**Petition to Change Consent Form Required Language**

**Statement on Consent Forms Reviewed by the MCW IRB**

The MCW 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, final say rests with the MCW IRBs’ interpretation of regulations and policies, and the IRBs’ translation of local ethics.

The MCW 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. This petition 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 eBridge until you have received written permission. Petition reviews will be completed within two weeks of the submission date.

*Changes must be proposed per section. If you are petitioning to change more than one section of the template, complete one additional form for each section. All requests for the same PRO should be sent in one email. 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:** IRBOffice@mcw.edu **Date of Request:** Click or tap to enter a date.

**eBridge PRO#:**  **Principal Investigator:**

**Template type:** Choose an item.

**Version date:** Choose an item.

*If Other, please specify:*

**Letter/number (e.g. C3) 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 every 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.*

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| **HRPP Office Use Only:****Template Change Decision** |
| **Date of decision**: Click or tap to enter a date. |
| [ ] Approve as submitted[ ] Request Denied Reason Denied:      [ ] Changes Required. Petition is approved if changes, as specified below, are made. Changes:       |  |
| **Reviewed by**:       |