Where We Are: NCI's Informed Consent Template and Updates to Address Changing Needs

Andrea M. Denicoff, MS, RN

Cancer Therapy Evaluation Program

Division of Cancer Treatment & Diagnosis

NIH NATIONAL CANCER INSTITUTE

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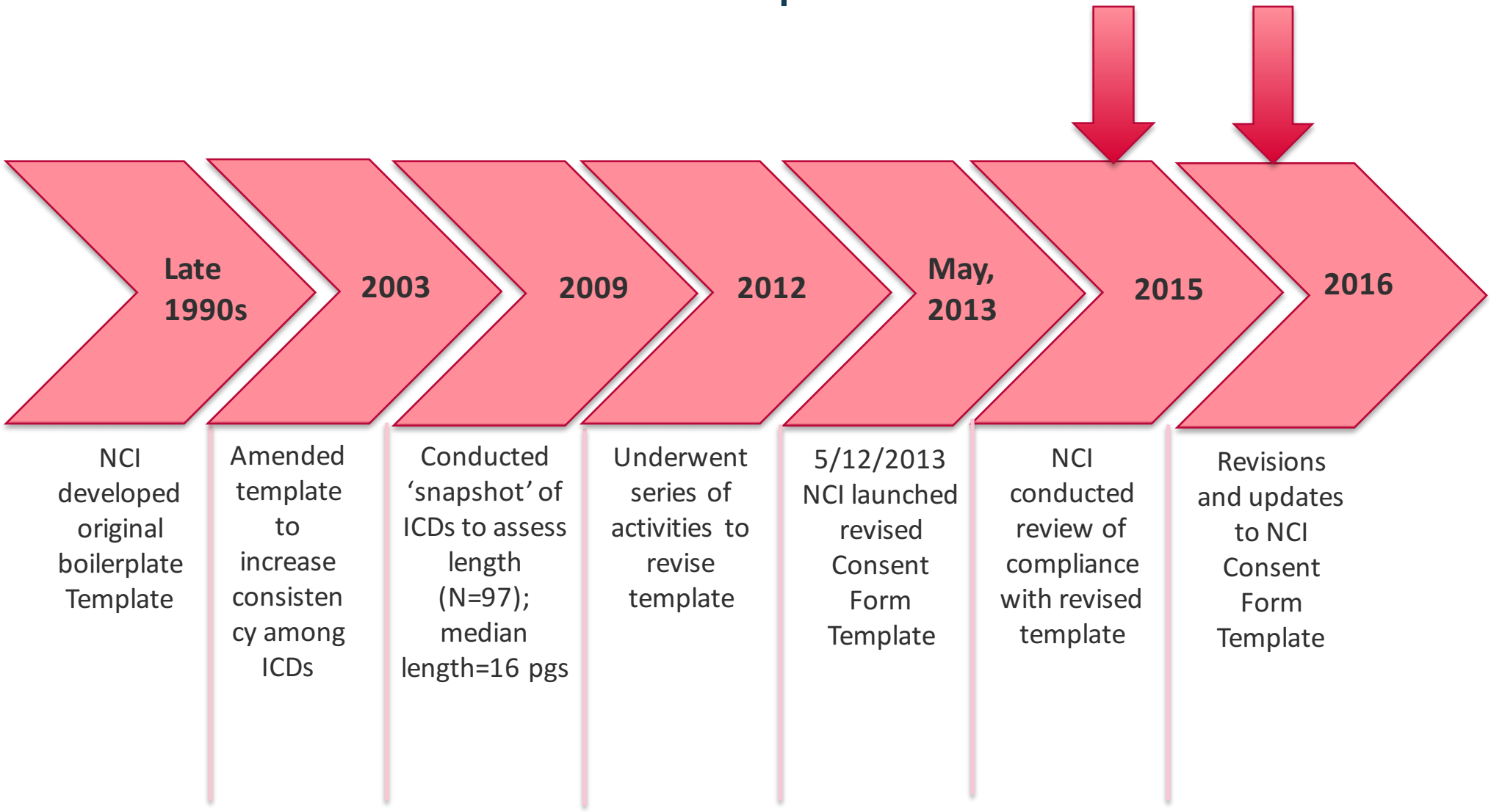
Outline

1. Provide brief background on issues prompting updates to the NCI Informed Consent Document (ICD) Template
2. Present process for gathering input
3. Describe the sections of the ICD with major changes
4. List next steps to finalize and implement

ICD Compliance Review with Areas Identified Needing Updates

NCI Informed Consent Template Timeline



Comparison of ICD Length & Readability Statistics

(Means)	Old Template	Revised Template	% Change	p-value
Number of Pages	15.0	12.0	-20.4%	<.001
Number of Paragraphs	264.3	208.9	-21.0%	<.001
Words per Sentence	15.8	16.4	3.6%	.016
Characters per Word	4.6	4.5	-1.8%	<.001
Reading Grade Level	8.9	8.8	-0.9%	.585
Ease of Readability *(higher score indicates greater ease)*	58.8	60.6	3.1%	.009
Percent Passive Sentences	24.2	23.6	-2.4%	.460

