

NCI Informed Consent Document (ICD) Template – 2017 Revision

Grace Mishkin, MPH

Andrea Denicoff, MS, RN, ANP

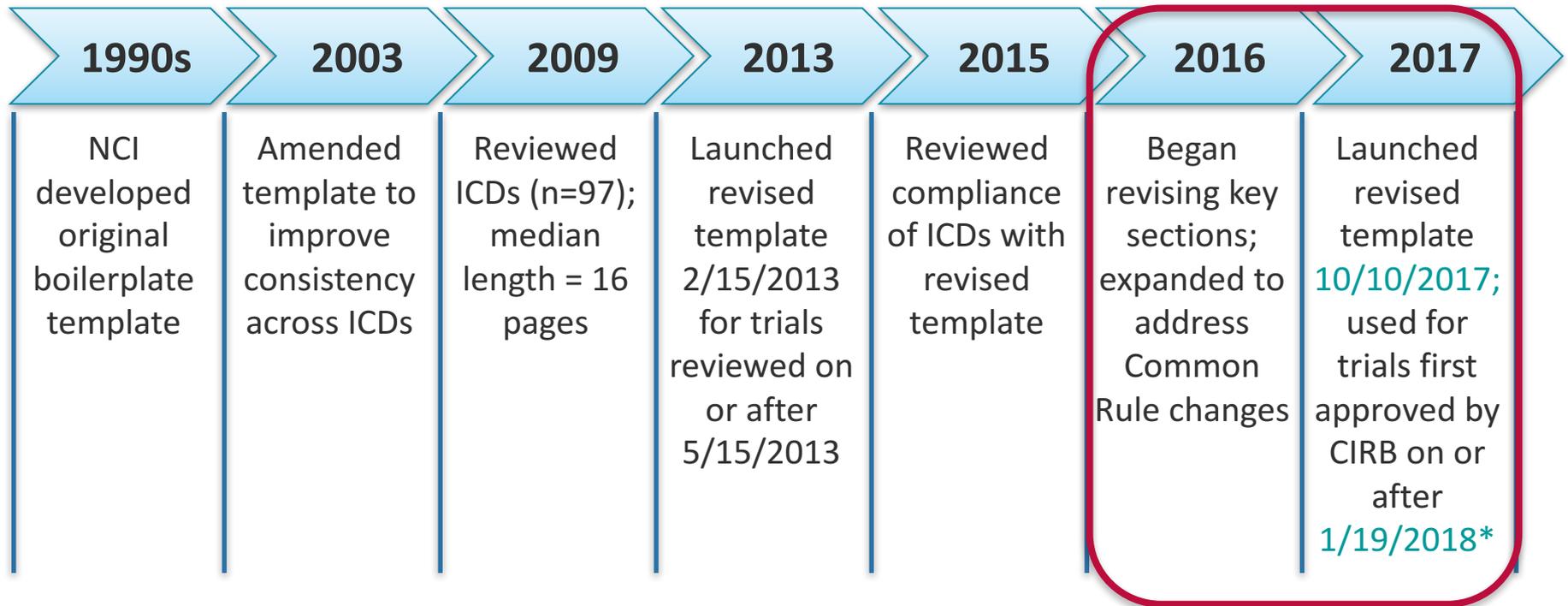
Cancer Therapy Evaluation Program



a National Cancer Institute program

November 2, 2017

NCI Informed Consent Template Timeline



***Note:** If the implementation of changes to the Common Rule is delayed, NCI will provide additional information about use of the October 2017 ICD Template

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**

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

- Formatting changes to improve usability for ICD authors
- 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

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: New OHRP Common Rule Requirements

- To satisfy these expectations, the revised template's new "Overview and Key Information" includes the following brief sub-sections:
 - What am I being asked to do?
 - Taking part in this study is your choice.
 - Why is this study being done?
 - What is the usual approach to my (*insert cancer/condition*)?
 - What are my choices if I decide not to take part in this study?
 - What will happen if I decide to take part in this study?
 - What are the risks and benefits of taking part in this study?
 - If I decide to take part in this study, can I stop later?
 - Are there other reasons why I might stop being in the study?
- Some of this information is also explained in more detail later in the consent, but ICD authors and site users must include both instances as laid out in the template

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: Certificate of Confidentiality (CoC) Questions

- NIH Certificate of Confidentiality Policy
<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 information, but we have determined that the relevant information is already conveyed in the NCI ICD template**

NCI Informed Consent Template Revision: Key Dates

- **October 10, 2017:** Revised Informed Consent Template is published on the CTEP website
- **January 18, 2018:** Protocols that have an approval (either Approval Pending Modification or full Approval) by the CIRB before this date **do not need to use** the revised Informed Consent Template.
 - However, protocols that have not yet activated **can** begin using the revised Informed Consent Template for submissions from this point forward
- **January 19, 2018:** Protocols that are **initially approved** by the CIRB on or after this date **must use** the revised Informed Consent Template, which includes those studies that receive an “Approval Pending Modification” from NCI’s CIRB.

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