Continuing Review
IRB Reviewer Checklist
[Insert 1st line of Agenda Item]

Instructions: Complete this checklist prior to the meeting. The entire eIRB record for this study is available for your review. Use the checklist to organize your review and presentation to the Board members. **Email or hand in this checklist at the end of the meeting**, it will be used to create the meeting minutes and letters to the PI.

If you have a conflict of interest, contact the HRPP Coordinator or Chair immediately

- You may write comments on the checklist or other documents (consent, protocol, etc.). If you write comments on other documents, turn those in with this checklist at the end of the meeting.

[Insert Agenda Item Information]

Stipulations Summary:

CITI Training:
Researcher Refresher (Human Subject Protection) training is required for:

-

GCP Refresher (Good Clinical Practice) training is required for:

-

Conflict of Interest training is required for:

-

A 20__ Conflict of Interest (COI) Statement of Financial Interest is required for:

-

REVIEWER:

Checklist Items

1) RISKS TO SUBJECTS ARE MINIMIZED AND REASONABLE IN RELATION TO ANTICIPATED BENEFITS			
[Note: consider only those risks and benefits that may result from the research component (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).]			
Risks	**YES**	**NO**	**N/A**
Is there any new information related to new risks or changes to previously identified risks in the Continuing Review? (consider the following sources of information)			
• Detailed description of the reason for withdrawal. • Summary of local progress. • Previously reported and new (unreported) adverse event UPIRSOs (Reportable Events) • Previously reported and new (unreported) non-AE UPIRSOs (Reportable Events) • Information from an independent safety monitoring entity (e.g., med monitor, DSMB, etc.) • Information from multi-center sponsor • Information from the literature or other sources			
Benefits	**YES**	**NO**	**N/A**
Is there any new information related to the benefits of the study in the progress report?			
SUMMARY – Risks minimized and Risks Reasonable in Relation to Benefit	**YES**	**NO**	**N/A**
Considering all new information and information provided in the progress report, do you agree the risks to subjects continue to be minimized?			
Considering all new information and information provided in the progress report, do you agree the risks continue to be reasonable in relation to the anticipated benefits to subjects or the knowledge to be gained?			

Comments/Questions – specify if required or suggested:

Reviewer Comments/Questions – specify if required or suggested:

2) SELECTION OF SUBJECTS IS EQUITABLE			
[Should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.]			
Subject Selection and Vulnerable Populations	**YES**	**NO**	**N/A**
Is there any new information related to subject recruitment that indicates an issue with equitable selection of subjects? (dealing fairly and equally with all concerned) Consider gender/ethnic/racial information			
Is there any new information related to protecting vulnerable populations? Consider vulnerable populations Consider adult surrogate consent (impaired decision making capacity)			
SUMMARY – Equitable Subject Selection	**YES**	**NO**	**N/A**
Considering all new information and information provided in the progress report, do you agree the subject selection continues to be equitable?			

Comments/Questions – specify if required or suggested:

Reviewer Comments/Questions – specify if required or suggested:

3) INFORMED CONSENT/ ASSENT			
Informed Consent Document	**YES**	**NO**	**N/A**
Given the information provided in the progress report, is the consent document accurate, complete and up-to-date? Current approved consent(s)			
Do any significant new findings that may relate to the subject's willingness to participate need to be added to the consent addressed?			
Where any problems identified related to consent that were not adequately resolved? Question addressing the consent process			
SUMMARY – Informed Consent and Documentation	**YES**	**NO**	**N/A**
Considering all new information and information provided in the progress report, do you agree informed consent will continue to be sought (or waived)?			
Considering all new information and information provided in the progress report, do you agree informed consent will continue to be appropriately documented (or waived documentation)?			

Comments/Questions – specify if required or suggested:

Reviewer Comments/Questions – specify if required or suggested:

4) PLAN for MONITORING DATA for SAFETY	YES	NO	N/A
Is there any new information that indicates the need to revise the local plan for continuously collecting and monitoring the safety data of subjects? (e.g., new indicators, more frequent assessments, changes to reporting)			
Is there any new information to indicate the need to revise the prompt reporting of UPIRSC (reportable events)?			
SUMMARY – Data Safety Monitoring	**YES**	**NO**	**N/A**
Considering all new information and information provided in the progress report, do you agree the data and safety monitoring continues to be adequate?			

Comments/Questions – specify if required or suggested:

Reviewer Comments/Questions – specify if required or suggested:

5) SUBJECT PRIVACY & CONFIDENTIALITY	YES	NO	N/A
Is there any new information that indicates the need to revise the plan to protecting privacy and assuring confidentially?			
SUMMARY – Privacy and Confidentiality	**YES**	**NO**	**N/A**
Considering all new information and information provided in the progress report, do you agree the plans to protect privacy and maintain confidentiality continues to be appropriate?			

