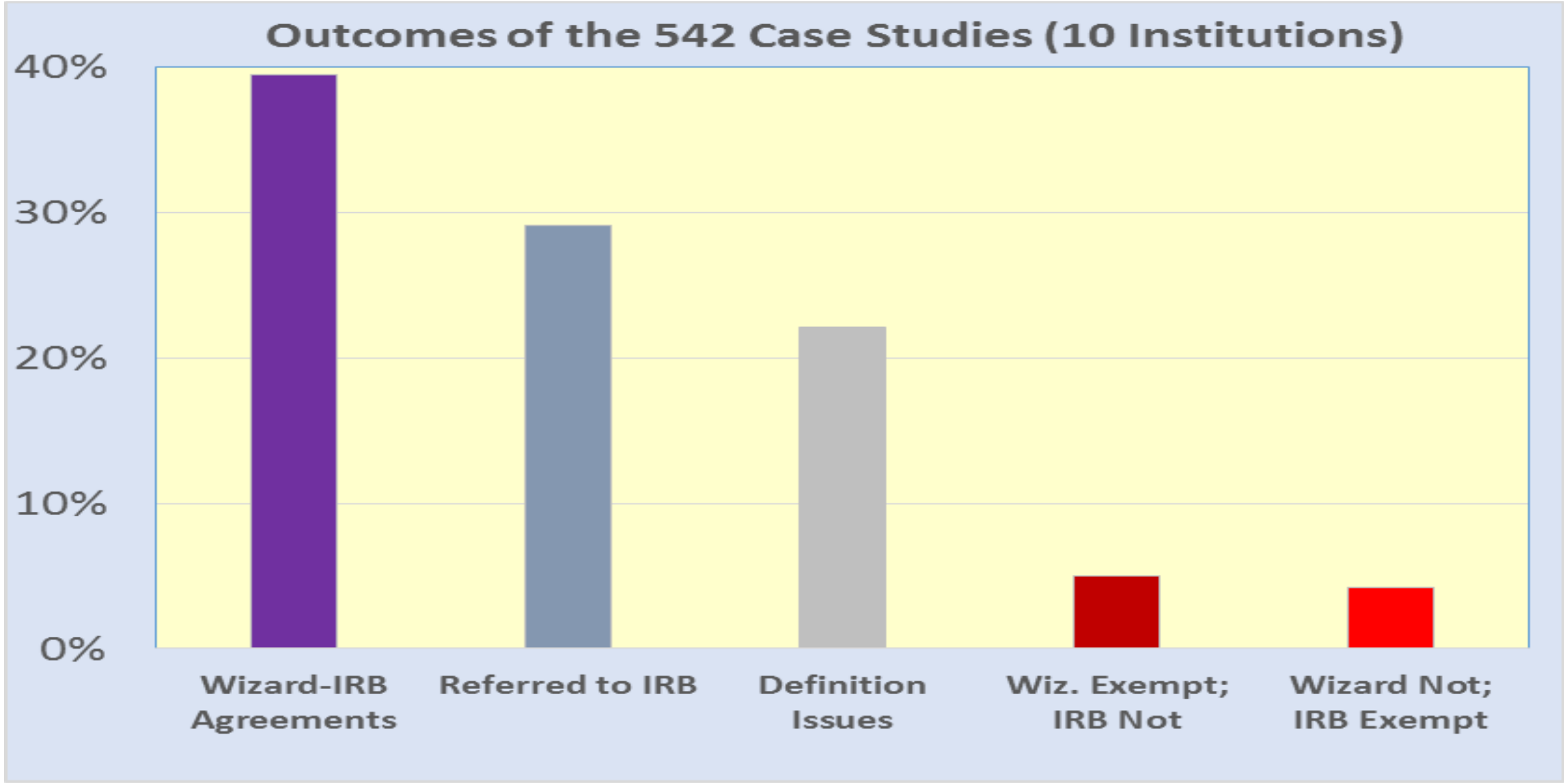
Wizard Demonstration Goals

- **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



Wizard-Institution IRB Agreements: Exempt

Exempt Category	(of 130 Studies) Prevalence (%)	Minimal risk studies involving
1	15	educational settings involving normal educational practices
2	82	educational tests, surveys, interviews or public observation
3,4,5,6,?	6	Other or not specified

Wizard-Institution IRB Agreements: Expedited

Includes Expedited Category	Prevalence (% of 52) (Often multiple categories cited)	Limited set of minimal risk studies involving
1	0	drugs or medical devices
2	17	blood samples
3	2	biological specimens
4	46	noninvasive procedures
5	23	archival materials
6	27	recordings
7	87	behavioral measures
8, 9	4	special continuing review

Wizard-Institution IRB Disagreements

- **Wizard Said Exempt, Institution IRB Said Expedited (27 of 542; 5%)**
  - Problem with Wizard?
  - Overly strict IRB?
  - Inconsistent answers by PI?
- **Wizard Said Not Exempt, Institution IRB Said Exempt (23 of 542; 4%)**
  - Problem with Wizard?
  - IRB missed issue?
  - Inconsistent answers by PI?

