Inclusion of Women and Minorities in Clinical Research: Update on Re-Engineering Efforts

Advisory Committee on Research on Women’s Health
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Meredith D. Temple-O’Connor, Ph.D.
NIH Inclusion Policy Officer
Office of Extramural Research
National Institutes of Health
Goals of Today’s Presentation

• Brief overview of NIH inclusion policy
  ▫ Defining the universe
  ▫ What it means to include
  ▫ Where we are headed

• Re-Engineering Inclusion at the NIH
  ▫ Key changes
  ▫ New NIH Electronic Research Administration (eRA) data system: Inclusion Management System (IMS)
  ▫ What we’re learning
  ▫ Impact of changes on reporting
Brief Overview of NIH Policy on the Inclusion of Women and Minorities in Clinical Research
Defining the Universe

- Inclusion of women and minorities in all NIH funded or supported clinical research is mandated by law
- What is subject to the statute/policies?
  - All studies (intramural, extramural, contracts) that meet the NIH definition of clinical research
    - NIH definition of clinical research: (1) Patient-Oriented Research: Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual (e.g., IRB Exemption 4). Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical studies, or (d) development of new technologies; (2) Epidemiologic and Behavioral Studies; and (3) Outcomes Research and Health Services Research
  - Additional requirements for NIH-defined Phase III clinical trials related to unbiased design and assessment of potential differences
But what does it mean to include?

- **Purpose Statement:** NIH supported clinical research should address/include the population(s) at risk for the disease or condition under study. The purpose of NIH Inclusion Policies is to ensure that the distribution of study participants by sex/gender, race, ethnicity, and age reflects the population needed to accomplish the scientific goals of the study, rather than enumeration of research participants. **All NIH-funded studies that meet the NIH definition for clinical research are subject to NIH Inclusion Policies, regardless of funding mechanism**. (*Funding mechanism includes any activity code associated with extramural grants, R&D contracts, and cooperative agreements as well as intramural projects and R&D contracts)*

- **Bottom line:** Does the study have the right people for the science?
Some Key Events on NIH Inclusion Timeline

- Previous activities and policies regarding inclusion (1980s)
- Inclusion of women and minorities mandated by law (1993)
- NIH Tracking and Inclusion Committee established (~1994)
- New NIH policy on inclusion (1994)
- Updates to NIH policy (2001)
- Electronic data system (2002)
- Inclusion Task Force to assess current status of monitoring (2010)
- Reorganized governance structure (2011)
- Re-engineering business processes and data systems (2011-present)
It’s All in the Perspective…

Is this window facing right or left?

• Same law
• Same NIH policies

• Shift in how we look at inclusion
Re-Engineering Inclusion at NIH
Key Changes Underway

- Modified forms layout for investigators reporting inclusion data to the NIH
- Streamlined processes and procedures
- Updated critique templates and reviewer guidelines
- New and updated training, FAQs, and other resources/materials
- New NIH data system for monitoring inclusion: Inclusion Management System (IMS)
Changes to Layout of Inclusion Forms

Planned Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Domestic/Foreign: (D/F drop down)

Comments:

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Ethnic Categories</th>
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<td>Native Hawaiian or Other Pacific Islander</td>
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<td>Black or African American</td>
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</table>

Cumulative Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Comments:

<table>
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<tr>
<th>Racial Categories</th>
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Review-Specific Changes

- Updated critique templates
  - SRO guidance issued
- Updated reviewer guidelines
Revised Critique Template

What does it look like on the reviewer template?

<table>
<thead>
<tr>
<th>Inclusion of Women, Minorities and Children Applicable Only for Human Subjects Research</th>
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</thead>
<tbody>
<tr>
<td>Previous</td>
</tr>
<tr>
<td>G1A - Both Genders, Acceptable</td>
</tr>
<tr>
<td>M1U - Minority and Non-minority, Unacceptable</td>
</tr>
<tr>
<td>C3A - No Children Included, Acceptable</td>
</tr>
<tr>
<td>Comments (Required Unless Not Applicable):</td>
</tr>
<tr>
<td>·</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inclusion of Women, Minorities and Children Applicable Only for Human Subjects research and not IRB Exemption #4.</th>
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<tr>
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<tr>
<td>Sex/Gender: Distribution justified scientifically</td>
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<tr>
<td>Race/Ethnicity: Distribution not justified scientifically</td>
</tr>
<tr>
<td>Inclusion/Exclusion of Children under 21: Including ages &lt; 21 not justified scientifically</td>
</tr>
<tr>
<td>Comments (Required Unless Not Applicable):</td>
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</tbody>
</table>

Acceptable

Unacceptable
Monitoring Inclusion with the Inclusion Management System (IMS)
Inclusion Management System (IMS)

- Will replace our current inclusion data system
- Streamline data entry
- Engage investigators more directly
- PI access to IMS through the Commons
- Enhance data accuracy, ownership, accountability
- Better integration with award workflows
- Tools for staff to monitor progress
What are we learning with the re-engineering efforts?
Some Key Elements Identified

• Communication
  ▫ What is subject to the policy?
  ▫ What are the expectations for inclusion?

• Understanding our portfolio at different levels

• Changing the perspective and enhancing the value
Impact of Re-Engineering and IMS on Inclusion Reporting

- **October 2014:**
  - Updated procedures implemented
  - IMS will be released in October 2014
  - Timed with change in FY
- **Biennial Report for FY2013 and FY2014**
  - Reported to ACRWH Spring 2015
- **Transition between data systems and what that means for future reports**
Questions?