Comments/Questions – specify if required or suggested:

Reviewer Comments/Questions – specify if required or suggested:

6) STUDY PERSONNEL	YES	NO	N/A
Do those who are listed as engaged in research have required IRB education?			
Are those listed in the current consent form(s) also found on the Study Personnel list?			
Do those who are listed in eIRB have current COI disclosures on file?			

Comments/Questions – specify if required or suggested:

Reviewer Comments/Questions – specify if required or suggested:

7) Other concerns	**YES**	**NO**	**N/A**
Changes to the study			
Were any changes made without IRB approval?			
If yes, were the unapproved changes necessary to protect welfare of subjects?			
If no – is this deviation considered to be possible serious or continuing non-compliance?			
FDA Regulated Drug/Device			
Any changes to use of drug/devices since last review?			
Involves the use of an approved drug in a manner not approved by FDA, and there is no new information that significantly increases the risks associated with the use of the drug			
Involves the use of an unapproved device or an approved device used for a new indication, and there is no new information that changes the non-significant risk device designation.			
Do changes affect the IND, IDE, approval category?			
Number of Subjects			
Are the withdrawals from the study acceptable?			
Are there any concerns about the study enrollment progress?			
Other Study Materials and Considerations			
Are there any notable conflicts of interests?			
Are there any indications from the information provided that this study should be audited to verify that no changes are made without approval?			

Comments/Questions – specify if required or suggested:

Reviewer Comments/Questions – specify if required or suggested:

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Conclusions of the Reviewer – Summary Page

Summarize your detailed review below. This section can be used to present your review to the Board at the convened meeting.

Step 1 - Risk Assessment – based on the progress report, the overall risk level of the study is:

☐	Minimal risk	☐	More than minimal risk	☐	Minor increase over minimal *(Children 46.406 only)*

Step 2 - Required Determinations to Re-approve the Research	**YES**	**NO**	**N/A**
Do the risks to subjects continue to be minimized?			
Do the risks continue to be reasonable in relation to the anticipated benefits?			
Does the selection of subjects continue to be equitable?			
Will Informed consent continue to be sought from each prospective subject or legally authorized representative **or** is the waiver of consent acceptable?			
Will informed consent continue to be appropriately documented **or** is the waiver acceptable?			
Does the plan to monitor data to ensure the safety of subjects continue to be acceptable?			
Do the provisions to protect privacy and maintain confidentiality continue to be adequate?			

Step 3 - Are all the required determinations listed in Step 2 checked "YES"?

	Yes. **If yes**, are there any minor changes needed to the progress report? *the clarifications/modifications <u>are not</u> directly relevant to the "Determinations required for re-approval" listed above]*
	Yes - your motion should be to **Approve with Conditions** (stipulations) **Continue to Step 4**
	The stipulations should be reviewed by: ☐ IRB Staff (administrative changes) or ☐ Expedited Reviewer (minor changes)
	No - your motion should be to **Approve As Written** **Skip to Step 5**
	No. [Notify the IRB Chair or Director <u>before</u> the meeting if this is your motion] **If No**, is there a reasonable possibility that the major issues can be resolved?
	Yes - your motion should be to **Defer** (table discussion to another convened meeting) **Skip to Deferred Section**
	No - your motion should be to **Disapprove** **Skip to Disapproved Section**

Step 4 - Additional Determinations for motions to **Approve** or **Approve with Conditions**	**Acceptable**	Requires **minor** corrections noted in the appropriate sections of this checklist:	**N/A**
The use of **radiation** continues to be	☐	☐	☐
The inclusion of **incompetent adults** or adults with impaired decision making continues to be	☐	☐	☐
The inclusion of pregnant women, fetuses &/or non-viable or uncertain viability neonates continues to be	☐	☐	☐
The inclusion of prisoners continues to be	☐	☐	☐
The inclusion of **children** continues to be	☐	☐	☐
The **COI** management plan continues to be	☐	☐	☐

Step 5 - Approval Period				
☐	One Year	☐	Less than one year*	Specify approval period and reason for shortened approval here:

Defer (defer re-approval at this meeting) due to **major** issues.
[Major = the clarifications/modifications listed here are directly relevant to the "Determinations required f approval" listed above]

In this section, describe **major** (substantive) issues resulting in deferring protocol. **Include one or more of the following required determinations that could not be met due to the issues.**

- Risks to subjects minimized
- Risks reasonable in relation to the anticipated benefits
- Selection of subjects equitable
- Informed consent be sought from each prospective subject or legally authorized representative and/or the waiver of consent acceptable
- Informed consent be appropriately documented or the waiver of documentation acceptable
- The plan to monitor data collected to ensure the safety of subjects acceptable
- Provisions to protect privacy and maintain confidentiality is adequate

Insert Deferral Rationale here:

Disapprove (deny the request for approval – study will be withdrawn from further IRB review due to **major** irresolvable issues.

Provide the reason for disapproval: