

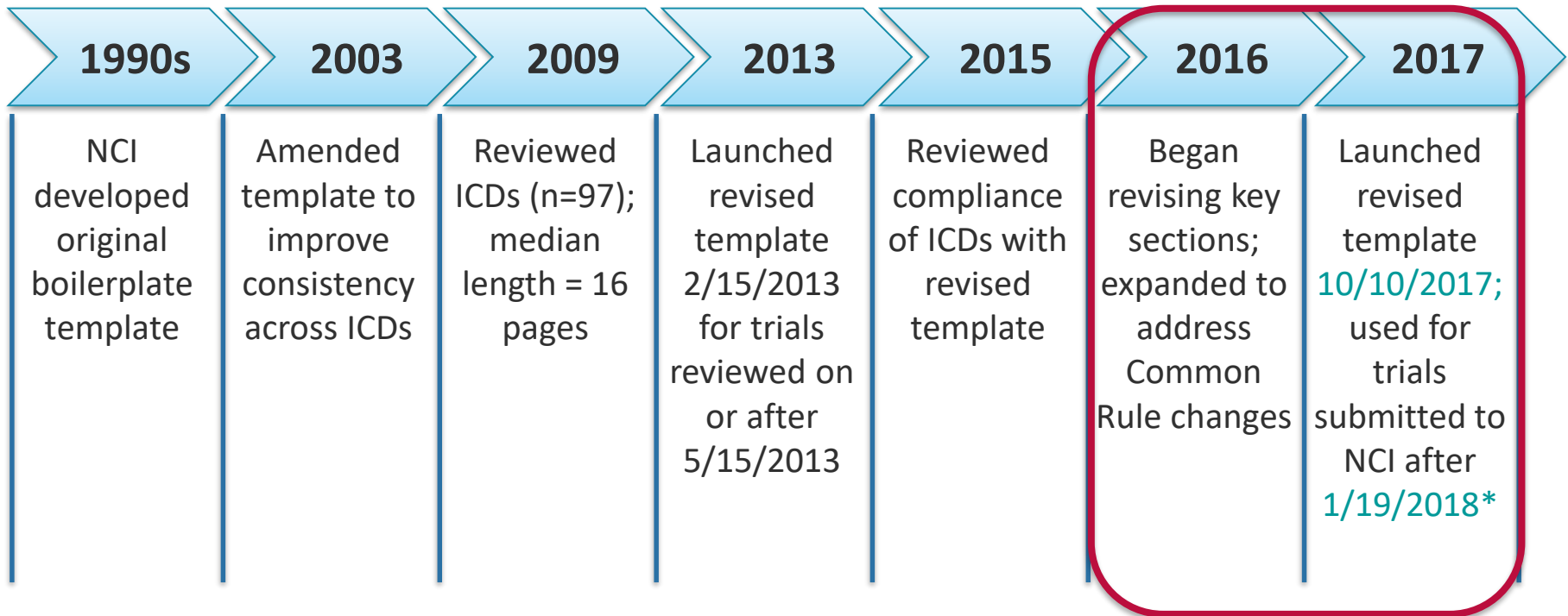
NCI Informed Consent Document (ICD) Template – 2017 Revision



a National Cancer Institute program

2018 Updates to
Implementation

NCI Informed Consent Template Timeline



***Note:** OHRP delayed full implementation of the Common Rule to July 19 instead of January 19, 2018. However, they allowed use of the informed consent updates; therefore, NCI will continue with implementation.

View the delay information at: <https://www.hhs.gov/ohrp/interim-final-rule-common-rule.html>

NCI Informed Consent Template Revision: Process

- **Internal revision process in 2016**

- Revised key sections identified through prior evaluations, including costs, extra tests, and general integration of biomarker research
- Met internally to review and finalize Revision #1

- **Stakeholder review in 2016**

- Distributed Revision #1 to prior working group members, Groups, and other NCI entities
- Received 29 responses; reviewed and reconciled comments and edits

- **Final Revisions to the Common Rule, January 2017**

- Released by OHRP on January 19, 2017 and effective January 19, 2018
- NCI implemented changes to the consent template to comply with the Final Rule requirements¹
- Conducted iterative review with plain language specialist and finalized Revision #2

- **Stakeholder review in 2017**

- Circulated Revision #2 & received 18 responses; reviewed and reconciled comments and edits

- **Final revised template published, October 2017**

- **Two minor updates published December 12, 2017**

1. Information about the Final Revisions to the Common Rule available at:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

NCI Informed Consent Template Revision: Key Changes

- Compliance with new 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
- Additional information and examples for trials with genomic testing
- 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
- Improvements to readability and language to facilitate patient understanding
- Formatting changes to improve usability for ICD authors

NCI Informed Consent Template Revision: Usability for ICD Authors

Color-Coded Information:

~Instructions to consent authors for are highlighted in this color and set apart by the tilde symbol, “~”. This text should not be included in the consent form for patients.

