

**INSTITUTIONAL REVIEW BOARD
EAST TENNESSEE CHILDREN'S HOSPITAL**



CONTINUING REVIEW FORM

Date of Requested Review: _____ ETCH #: _____

Initial Review Date: _____ Last Continuing Review Date: _____

Protocol Title: _____

Principal Investigator/Sponsor: _____ / _____

1. During the past review period, how many participants have you enrolled in this study locally? _____

How many participants have been enrolled locally since initiation of the study? _____

2. If your research required written consent:

A) Was a written consent obtained from each participant or parent of the participant? Yes _____ No _____

B) Where are signed consents retained? _____

C) Did participants receive a copy of the consent form? Yes _____ No _____

3. Since the last review:

A) Have you received any amendments? Yes _____ No _____

If yes, please list amendment number or identifier, note if consent was changed and the date the revised consent was approved by the IRB.

Amendment number/id	Consent changed?	Date IRB approved
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1) _____	Yes _____ No _____	_____
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2) _____	Yes _____ No _____	_____
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PLEASE CONTINUE ON THE BACK

B) Have risks to participants changed during this review period?

Yes _____ No _____

If yes, does current consent reflect these changes? Yes _____ No _____

Have participants been notified of changes? Yes _____ No _____

Supporting documentation of notification to participant: _____

C) Have any of your participants had an unexpected serious event?

Yes _____ No _____

If yes, does current consent reflect these changes? Yes _____ No _____

D) Have any of your participants been lost to follow-up or dropped out of the study? Yes _____ No _____

If yes, please list reason(s): _____

4. Is this study still being conducted? Yes _____ No _____

If no, is termination permanent? Yes _____ No _____

If discontinued, please state reason for termination and attach a summary of your findings

5. A) Study to stay on Continuing Review? Yes _____ No _____

B) Remove from Continuing Review? Yes _____ No _____

C) Place on Longterm Follow-Up? Yes _____ No _____

I certify the consent currently being used is the most current form:

Original consent is being used or,

Form last revised in _____ is being used.

Signed _____

Date _____

PLEASE SUBMIT A COPY OF THE CONSENT CURRENTLY BEING USED

(DO NOT ATTACH A SIGNED CONSENT FORM)