DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

December 12, 2017

Dear Investigators and Research Teams:

The National Cancer Institute (NCI) Informed Consent Document (ICD) Template for use in NCI-supported clinical trials in adults was revised and published on October 10, 2017 to comply with the OHRP Common Rule requirements published in January 2017.

In our letter informing investigators of the changes, we announced that this ICD template would be a "living document" to be updated as needed. In keeping with this goal, this memo is to announce two new additions to the template.

1. **Note on Certificate of Confidentiality Issues:** Beginning with the December 12, 2017 version of this template, the new Certificate of Confidentiality protections covering all NIH-funded research are addressed in the first paragraph under the section, "Who will see my medical information?" on page 43 in the template. The language in this template has been edited from NIH's suggested consent language to align with our health literacy and plain language goals of the NCI template. Please note that currently NCI CIRB approved consent forms do not need to have this addition, but this paragraph should be used in all consent forms being updated with amendments.

2. **Updated risk** added in the section: "What risks can I expect from taking part in this study?" on pages 28-29 in the general risk section and on page 49 in the section, "What are the risks in this optional sample collection?" Many cancer clinical trials require pathology specimens be submitted as part of the clinical trial and additional blocks and/or slides are requested for correlative science studies embedded in the trial. This new language should be used in clinical trials where there is concern that patient tissue may all be utilized for research and may not be available for possible future clinical use.

The revised December 12, 2017 version of the NCI ICD Template is now posted on the CTEP website at https://ctep.cancer.gov/protocoldevelopment/informed_consent.htm. Additionally, this webpage contains several other ICD-related resources, such as instructions for using readability tools, concise tables of side effects for commercial anti-cancer drugs and regimens for inclusion in ICDs, and instructions on how to build such tables.

As a reminder, this revision of the NCI Informed Consent Template will become effective January 19, 2018 in order to comply with the Final Rule. Consents that were IRB reviewed and approved before January 19, 2018 are considered "grandfathered", which means they will not be required to comply with the new changes in the final rule.

For comments related to these NCI ICD template additions or the previous revision, please contact us at: NCICTEPComments@mail.nih.gov

Again, we thank all of you who sent us valuable comments on the template.

Sincerely,

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