

FEDERAL DEMONSTRATION PARTNERSHIP

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Proof of Concept: Use of a Wizard for Self-Determination of IRB Exempt Status

**Prepared by the Federal Demonstration Partnership Human Subjects Subcommittee of the
Research Compliance Committee**

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The FDP IRB Wizard Pilot: Final Report

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In 2012, the Federal Demonstration Partnership (FDP) conducted a survey to examine the amount of time that federally-funded faculty spent on administrative rather than scientific duties. The results of the 2012 FDP Faculty Workload Survey (http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pgasite_087667.pdf) showed that federally-funded researchers report spending an average of 42% of their research time on administrative tasks. One of the most time-consuming activities was completing procedures required for assuring the protection of human subjects. Although all agree that protecting human subjects is essential, there is also broad agreement that the process could be made more efficient.

One of the most promising targets for potentially reducing unnecessary administrative burden is the large subset of research projects that involve minimal or no risk to participants. Many of these qualify for exempt status based on the categories described in the Office of Human Research Protections (OHRP) regulations, which allows for an abbreviated review process. The regulations state the criteria for exempt status but do not require that the review of these criteria be conducted by an IRB administrator or board member. Provided a record of the review is kept, the review could potentially be conducted through an automated self-review. The goal of the FDP Wizard Pilot was to provide a proof of concept showing that an electronic smart form, or “wizard,” could allow investigators to accurately self-determine exempt status through an automated process.

The wizard was created based on OHRP guidelines, adhering closely to decision flowcharts that the OHRP makes available on its website. Special considerations included: adoption of language throughout that would be acceptable to regulatory agencies, availability of all answers about each project in a database for IRBs to track, and a researcher-friendly interface. There was also recognition that a built-in mechanism would be needed to identify projects that would be difficult to assess within the wizard and to refer these instead to the IRB for review (for example, when vulnerable participant populations are involved).

Once developed, initial testing showed that researchers could evaluate their project in less than 15 minutes. If successful, this suggested an enormous potential benefit to researchers, giving them an almost immediate determination if the study were indeed exempt. It also suggested a large potential savings in IRB staff time for all those exempt projects that could be resolved by the wizard without further review.

Wizard Pilot Study Method

The purpose of the wizard demonstration was a **proof of concept**; that a smart form could be used as a part of IRB Human Subjects study reviews to identify many exempt studies. It was not intended to be a final product, but to assess plausibility and identify areas for future development. Criteria for

development included: use of language acceptable to regulatory agencies, sufficient information for IRBs to track, a built-in mechanism to identify “it depends” situations for referral to IRBS when necessary, and a researcher-friendly interface.

To determine how well the wizard would function, we enlisted the help of 10 volunteer universities. They asked investigators whose studies had already been reviewed by the IRB to also complete a review by the wizard. These investigators independently completed the wizard process, answering its questions until a determination was made.

The pilot concluded with complete data from 542 studies. In order to be considered complete, the study had to be fully reviewed independently via the wizard and by the university’s IRB. Personnel from the university’s IRB had to record their determination (without knowledge of the wizard outcome) and forward it to us for comparison.

Wizard Pilot Results

Results for the 542 case studies were separated into two sets. The first set included the 264 studies (49%) that received a final decision regarding exempt or non-exempt status by both the Wizard and the Institution’s IRB. The second set included the remaining 278 studies (51%) that were flagged at some point during wizard processing, and deemed ineligible for a final evaluation within the Wizard. Both of these sets were instructive. The completed set was evaluated to see the level of agreement between the Wizard and Institution IRBs, and the flagged set was evaluated to determine (1) the prevalence of various issues that might preclude use of the Wizard and (2) possible areas for refining the Wizard to improve its usefulness.

Completed Evaluation Set (264 Studies)

Figure 1 shows the results for those studies involving Wizard-IRB agreements. Among the 264 studies that were fully reviewed by both the institutional IRB review and the Wizard, there was 81% agreement overall between the board and wizard, for projects deemed both exempt and expedited. This rate is promising and demonstrates that the wizard can be successful in allowing investigators in many cases to accurately self-determine exempt status, or to learn that their projects should not be exempt when given a “not exempt” determination by the Wizard.

