3. **Explanation of subject accrual demographics.** The demographics of the subject population must not reflect a disproportionate representation of one gender or minority/majority group which was either not approved by the IRB or is not reflective of the study site population. Explain how the subject accrual demographics comply with this requirement.

B. PROBLEMS, COMPLICATIONS, SUBJECT WITHDRAWAL – Mark N/A if non-applicable

1. **Non-medical problems or complications.** Since the last IRB review, were there any non-medical problems or complications in the study that affected the subject or others? If the answer is yes, a description of any problems or complications must be provided.

2. **Unanticipated adverse event(s) reported to the IRB.** Did any subject suffer an unanticipated adverse event that was reported to the IRB since the last IRB review? If the answer is yes, specify the number of reported events and describe briefly their nature and significance (SAE - serious adverse event).

(Or attach the SAE – report separately)

Date	SAE r/t	
<u>Reported</u>	<u>Device</u>	<u>Status/Discharge</u>

Patient #

Name of SAE

SAE r/t

Device

Status/Discharge

3. **Unanticipated adverse event(s) not reported to the IRB.** Did any subject suffer an unanticipated adverse event in this study that has not yet been reported to the IRB? If the answer is yes, this event must be submitted to the IRB in conjunction with this Application for Continuing Review.

4. **Frequency of serious adverse events.** Was there any unusual increase in the frequency of serious but **expected** adverse events? If the answer is yes, a description of this finding should be provided.

5. **Adverse events which occurred at external sites.** Since the last IRB review, were any serious external adverse events submitted to the IRB? If the answer is yes, provided a brief summary of serious adverse events related or possibly related to the drug or other intervention.
(Or attach the SAE report)
Date SAE r/t
Reported Patient # Name of SAE Device Status/Discharge

6. **Involuntary subject withdrawal.** Was any subject withdrawn from the study because of medical problems or complications? If the answer is yes, a description of the medical problem/complication must be provided for each subject who was involuntarily withdrawn.

7. **Voluntary subject withdrawal.** Did any subject voluntarily withdraw from the study for non-medical reasons? If the answer is yes, a description of any known reasons for each subject withdrawal must be provided.

C. STUDY RESULTS AND RISK/BENEFIT ASSESSMENT

1. **Results. Provide a brief summary of any results** (preliminary or final) obtained in the study. If the study is part of a multi-center trial, this should be clarified and any available results provided. If there are no results that are appropriate to report to the IRB at this time, this should be stated and explained. (If abstract or final report completed – please attach)

2. **Current risk/benefit assessment.** Has anything occurred since the last IRB review that may have altered the risk/benefit relationship? Specifically, positive answers to Section II B1-7 as well as positive clinical outcomes should be considered. If the answer is yes, provide a current assessment of the risk/benefit relationship of the research based upon the results, internal and external adverse events, and other factors.

D. INFORMED CONSENT EVALUATION (Since last IRB review)

1. **Obtainment and documentation.** Did any problems occur relative to the obtainment and documentation of informed consent? If the answer is yes, the problem should be explained.

2. **Current information accuracy assessment.**

Is the information contained in the informed consent still accurate and complete?

Is there is any new information that may have been obtained since the last IRB review that should be disclosed to the subject?

Is the consent form(s) still acceptable?

If, revisions are necessary, this should be addressed in response to Section E. #2.

E. ADDITIONAL MATERIALS REQUIRED

- 1. Publications.** Attach a reprint of any publications derived from the study.
- 2. Current consent form.** Submit a copy of a clean (IRB unstamped) informed consent. If during the preparation of this application it is determined that the consent form required revision, **please submit the changed and revised consent form** according to IRB requirements in conjunction with this application.

****Submit a copy of the Informed Consent used for the last subject enrolled in this study - with only the subject's name whited out to protect confidentiality.**
(This copy should can be scanned and submitted –OR it may be mailed or faxed to the Office of Research)

Any questions, contact:
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