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

Human Subjects Subcommittee Agenda

Opening Remarks

Introductions

Role of the Subcommittee

Focus areas for the Coming Year

Invitation to Collaborate

IRB Wizard update

Human Subjects Subcommittee

Opening Remarks

Welcome

John R. Baumann, Ph.D.

Debra Murphy

Human Subjects Subcommittee Update

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

Human Subjects Subcommittee

Self Introductions by Subcommittee Member –

Mariette Marsh – University of Arizona

Human Subjects Subcommittee

Self Introductions by Subcommittee Member –

Rachel Wenzl – University of Nebraska

Human Subjects Subcommittee

Self Introductions by Subcommittee Member –

Sarah Kiskaddon – Dana Farber/Harvard Cancer Center

Human Subjects Subcommittee

Self Introductions by Subcommittee Member –

Michelle Stickler – University of Texas - Austin

Human Subjects Subcommittee

- 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.

Human Subjects Subcommittee

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

Human Subjects Subcommittee – Wizard

Questions?

FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Wizard 2.0

Live Demonstration

Debra Murphy, ASU

Drew Brown, Ph.D., ASU

Wizard - Background

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

Wizard Proof of Concept

Institutions Participating in Demonstration

ASU

Drexell

NYU-Washington Square

Northwell Health

Temple

Cal Tech

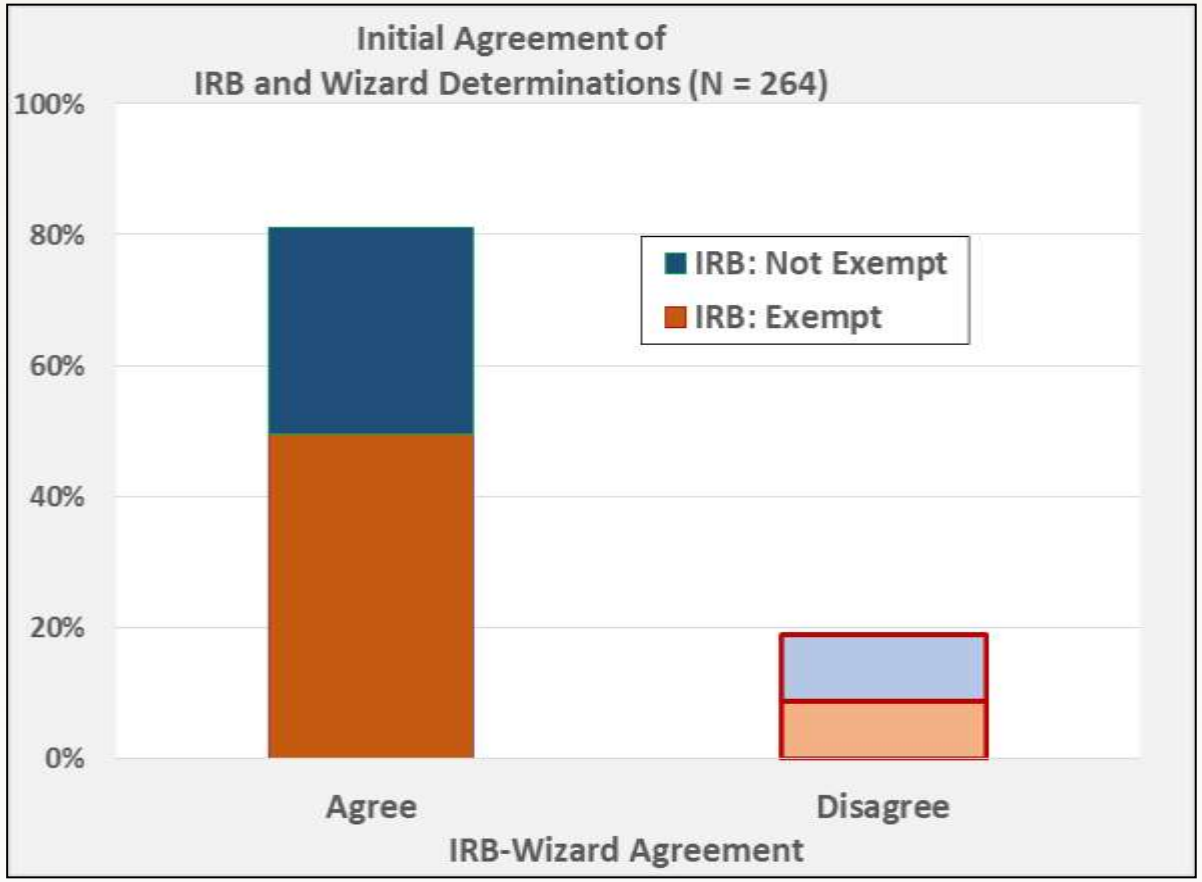
Harvard

Northern Illinois

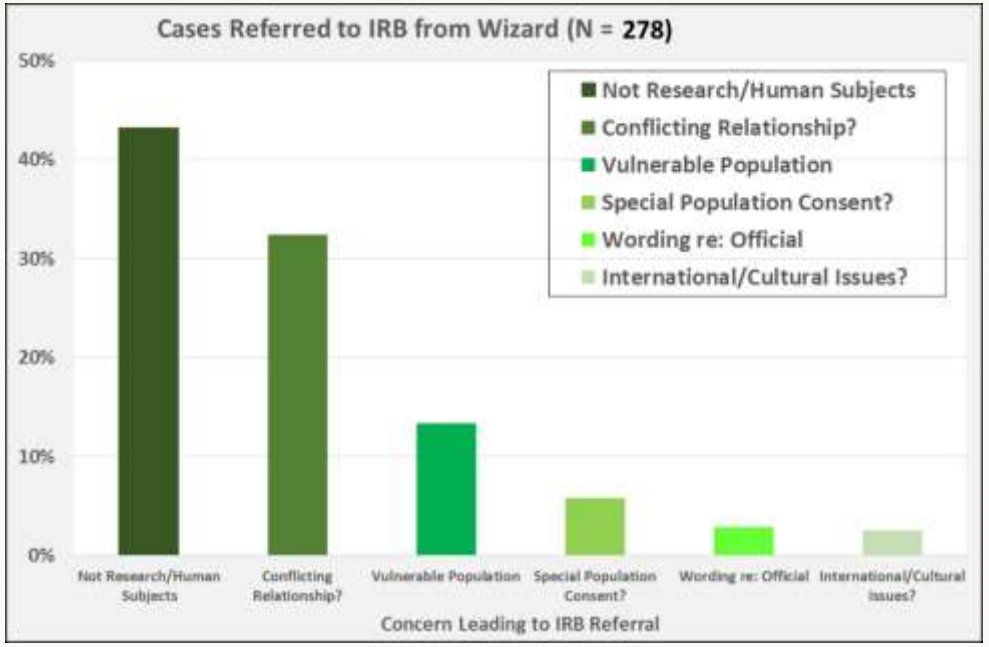
Texas Tech

Wizard Proof of Concept

Figure 1. Agreement in Wizard and IRB Evaluations for the 264 Completed Evaluation Studies



Wizard Proof of Concept



Changes

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

Wizard Link

- https://asu.co1.qualtrics.com/jfe/form/SV_bNNPeeH9Dw8odi5

Human Subjects Subcommittee – Wizard

IRB Wizard Demonstration

Case Study

- 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.

References

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

The FDP IRB Wizard Pilot: Final Report , Submitted by Sandra L. Schneider and Jane McCutcheon, March 6, 2018.

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