*Higher values indicate greater ease

ICD Sections with Greatest Concerns

	% Correct (both text and length)	% Correct length, incorrect text	% Correct text, too long	% All incorrect
answer questions	98	2	0	0
get more info	95	5	0	0
if injured/hurt	93	7	0	0
rights	90	0	7	3
costs	85	2	12	0
title	85	0	15	0
stop taking part	85	0	15	0
other choices	81	12	7	0
benefits	71	20	5	5
usual approach	66	24	2	7
possible risks	63	12	22	2
see my med info	44	0	51	5
why this study	37	12	46	5
extra tests	34	34	20	12
study groups	29	5	29	37
how long in study	27	2	54	17

Went off-script, but kept it short

Used recommended text but added extra words

ICD Updates: Extramural and Community Input

- NCTN Meeting to Address Accrual Challenges in Clinical Trials (December 2014)
- ASCO – NCI Symposium on Clinical Trial Coverage Analysis for Multi-Center Trials (August 2015)
- NCI directed the Cancer Trials Support Unit (CTSU) to pilot effort to conduct National Coverage Analysis (NCA) - Pilot began April 2016
- Precision Medicine Trials – increasing ICD content needed to describe patient risks associated with investigational biomarkers, secondary findings from genetic testing and related patient privacy issues

Reviews of ICD Template Updates

Engaging the Community for Change

NCI Reviewers of ICD Template Updates

Division of Cancer Treatment and Diagnosis (DCTD)

DCTD Cancer Diagnosis Program (CDP)

DCTD Cancer Therapy Evaluation Program (CTEP)

- Clinical Investigations Branch (CIB)
- Clinical Trials Monitoring Branch (CTMB)
- Clinical Trials Operations and Informatics Branch (CTOIB)
- Investigational Drug Branch (IDB)
- Pharmaceutical Management Branch (PMB)
- Regulatory Affairs Branch (RAB)

Division of Cancer Prevention (DCP)

Division of Cancer Control and Population Sciences (DCCPS)

Division of Cancer Epidemiology and Genetics (DCEG)

NCI Center for Cancer Research (CCR - Intramural program)

NCI Office of Communication and Public Liaison (OCPL)

Community and Government Reviewers

- ASCO
- FDA
- NCI CIRB
- NIH Department of Bioethics
- Office for Human Research Protections (OHRP)
- NCTN and NCORP Groups & Investigators
- Patient Advocates
- Working Group Co-chairs from the 2013 ICD Template Reviews
- Academic Bioethicists
- Billing Compliance Experts
- Clinical Trial Site Administrators, Research Nurses and CRAs
- Plain language expert & patient education writer

ICD Sections with Substantial Changes

Revisions: “Extra tests” changed to “What exams, tests…”

- Revised author instructions and examples
- Separated section into 2 parts: clinical tests & research tests
- Intent: describe only clinical tests needed to prevent and monitor toxicities for the investigational agent that would not be done with SOC (NCCN guidelines)
- The protocol listing of tests should line up with the study calendar, ICD, funding memo and coverage analysis
- Aligns with Medicare’s Coverage of Routine Costs in Clinical Trials NCD 310.1 states these include, “the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications”
  - https://www.cms.gov/medicare-coverage-database/
- Research tests and procedures should be listed with brief rationale and the risks of them, such as a research blood draw or biopsy, should be listed in the risk section

Draft ICD Revisions (2): “What are the risks ”

- Added instructions to authors on the need to present risks associated with precision medicine trials using genetic testing that is investigational or nonstandard, such as:
  - Risks associated with nonstandard genetic testing that might identify mutations that are potentially inheritable
  - Studies requiring waiting for test results prior to starting the study, describe risks associated with delaying treatment

- Updated and improved reproductive risks section

Draft ICD Revisions (3)

- "What are the Costs" section revised and now includes 2 sub-headers for clarity:
  - "Your Potential Costs"- help patients understand that insurance will be billed for care, tests, etc. and should align with coverage analysis
  - "Costs paid by the study"- specify exactly what is paid for by the study sponsor and should align with funding memo

- Updated "benefits" section to use language for early phase trials with therapeutic intent
  - Phase I study "may or may not help you" from "unlikely to help you"

Draft ICD Revisions (4) Additional Studies Section

- Updated language regarding optional sample collections for research and/or biobanking of genetic data, including possible risks and information about keeping the data private
- Updated resource on donating tissue for research

- New example of patient study calendar to attach at the end of ICD

Feedback thus far….

- Improve template instructions to authors to write in a patient-centered approach: keep language patient-friendly, non-technical and concise!
- Requests for NCI to require an easy to understand study schema instead of it being optional and include patient-friendly study calendars
- Additional expertise and review of GCP requirements to ICD template with recommended changes.
  - For example, the need to clearly explain to trial participants the probability for random assignment, such as: “You will have an equal chance of being in Group 1 or Group 2.” or appropriate language for study designs with 2:1 randomization, etc.

- “Overall I think this ICD template is an improvement- I’ll keep my fingers crossed that this new template is used thoughtfully.”

Next Steps to Finalize ICD Template Revisions

- Awaiting OHRP review and then will incorporate community feedback
- Test revised template language and compare with 2013 version to carefully review and ensure this update is not lengthening or reducing readability.
- Collaboratively develop a plan to launch new template and increase awareness of the changes and need for the alignment of all protocol associated documents with funding and coverage analysis, such as webinars, meetings, etc.
- Decide on an appropriate launch date for future protocols to use new ICD Template

Thank you to all the Alliance Staff, Investigators, Members and Patient Advocates for all the critical and thoughtful input!

Discussion

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