Depending on the instructions, the text that follows should either be included in your consent word-for-word or with changes to make the text accurate for your study. ~

#Headers that indicate that the following text includes examples that could be adapted for use in your consent, if appropriate, are highlighted in this color and are set apart by the hash symbol, “#”. This header text should not be included in the consent form for patients. #

Sections where you should enter or modify text are (*highlighted in yellow and listed between parentheses and asterisks*). Adapt and enter the text as necessary. Remove the parentheses, asterisks, and highlighting in the consent form for patients.

^Sections that will require edits from local site investigators are highlighted in this color and are set apart by the carat symbol, “^”. These instructions and formatting should remain in the consent form for the local sites. Local sites should remove them from the consent form for patients. ^

NCI Informed Consent Template Revision: New OHRP Common Rule Requirements

- Regulatory language on the new Key Information section from the Final Rule to revise the current 45CFR 46, Subpart A (Common Rule):
 - Final Rule language at § 116(a)(5)(i): “Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.”

NCI Informed Consent Template Revision: New OHRP Common Rule Requirements

- Official guidance has not been published, but the commentary accompanying publication of the Final Rule described the expectations for this new section:
 - “In general, we would expect that to satisfy § ll.116(a)(5)(i), the beginning of an informed consent would include a concise explanation of the following: (1) the fact that consent is being sought for research and that participation is voluntary; (2) the purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research; (3) the reasonably foreseeable risks or discomforts to the prospective subject; (4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.”

NCI Informed Consent Template Revision: Genomic Testing

Studies Using Investigational Genetic Test Results to Determine Study Eligibility and Assign Patients to Study Groups

As part of this study, we are also studying a genetic test. The test is designed to find out if your tumor has the genetic changes that are needed for this study. If it does, we will assign you to a study group based on the genetic changes in your tumor.

Because this genetic test is still being studied, there is a risk that the test results may be wrong. If the test results are wrong, you may be included in this study even though it may not offer the best treatment option for you. Or, you may not be included in this study even though it may offer a good treatment option for you.

NCI Informed Consent Template Revision: Genomic Testing

Studies Using Genetic Testing of Tumor Tissue Alone to Identify Potentially Inheritable Mutations

The genetic test used in this study will test your tumor for (*a genetic change or genetic changes*), (*specify which changes, e.g., BRCA1*). This change also may be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Since this study is only testing tumor tissue, we will not know if a genetic change in your tumor is also in your normal tissue. If you want to find out if the change is in your normal tissue, then you will need to get other tests done outside of this study.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your study doctor will talk with you about what testing your normal tissue may mean for you and your family. He or she also may suggest that you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for any genetic tests and visits to a genetic counselor done outside of this study.

NCI Informed Consent Template Revision: Costs and Tests

~~What **extra** tests and procedures will I have if I take part in this study?~~



What exams, tests, and procedures are involved in this study?

- **What are the costs of taking part in this study?**

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

NCI Informed Consent Template Revision: Formatting and Readability for Patients

Optional Resource: Using Online and Manual Readability Tools to Assess the Reading Level of Informed Consent Documents

Note: This resource is provided to assist Informed Consent Document authors in assessing the readability of their documents. It is an optional resource.

Readability formulas are used to estimate the reading difficulty of text.^{1,2} In general, they measure the average number of syllables in words and the average number of words in sentences. Most formulas provide results as grade levels, such as the 8th grade reading level. However, because readability depends on so many issues, achieving a certain grade level is not a guarantee of comprehension.

Types of readability formulas: There are numerous readability formulas including Flesch-Kincaid, Flesch Reading Ease, SMOG, Fry, Fog Index, and Dale-Chall.³ They are generally accurate to ± 1.5 grade levels.

NCI Informed Consent Template Revision: Certificate of Confidentiality (CoC) Updated 12/12/2017

- NIH Certificate of Confidentiality Policy- updated 10/01/2017
 - <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>
 - NIH CoC “kiosk”: <https://humansubjects.nih.gov/coc/index>
 - “(A)ll ongoing or new research funded by NIH ... that is collecting or using identifiable, sensitive information is automatically issued a CoC.”
- NIH CoC website has suggested consent language. The NCI template edited the NIH’s version to align with our health literacy and plain language goals. This update was added to the NCI consent in the section, “Who will see my medical information?” on page 43.
 - 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.

NCI Informed Consent Template Revision: Optional Risk of Tissue Depletion added 12/12/2017

- The NCTN Group Banking Committee recommended the addition of informing patients on the possible risk of tissue depletion in some studies.
- Most clinical trials require pathology specimens be submitted as part of the clinical trial and many are also asking for additional blocks and/or slides for correlative science studies embedded in the trial. This new risk should be included in consents for trials where there is concern that patient tissue may all be utilized for research and may not be available for possible future clinical use.
- Language 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?”

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.
 - Review your protocol timelines and revise consent forms in your protocols that do not have an IRB approval as needed to meet this deadline.

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

Thank you to everyone who assisted with the revision process!

Including...

- NCTN Group members and staff
- Patient advocates
- 2013 Working Group Members for the NCI Concise Informed Consent Template Project
- NCI and Government colleagues

Questions