DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

November 27, 2018

Dear Lead Protocol Organizations and Investigators:

The NCI is providing updates to the Informed Consent Document (ICD) Template for use in NCI-supported clinical trials in adults. In keeping with our goal to provide timely updates to the ICD Template as the regulatory, ethical and scientific issues arise, this memo outlines the changes in the table below. In addition, a track version pdf of the previous December 12th, 2017 version of the ICD template is attached to easily locate the updates.

Table 1: Major Updates to the NCI Informed Consent Document (ICD) Template

#	Page in Template and ICD Section	Consent Issue and Update
1	**Page 7**: "What am I being asked to do?	Language was added to inform potential participants that this study has public funding from the NCI, part of the NIH and federal government. This was added to the beginning of the consent to clarify the major funder of the study as it has impact later in the consent about NIH data sharing policies for publicly funded trials and NCI resources available for more information.
2	**Page 39:** Instructions for "Imaging Risks"	Instructions to authors was added to include risks when protocols include imaging studies that are not standard of care to describe additional risks involved.
3	**Page 44:** "Who will see my medical information?"	Several clarifications were added to the organizations that may review study records.
4	**Page 45:** "Optional Sample Collections" new direction header, "All NIH studies must use the following three paragraphs of required text."	Additional language was added to fully comply with the NIH data sharing policy and issues related to public research databases. Clinical trial participants in NIH supported studies must be made aware that some of their de-identified health information and banked biospecimens collected as part of the study will be kept in publicly controlled access databases per NIH policy.
5	**Pages 50-51:** "All NIH-sponsored studies banking specimens for future unknown studies…"	New direction header and text examples have been added for tissue banking and possibility of germ line or somatic genomic DNA sequencing.

The revised version of the NCI ICD Template dated 11/27/2018 is now posted on the CTEP website at https://ctep.cancer.gov/protocoldevelopment/informed_consent.htm.
Consents that were initially NCI CIRB reviewed and approved before 12/31/2018 are considered "grandfathered", which means they will not be required to comply with these changes. When

investigators are making changes to previously approved consent forms, they should incorporate these new updates in studies actively recruiting new patients. For comments related to these NCI ICD template additions, please contact us at: NCICTEPComments@mail.nih.gov .

The other major change to this ICD Template was to remove all notes for Local Site Investigators. The goal of removing these instructions is to increase awareness for Local Sites and facilitate their implementation of instructions from the NCI's CIRB, as well as avoid confusion to the authors writing the main consent. Guidance to Local Site Investigators for permitted local boilerplate language to the model consent form for multi-institution studies is available at the NCI's Central IRB (CIRB) website: https://ncicirb.org/content/guidelines-permitted-boilerplate-language-additions .
Any questions related to this guidance or questions related to this policy, please contact the CIRB at: ncicirbcontact@emmes.com .

Again, we thank everyone who has sent us valuable comments and input.

Sincerely,

Jeffrey Abrams, MD
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Acting Director for Clinical Research
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