



National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

November 27, 2018

Dear Investigators and Research Staff:

Through our audit process as well as a review of institution feedback, NCI found a varying degree of adherence to the NCI Informed Consent Template. NCI recognizes the need for more specific guidance on the use of the template to ensure compliance in the future.

NCI's goal is to greatly limit any changes to the model consent form, and ensure that any information added to the form is related to research. The NCI CIRB will be consistent in their review and approval of consent changes made by local institutions. Changes allowed in the past may no longer be accommodated and your boilerplate language may require revisions. Your institution must comply with the NCI Informed Consent Template verbatim, except as outlined below.

In agreement with NCI's guidance, the NCI CIRB will no longer approve any deletions of template language in the CIRB-approved model consent form. The only exception will be deletions permissible for reproductive language specific for faith-based institutions. Additions to the model consent form for local boilerplate language will be limited to the sections of the model consent form detailed in the CIRB Quickguide. The CIRB will be circulating this Quickguide to provide more guidance on permissible local changes.

Please carefully review your institution's boilerplate language and ensure that it complies with the NCI Informed Consent Template (November 27, 2018 version) and the Quickguide. Boilerplate language changes that are necessary to achieve compliance with the revised requirements may begin immediately and must be implemented no later than your up-coming annual submission for local context. Boilerplate language that is not in compliance after annual submission could result in a deficiency at the time of audit.

For questions related to this policy and the new Quickguide, please contact the CIRB at:
ncicirbcontact@emmes.com.

Sincerely,

A handwritten signature in blue ink, appearing to read "J. Abrams".

Jeffrey Abrams, MD
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Acting Director for Clinical Research
Division of Cancer Treatment and Diagnosis
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