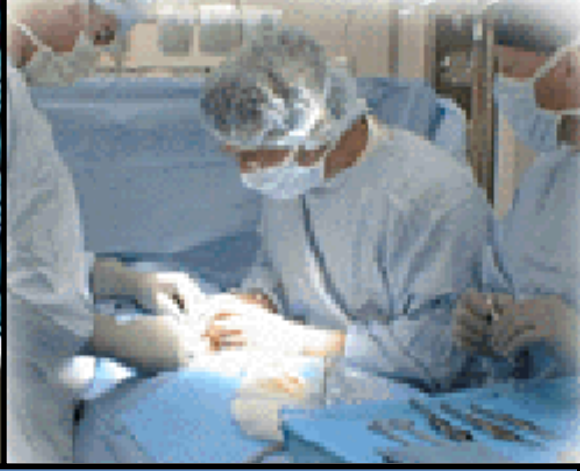
National Cancer Institute





# Making the ICD More Concise:
## Revising the Informed Consent Template

*Presented to :*

*Clinical Trials and Translational Research Advisory Committee*

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

# NCI Informed Consent Template - Background

- 1997 – concerns voiced by research participants and investigators about informed consent documents for cancer treatment trials
  - *Too long, difficult to understand complicated concepts*
- NCI, OPRR, and FDA formed Informed Consent Working Group
  - *Investigators, nurses, advocates, IRB members, ethicists, legal experts, communication experts, pharma representatives*
- Resulted in:
  - *NCI Informed Consent Template*
    - Used by authors and IRBs
    - Included all Federally required elements, written in lay language using NIH plain language principles
    - Minor revisions: 2004, 2009
  - *Website with recommendations for process as well as document* http://www.cancer.gov/clinicaltrials/education/simplification-of-informed-consent-docs/page2

# Identification of a Problem

- In the Literature
  - Albala (2010) *"…Among the problems…are excessive length, complexity of wording."*
  - Beardsley (2007) *"The length of patient information and consent forms…is increasing with time. QuIC-A scores [which rates participants' objective knowledge of the clinical trial] were significantly higher for trials in which the …page count was seven or less."*
- Elsewhere
  - AHRQ (2009) *"[Informed consent] documents are long and written at a reading level beyond the capacity of most potential subjects."* http://www.ahrq.gov/fund/informedconsent
  - Recent letters from IRB Chairs from Illinois, Maryland, and Ohio
    - *"…consent forms are becoming longer and longer"*
  - Comments from patient advocates, investigators, CRAs
  - AAMC, IOM
  - NCI staff members (who review consents from studies nationwide) share the same opinion

# Immediate Actions Taken

- 'Snapshot' audit - length of phase 3 CTEP treatment trials
  - *97 studies*
  - *Range: 5 to 35 pages*
  - *Median: 16 pages*
- Surveyed NIH Institutes for their ICD approaches
  - *Finding: many NIH Institutes using the NCI IC Template*
- Conducted literature search for general and specific guidance on ICD format and content
  - *Resulted in Table of Evidence*
- Compilation of recommendations from patient advocacy organizations
  - *Recommendations categorized by Working Group assignments*
- Developed Background Document to provide rationale for project

# Next Step: Draft Concise Template

- Methodology
  - 'Blank slate' approach
    - *Addressed 'basic' and 'additional' elements of informed consent per OHRP and FDA regulations*
    - *Goal was brevity yet including key concepts about trial that might affect one's decision to participate*
  - Retained plain language principles, including:
    - *Writing for the reader*
    - *Using common, everyday words*
      - *Short words, sentences, and paragraphs*
    - *Displaying material correctly*
      - *Q&A format of Template titles and responses*
      - *Providing white space*
  - Eliminated repetition of information

# Three Test Cases

- Applied draft concise informed consent template to three ICDs from existing CTEP-sponsored phase 3 trials
- Test cases were chosen based on length of ICD
  - *Chose those with 16 pages - median length from 'snapshot' audit*
  - *Studies in lung, breast, and lymphoma*
- Rewriting the ICDs, using the concise Template, reduced ICD length by more than half
  - *4,822 → 2,165 words, 7 pages (Test case 1)*
  - *5,777 → 2,388 words, 7 pages (Test case 2)*
  - *5,143 → 2,352 words, 7 pages (Test case 3)*

# Concise Template – Developmental Strategy

- Planning Committee was assembled, composed of representatives from NCI Divisions collaborating with CTEP on treatment trials:
  - *Office of the NCI Director*
    - *Coordinating Center for Clinical Trials*
    - *Office of Advocacy Relations*
    - *Office of Communications and Education*
  - *Center for Cancer Research*
  - *Cancer Diagnosis Program*
  - *Cancer Imaging Program*
  - *Cancer Therapy Evaluation Program*
  - *Division of Cancer Control and Populations Sciences*
  - *Division of Cancer Prevention*

# Developmental Strategy (continued)

- Planning Committee :
  - *Discussed the problem*
  - *Reviewed relevant documents*
  - *Developed approach which would result in more concise ICDs for CTEP-sponsored trials*
- Approach consisted of:
  - *Constituting five working groups, each co-chaired by two individuals with specific expertise*
    - *Comprised of key stakeholders:*
      - Patient Advocates, IRB Chairs, Cooperative Group regulatory and protocol development staff, nurses, CRAs, investigators
    - *Tasked with addressing the sections of the draft template, including companion studies and the possible addition of informational attachments*

# Method Used for Populating Working Groups

- Planning Committee nominated qualified individuals to serve as co-chairs
- Planning Committee also nominated individuals by category to serve as working group participants
  - *Patient Advocates, IRB Chairs, Cooperative Group regulatory and protocol development staff, nurses, CRAs, investigators, bioethicists, CIRB and CTEP representatives*
- Planning Committee met in March with working group co-chairs to outline tasks, goals, questions to consider, and deliverables
- Each working group drafted their assigned section of the IC Template to be more concise and developed responses for the questions provided

# Working Group Co-chairs

- Working Group 1 (Beginning of Template: background, required tests, intervention sections):
  - *Shlomo Koyfman, MD – clinical investigator*
  - *Joan Westendorp, RN, MSN, OCN, CCRA – protocol coordinator*
- Working Group 2 (Risks and benefits sections):
  - *Roy Smith, MD – former CIRB Chair*
  - *Michael Paasche-Orlow, MD, MA, MPH – ICD expert*
- Working Group 3 (Alternatives, privacy, injury, cost, rights, signature):
  - *Edward Goldman, JD – ICD expert*
  - *Nancy Morton, MT, MPH – protocol coordinator*
- Working Group 4 (Possible attachments):
  - *Barbara LeStage, MPH – patient advocate*
  - *Mary McCabe, RN, MA – ICD expert*
- Working Group 5 (Companion studies):
  - *Lisa Carey, MD – clinical investigator*
  - *Laura Beskow, MPH, PhD – translational investigator*

# Federal Regulatory Advisors Participating

- FDA
  - Sandra Casak, MD
  - Ruthann Giusti, MD
  - Joanne Less, PhD
  - Shan Pradhan, MD
- OHRP
  - Jerry Menikoff, JD, MPP, MD
  - Julie Kaneshiro, MA
  - Lisa Rooney, JD
  - Lisa Buchanan, MA

# Current Status

- June 28/29 Face-to-face meeting
  - *Each Working Group's Co-chairs presented assigned drafts to assembled group including Planning Committee, Regulatory Advisors, and other Working Group members*
- Working Group recommendations for ICD include:
  - *Include a lay title and brief description of standard treatment to set stage for study discussion*
  - *Focus on how study is different from standard treatment rather than using limited space to describe standard treatment*
  - *Concern about how to avoid drift in length over time*
    - *Page counts*
    - *Word counts or reading time estimates*
  - *Attachments should be informative and optional*

# Current Status (continued)

- Recommendations about risks section
  - *Format risks into tables*
    - Use different tables for experimental and standard arms
    - Lump risks by body system, keeping description at a more general level such as 'heart attack', 'irregular heartbeat', or 'kidney damage' instead of including details often provided about specific abnormalities, like 'ventricular tachycardia' or 'nephrotic syndrome'.
    - Describe risks by how study participant will experience them
    - Avoid including lab findings such as hypokalemia or hypercalcemia
    - OHRP suggested making risk descriptions meaningful, stating how effects of study intervention are different from standard treatment
  - *Develop repository of side effects of commercial drugs*
- Final Revised Template is being prepared
  - *Post-meeting, once all changes are included, the revised template will be vetted by the NCI Working Group*
  - *Additional comments on final version will be solicited from OHRP and FDA*

# Additional Discussion

- How should new Template be rolled out?
  - *Suggested a subcommittee to plan rollout*
  - *Definitely wanted a memo to IRB chairs prepared that provides rationale for the shorter ICD*
  - *Encouraged engaging OHRP and FDA to support new Template*
  - *Proposed development of a white paper on this initiative*
  - *Suggested presentations about how new Template was developed and expertise of those involved to the following:*
    - Cooperative Group Annual Meetings
    - PRIM&R – engage IRB support
    - National IRB Chair conference call
    - AAHRPP
- Other topics
  - Use of technology during informed consent process?
    - Recommended not mandating as resource-intensive; consider per trial
  - How should Template address ICD differences between:
    - Early/later phase trials and treatment/prevention trials?
      - Sample language included in Template
      - Additional text and deviations from Template to address uniqueness

# NCI OMRE Evaluation Methods

- Formative evaluation - conducted during development
  - *Qualitative - Gather input from advocates during revised Template's development*
  - *Funded through OMRE existing contract mechanisms*
- Outcome evaluation – conducted prior to implementation
  - *Randomize cancer survivors to ICDs written using current Template vs. concise version (same trial)*
  - *Funded through NIH set-aside evaluation funds*
  - *IRB and OMB clearances will be obtained*

# Questions to CTAC

- Does CTAC support the effort to reduce the length of the average consent form from 16 to 6 or 7 pages?
- Does CTAC feel that page limits on ICDs are an effective way to ensure against future length 'drift'?
- While there is compelling evidence that lengthiness of the consent form is a major hindrance to patient comprehension, how can we convince IRBs that shortening the form is beneficial?

# References for Slide 2 Citations


Albala, I., Doyle, M., & Appelbaum, P.S. The evolution of consent forms for research: A Quarter Century of Changes. IRB: Ethics & Human Research, 2010, 32(3), 7-11.

Beardsley, E., Jefford, M., & Mileshkin, L. Longer consent forms for clinical trials compromise patient understanding: so why are they lengthening? Journal of Clinical Oncology, 2007, 25, e13–e14.

# Background of CIRB Model Change

- Current Model: NCI CIRB and LIRB share regulatory responsibilities
  - CIRB's primary responsibility is *initial and continuing review* of studies, including amendments and other study-specific documents distributed by the Cooperative Group.
  - The local institution's primary responsibility is *consideration of local context and oversight of conduct of the trial.*
  - *"Facilitated Review"* – the review during which the local IRB reviews the CIRB-approved study for local context considerations.
- Proposed new model: NCI CIRB has all regulatory responsibilities
  - *CIRB will continue to review study-specific documents*
  - *CIRB will review local context considerations for new studies*
    - *Facilitated review no longer necessary*
  - *CIRB is IRB of Record, when investigators use CIRB*

# Rationale and Impact of CIRB Model Change

- Rationale
  - *Significant number of institutions have requested a model change*
  - *Should increase CIRB enrollment and utilization*
  - *Positions the CIRB well for AAHRPP accreditation*
    - Accreditation is indicator of quality to IRB community
- Anticipated Impact
  - *Eliminates facilitated review*
    - Potential for additional time and effort savings over current model for institution
    - Local IRB has no review responsibilities
  - *Continues CIRB study-specific review for human subjects protection*
    - High-level expertise of CIRB members

# Key Features of Model Change

- CIRB informed of local context considerations via the following:
  - *Annual Institution Worksheet*
    - *Contains descriptions of state and local laws, including required boilerplate language*
  - *Annual Principal Investigator Worksheet*
    - *Provides research activity descriptions*
- PIs open a new study by submitting a Study-Specific Worksheet directly to the CIRB
- Study-specific potential unanticipated problems and/or serious or continuing noncompliance reported directly to CIRB
  - *PI/Institution submits management plan, when applicable*
  - *CIRB makes determination and does reporting, when applicable*

# Why a Pilot Study?

- NCI wants to learn:
  - *Impact on local institutions*
  - *Feasibility for the CIRB Operations Office*
  - *Best practices for new model operations*
- Key points of Pilot
  - *Population – 20 currently enrolled plus 5 not enrolled institutions*
  - *Duration – 9-12 months*
  - *Evaluation - conducted by NCI's OMRE*
    - *Analysis of completed surveys and report available late summer 2012*
- Timeline
  - *June 2011 – CIRB invites institutions to participate*
  - *August 2011 – 25 institutions identified to participate in Pilot and interactive forms available*
  - *Early September 2011 – Pilot operational*
  - *Late Summer 2012 – Analysis of evaluation report*
  - *Late 2012 – NCI makes decision regarding the model change*

# Questions to CTAC

- IOM report and ASCO letter recommend sites use the NCI's CIRB for multi-institutional, Cooperative Group trials. Does CTAC have any additional strategies to suggest that would accomplish this?

- Many sites in the CIRB Initiative feel that a switch to an independent model will be beneficial. Do CTAC members have any suggestions about this new approach?

# Contact the NCI CIRB

- Email: ncicirbcontact@emmes.com
- CIRB Toll-free Number: 888-657-3711
- Fax Number: 301-560-6538

NCI CIRB Website: http://www.ncicirb.org