Human Subjects Subcommittee Update

Co-Chairs –
John R. Baumann, Ph.D.
Associate Vice President for Research Compliance
Indiana University

Debra Murphy
Director, Research Operations and Sr. Compliance Officer
Arizona State University
Opening Remarks
Introductions
Role of the Subcommittee
Focus areas for the Coming Year
Invitation to Collaborate
IRB Wizard update
Opening Remarks

Welcome

John R. Baumann, Ph.D.
Debra Murphy
Subcommittee Members –

Mariette Marsh – University of Arizona
Rachel Wenzl – University of Nebraska
Sarah Kiskaddon – Dana Farber/Harvard Cancer Center
Michelle Stickler – University of Texas - Austin
Self Introductions by Subcommittee Member –
Mariette Marsh – University of Arizona
Self Introductions by Subcommittee Member –
Rachel Wenzl – University of Nebraska
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Sarah Kiskaddon – Dana Farber/Harvard Cancer Center
Self Introductions by Subcommittee Member –
Michelle Stickler – University of Texas - Austin
The Human Subjects Subcommittee is part of the programmatic umbrella of the Research Compliance Committee. The subcommittee is charged with reviewing existing and new administrative requirement for Human Subject Protection Programs. Our emphasis focuses on harmonization of requirements, reduction of redundancies and identifying best practices.
Consistent with our mission to explore options related to burden of IRB oversight, we propose the following focus areas:

• Deploying IRB Wizard

• New areas related to the Revised Common Rule
  1. Exempt and Limited IRB Review
  2. Single IRB (sIRB)
  3. Continuing Review

• Invitation to collaborate
Questions?
Wizard 2.0

Live Demonstration
Debra Murphy, ASU
Drew Brown, Ph.D., ASU
Faculty Workload Survey reported an increase in faculty burden related to IRB faculty activities.
Wizard Demonstration
Goals

• **Proof of concept**: Smart form for Human Subjects review to identify many exempt studies tested in the wizard were Exempt Categories 2 and 4.

• **Criteria**:  
  • Language acceptable to regulatory agencies  
  • Sufficient information for IRBs to track  
  • Mechanism to identify “it depends” situations  
  • Researcher-friendly

• **10 collaborating institutions**  
  • 542 studies reviewed through Wizard and independently by IRB
Institutions Participating in Demonstration

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<tr>
<th>ASU</th>
<th>Cal Tech</th>
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<tr>
<td>Drexell</td>
<td>Harvard</td>
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<td>Northwell Health</td>
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Figure 1. Agreement in Wizard and IRB Evaluations for the 264 Completed Evaluation Studies
Exclusion Questions were intended to exclude from Wizard Approval when there were sensitive research topics, children, and other vulnerable populations.
Participation

• Demographics
• Dual review of all exempt and expedited applications
• Excel spreadsheet with Institutional Determinations
• https://asu.co1.qualtrics.com/jfe/form/SV_bNNPeeH9Dw8odi5
IRB Wizard Demonstration
• The purpose of the study is to investigate how knowledgeable clinicians are in obtaining evidence for evidence-based clinical practice. An email through a list serve will be sent to graduates from the program with a link to a Qualtrics survey. All of the subjects are adults. The questions will be about what sources of information a clinician is most likely to use in determining best clinical practice. No identifiers will be collected.

• This is the study that will be used for demonstration.
IRB Exempt Self- Determination Wizard - The End is Finally Here! - FDP Presentation May 2020

Using an Automated Wizard to Process Minimal-Risk Research, Sandra L. Schneider, Jane A. McCutcheon, April 30, 2019

Next Steps

• Institutional Decisions
• Use of Qualtrics – Requirements
• Institutional MOU
• Release through FDP but not hosted
Next Steps

• Use of Qualtrics – Requirements
Next Steps

• Institutional MOU
Next Steps

• Unhosted release through FDP
Closing Remarks and Thank You