NCI Informed Consent Document (ICD) Template – 2017 Revision

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NCI Informed Consent Template Revision: Key Changes

- Clarification of “Costs” and “Exams, Tests, and Procedures” sections to address potential billing and insurance coverage issues
  - Better delineation between routine, clinically indicated tests and procedures that may be done more frequently than usual but are still billable, and tests and procedures done for research purposes that are not billable
- Additional information and examples for trials with genomic testing
- Improvements to readability and language to facilitate patient understanding
- Compliance with new 2017 OHRP Common Rule requirements
  - New “Overview and Key Information” section at the beginning of the ICD
  - More information about storage and potential use of identifiable information or identifiable biospecimens
- January 17, 2018 OHRP delayed implementation of Common Rule. However, allows updates to consent documents to move forward now.
  - https://www.hhs.gov/ohrp/interim-final-rule-common-rule.html

NCI Informed Consent Template Revision: Key Dates

- **October 10, 2017:** Revised Informed Consent Template is published on the CTEP website
- **December 12, 2017:** Template updated with CoC and new risk

- **January 19, 2018:** Protocols initially submitted to CTEP on or after this date **must use** the revised Informed Consent Template. Protocols that were submitted to CTEP before this date but not yet CIRB approved are encouraged to transition to the revised Informed Consent Template.

- **July 19, 2018:** Protocols that do not have an IRB approval (either Approval Pending Modification or full Approval by the CIRB) are **required** to use the revised template. Please review your protocol timelines and revise consent forms in your protocols to meet these deadlines.

NCI Informed Consent Template Revision: Website and Email Address

- Revised template is available on the CTEP website at: https://ctep.cancer.gov/protocoldevelopment/informed_consent.htm
- Or use the short URL: https://go.usa.gov/xn32M
- We expect this template to be a “living document”
  - We expect additional revisions based on new needs and changes in the science
  - Provide suggestions for changes to the email box we have created: NCICTEPComments@mail.nih.gov