REQUEST TO CHANGE CONSENT FORM REQUIRED LANGUAGE

Statement on Consent Forms Reviewed by the CHW IRB

The CHW IRB bears the main responsibility for complying with regulatory requirements (45 CFR 46; 21 CFR 50) for effective research consent documents. While we recognize that other parties (investigators, industry sponsors, cooperative research groups) have a large stake in the quality of the consent language, per guidance from federal regulators, final say rests with the CHW IRBs' interpretation of regulations and policies, and the IRBs' translation of local ethics.

The CHW IRB has developed compliant and flexible consent document templates that all investigators are required to use. Required language that cannot be altered by investigators appears in black type. The sample language in blue type can be changed within reason (wording but not format) to fit your study.

Instructions

If you have a compelling reason to ask the IRB for permission to change the required template language, complete this petition, and email this to the IRB office.

→This request **only** applies to the project indicated below and **cannot be used for other projects**.

→Do not submit consent forms containing altered "required template language" via IRBNet until you have received written permission. The project/package can be started in IRBNet as a "work in progress" but wait to submit the package until a decision is received so that if a change is approved the modified consent(s) and the request form with the decision can be added .

→If changes are approved, include this form with the decision with your package submission.

→If changes are approved, or a modified version of the requested change is approved, you will receive a consent form template back, with the applicable sections unlocked for editing, along with the decision.

→We anticipate a decision within 2 weeks of submitting the request, however some requests may take longer depending on the number and extent of the changes and whether entities such a Corporate Compliance or Legal need to review.

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If you are requesting changes to multiple sections of a consent, please clearly delineate which changes and rationale belong with which section to avoid delays in reviewing the request. A copy of the full consent form for the study must be attached for context. A draft of the consent form is acceptable.

Please note: Even if your petition is accepted, the IRB committee may still request modifications to the consent form when reviewed in the context of the entire project submission.

Email to: CHWIRB@chw.org **IRBNet#:**

Date of Request: **Principal Investigator:**

Template type and version date:

Heading/Title of section that contains language in question:

Cite below how would you like the section/paragraph to read:
Please highlight or use track changes to denote changes.

Justify <u>every</u> change proposed. The IRB will generally not agree with changes proposed for reasons of word-choice or style:
Requests will not be considered if a regulatory justification for the change has not been provided.

HRPP Office Use Only: Template Change Decision
Date of decision:
☐ Approve as submitted ☐ Request Denied Reason Denied: ☐ Changes Required. Petition is approved if changes, as specified below, are made. Changes:
Reviewed by: