Making the ICD More Concise: Revising the Informed Consent Template

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Jeanne M. Adler, RN, MPH
Nurse Consultant
CIB/CTEP/DCTD/NCI
adlerj@mail.nih.gov
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)
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
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?

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](http://www.ncicirb.org)