Continuing Review Form

For non-exempt studies that require continuing reviews, investigators must complete, sign, and submit this form in IRBNet. **Answer all questions. Do not leave items blank** (*if not applicable, mark N/A*). Please note that INCOMPLETE or INACCURATE forms will be returned for revisions, which could result in processing delays and the possible expiration of the project. Please see the last page of this document for a list of the other items that must be submitted in IRBNet to facilitate the continuing review process.

NTR IRB Project #: _____ Project Title: _____

Principal Investigator (PI): _____ Phone Number: _____

Contact Person and Phone # (if different from PI): _____

Department/Institute: _____ Institution: _____

Sponsor Protocol Number (or Funding Agency Award Number): _____

CURRENT STATUS OF THE PROJECT:

- ◯ Actively enrolling new participants
- ◯ Enrollment currently paused, but is intended or likely to resume in the future
- ◯ Enrollment complete, but research intervention continues*
- ◯ Enrollment and research intervention complete; participant follow-up continues*
- ◯ Enrollment, intervention, and participant follow-up complete; data analysis only*
- ◯ Project NOT YET STARTED (list reason and date expected to begin)

_____

Add any other relevant status information here:

NOTE:

*Informed consent-related documents and HIPAA authorizations will **only** be stamped for studies that intend to continue enrolling new participants. Please upload these, as applicable, within your continuing review submission in IRBNet.*

Status options where enrollment is complete (marked with a blue asterisk) will **NOT** be given new stamped consent / HIPAA forms; you do not need to upload them in IRBNet.*

SERIOUS ADVERSE EVENTS:

Did any **on-site** serious adverse events (SAEs) occur since you last reported on this study? Yes ◯ No ◯

If yes, indicate number of the following: **On-site** SAEs: Initial: Follow-up:

Was it necessary to modify the consent form as a result of the on-site and off-site SAE reports? Yes ◯ No ◯

If yes, indicate date of the IRB approved revised consent form:

COMPLAINTS:

Have any **complaints** from participants been received about this research study since the last review of this study?

Yes ◯ No ◯ If yes, list the date the participant made the complaint and the circumstances of the complaint:

Has the complaint been reported to the IRB? Yes ◯ No ◯ If yes, date the complaint was reported:

****** NOTE FOR MULTI-SITE STUDIES ONLY:*** ***If your project has multiple study sites, please duplicate this page as needed and enter participant enrollment and status information for each individual site. The first copy of this page should list the total amounts from all sites combined, and each copied page thereafter should show the breakdown for one study site at a time.***

******CLICK THE GRAY BUTTON NEAR THE BOTTOM TO DUPLICATE THIS PAGE******

PARTICIPANT ENROLLMENT	*(Complete only if applicable)* **Name of Study Site:**
Maximum number of participants currently approved by the IRB*	
Date FIRST participant consented (mo / yr)	
Date MOST RECENT participant consented (mo / yr)	
Total number of participants reported at the last CR *(if this is the first CR, write "N/A")*	
Number of new participants since the last CR *(if this is the first CR, write the # of ppts to date)*	
Total number of participants reported since the initial approval of the project*	

*__NOTE:__ *If your project is secondary data analysis only (e.g., a chart review), list the number of unique individuals' records accessed.*

CURRENT PARTICIPANT STATUS:	*Number of Participants***
Undergoing the research protocol	
Undergoing follow-up data collection only	
Completed the research protocol AND follow-up	
Participants who were withdrawn by the Principal Investigator *(including screen failures which occurred after providing consent)*	
Participants who chose to withdraw from the study	
Participants who were lost to follow-up	
Deaths *(__NOTE:__ All study-related deaths must be reported to the IRB immediately upon discovery)*	

***The sum of the "Number of Participants" column should equal the total number of participants listed in the last row of the first table.*

Reasons participants were withdrawn by the Investigator since the last CR *(if this is the first CR, list reasons for ppts so far)*:

Reasons participants chose to withdraw from the study since the last CR *(if this is the first CR, list reasons for ppts so far)*:

Of the total number of subjects reported to date, how many have been reported as:

	Number of Participants
Male	
Female	
Other Gender	
Gender Unknown / Not Recorded	

***Multi-Site Studies:** Click the button below to add a copy of this page for each additional study site. Copies will generate after the last page of the document.*

Click Here to Duplicate this Page

RISK/BENEFIT ASSESSMENT:

Has anything occurred since **initial** IRB review and approval which may have altered the risk/benefit relationship of the project? Yes ◯ No ◯

If yes, provide your current assessment of the risk/benefit relationship of the research based upon the results obtained, on-site and off-site SAEs, and any other relevant factors:

Has any new literature or findings been reported since you last reported on this study which would significantly impact the design of this study, or the risks associated with this study? Yes ◯ No ◯

If yes, attach a summary of these findings as a separate document in IRBNet.

PRINCIPAL INVESTIGATOR ASSURANCES:

In accordance with federal regulations, all individuals identified as "key personnel" must complete a Conflict of Interest (COI) disclosure at the beginning of, and during continuing review, for each research project involving human participants.

As a condition of continuing approval, the Principal Investigator certifies that the above research project and protocol has been and will continue to be conducted in full compliance with all federal regulations and IRB policies governing human subject research. Further, the Principal Investigator asserts that the information in this document is accurate. The Principal Investigator also notes that any changes in the research activity, study procedures and/or consent forms must be approved by the IRB prior to implementation, and that all serious adverse events must be reported to the IRB. The Principal Investigator states that any new literature or findings that would significantly impact this study or risk associated with this study have been duly noted and reported to the IRB. The Principal Investigator also assures that all key personnel associated with the project have successfully completed and maintained current educational training in the protection of human research subjects, and that all key personnel have completed and signed a new Conflict of Interest Disclosure relevant to this research project. Additionally, the PI is aware that it is the PI's responsibility to comply with any other regulations and/or institutional policies and procedures (such as those regarding participant compensation) that may apply to this project.

_____ _____

Principal Investigator's Signature Date

_____ _____

Contact Person/Study Coordinator's Signature (if applicable) Date

Additional Items that May Be Required for Continuing Review

As part of the Continuing Review submission, please submit the following documents in IRBNet:

- This IRB Continuing Review Form (completed and signed by the Principal Investigator)
- A CLEAN (un-stamped) version of all Consent Forms / HIPAA Authorization Documents (as applicable)
- Evidence of current Human Subjects Protection training (if it is not linked to the researcher's profile) for each member of key personnel on the project
- New (updated) Conflict of Interest (COI) forms (completed and signed) for each member of key personnel on the project

If Protocol Modifications are being requested at the time of Continuing Review, please also submit:

- **A TRACKED CHANGES / REDLINE** version of all revised documents
- A **CLEAN (unmarked)** version of all revised documents with all tracked changes accepted
- A **MEMO** listing all the requested modifications (signed by the PI, along with a brief justification for the changes)