



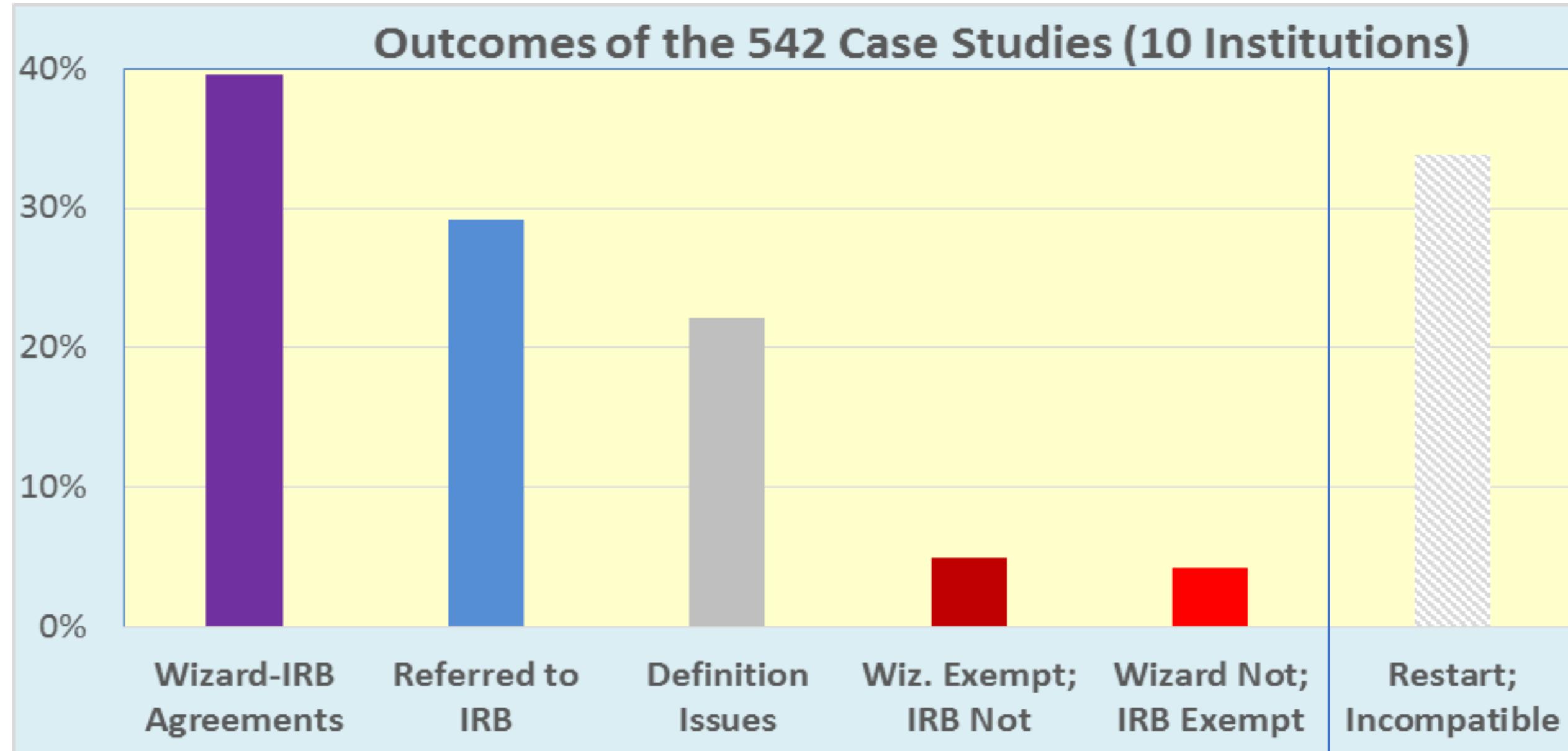
Wizard Demonstration Goals

- **Proof of concept:** Smart form for IRB Human Subjects review to identify many exempt studies
- **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 Demonstration Results

Outcomes of the 542 Case Studies (10 Institutions)





Wizard Demonstration Next Steps

- **Follow-up to Complete Wizard Demonstration**
 - Determine causes of/remedies for **Wizard-IRB disagreements**
 - Review Wizard **referrals to IRB** to resolve case in Wizard when possible and to divert to IRB sooner if not
 - Review **incompatible responses** to make recommendations for improvements to flow/wording of Wizard
- **Proposal for Related Initiative**
 - With collaborating institutions, review cases of definition issues regarding **OHRP-defined research** and **human subjects** to identify likely areas of confusion
 - Initiate **working group** to develop descriptions that **help everyone understand and agree** on the OHRP-intended meaning of both terms.