Wizard Exempt vs Institution IRB Not Exempt

With 16 of 27 institutional responses received:

9 – IRB judged project greater than minimal risk due to potentially identifiable, sensitive information
(but PI judged project as minimal risk in Wizard)

4 – potentially identifiable data but minimal risk research
(Could these be exempted?)

1 – intervention beyond surveys, observations
(Do people disagree on criteria?)

1 – potentially vulnerable population (minors)
(PI did not answer 'yes' to this question in the Wizard)

1 – IRB re-review changed judgment to Exempt 2

Wizard Not Exempt vs Institution IRB Exempt

9 of 23 studies: Issues Identifying Typical Classroom Activities

Does your research involve different treatment groups, or other types of interventions?

Specifically, does the research involve any intervention that goes beyond educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior? Example: You have some subjects who receive different services, tests or interventions that another set of subjects does not receive (the control group)? If so, answer yes.

Answer YES

Does the research ONLY involve educational practices? For example, typical classroom activities?

Answer NO

Wizard: **Stop (Not Exempt);**

but IRB judged measures to involve **typical classroom activity**.

Wizard Not Exempt vs Institution IRB Exempt

8 of 23 studies : Issues Selecting/Recognizing Fit to Procedure Category

Will the *only* involvement of human subjects be in one or more of the following categories?

- Research conducted in established or commonly accepted educational settings, involving normal education practices?
- Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
- Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?
- Research studying, evaluating, or examining public benefit or service programs?
- Research involving taste and food quality evaluation or consumer acceptance studies?

Answer NO

Wizard: **Stop (Not Exempt)**;
but IRB judged measures to **fit in one of these categories**.

Wizard Not Exempt vs Institution IRB Exempt

6 of 23 studies: Issues Identifying Normal Educational Practices

Does the project involve normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Answer NO

Wizard: **Stop (Not Exempt);**

but IRB judged measures to **involve normal educational practices**.

Reasons Studies Referred to Institution IRB

- **relationship to participants** (90 studies; e.g., client-therapist, student-teacher)
- **vulnerable populations** (37 studies)
- respondent suggested **no consent process** (vs consent form; 16 studies)
- **confusion** over **convoluted wording** re: public officials as participants (8 studies)
- **international or culturally sensitive** study content (8 studies)

Definitional Issues - Research

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(d)]

If the intent of the project is to generate conclusions which can be applied to or be predictive of similar circumstances then answer yes. If the intent is to generate knowledge about a specific circumstance then answer no.

Definitional Issues – Human Subjects

- Activity is research. Does the research involve obtaining information about living individuals? [45 CFR 46.102(f)]
- Answer YES if the research will obtain information concerning living individuals, regardless of whether it is obtained directly or indirectly from the individuals. Answer NO if the research will not obtain information about living individuals. Note. If information will be obtained FROM individuals, answer NO only if the information to be obtained does not reflect anything about the individuals (or others), including their attitudes or opinions. Example: Workers' reports of the output of a machine typically would not be considered information about the workers, so NO would be the appropriate response. However, workers' reports of their satisfaction with the work environment would provide information about the workers' personal views, so YES would be the appropriate answer in that case.

Wizard Demonstration Next Steps

- Follow-up to Complete Wizard Demonstration
  - Finish summarizing **causes of/remedies** for Wizard-IRB **disagreements**
  - Review Wizard **referrals to IRB** to resolve cases in Wizard when possible and divert to IRB sooner if not
  - Fix identified **pathway problems** (issue with erroneous“incompatible” message)
- Proposal for Related Initiative
  - With collaborating institutions, review **definition issues** regarding OHRP-defined research and human subjects to identify likely areas of confusion
  - Initiate **working group** to develop methods that help everyone understand and agree on the OHRP-intended meaning of both terms

→Please come to our initial meeting in **Yosemite Room (2nd floor)** at the next session (**2:20-3:35 p.m.**)

Future Directions for the Wizard

- Make changes informed by Wizard pilot
- Add in new exempt categories
- Add in limited IRB review pathway

→ Conduct expanded demonstration?