Among the exempt studies, we noted that over 60% were minimal risk studies from Exempt Category 2 involving “educational tests, surveys, interviews, or public observation,” with just over 10% from Category 1 of “educational settings involving normal educational practices.” This suggests that some applications of the Wizard (at least early on) might benefit from a simplified structure that would process only the subset of exempt categories that most often apply.

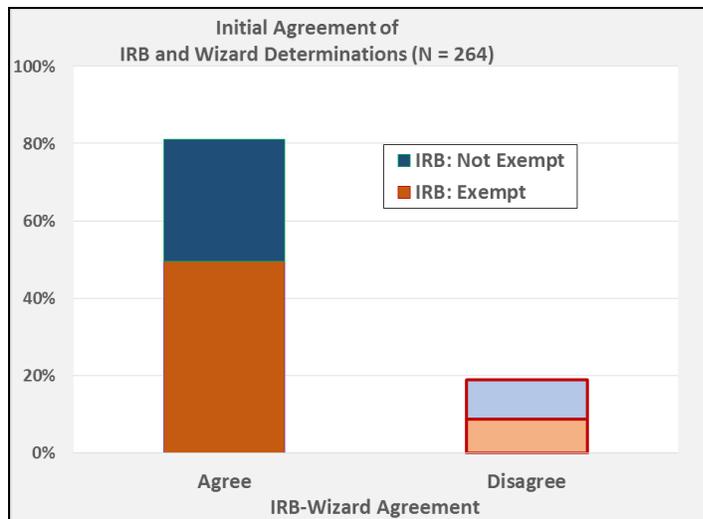


Figure 1. Agreement in Wizard and IRB Evaluations for the 264 Completed Evaluation Studies

Despite the admiral performance of the Wizard, there were also a number of cases in which the wizard and IRB determinations differed. We evaluated these discrepancies to determine their likely cause.

The type of **disagreement** of greatest concern would be a case in which the wizard judged a study as **exempt, when the study actually required expedited** review. This type of disagreement occurred for only **27 of the 264 studies (10%)** with cases occurring across five of the 10 volunteer universities. In these cases, the wizard judged the study as exempt, whereas IRB evaluation assessed the study as expedited. There are three potential explanations for discrepancies: (1) a **weakness** of the **wizard**, (2) **overly strict standards** in the institution's **IRB** review, or (3) **inconsistent answers** provided in the IRB application versus on the wizard.

In an attempt to determine the cause of the 27 disagreements, we asked institutions to provide additional information about their judgments in those cases. On review, 10 of these studies were judged to have been classified with overly strict standards and could have been exempted, thus cutting the number of disagreements down to 17 (6%). Nine of the remaining disagreements involved inclusion of what the IRBs deemed sensitive information (e.g., potential reports of criminal behavior or substance use), five involved potentially identifiable information--without distinguishing between studies with sensitive and non-sensitive information, two involved an intervention that was deemed non-exempt, and one involved a potentially vulnerable population. All of these cases suggest the benefit of adding clarifications to the Wizard to help investigators better identify study characteristics that may be outside the scope of exempted status. Based on the discrepancies we plan to add exclusion questions to the next version (wizard 2.0) to specifically ask about sensitive populations and interventions as well as clarifying when identifiers play a role in determining exempt status (sensitive versus non-sensitive information).

The other type of **disagreement**, wherein the wizard judged a study as **not exempt, but the institution's IRB exempted** the study, occurred for **23 of the 264 studies (9%)**, with cases across five universities. There are **three possible explanations** for these discrepancies: (1) the wizard may unnecessarily recommend **over-review** of studies that should be exempted, (2) the institution's IRB evaluation may

have **missed an essential feature** of the study that would bar it from an IRB exemption, or (3) **inconsistent answers** may have been provided on the IRB application compared to the wizard. If this represented an error by the wizard, it would have fewer negative repercussions given that the protocol would be referred to the IRB for additional review, but to avoid unnecessary burden, it was important to avoid inasmuch as possible.

To review these cases, we went back to the Wizard review to see at which point investigators were given the non-exempt determination. In nine cases, investigators reported that their intervention that was not educational in nature, eight did not select an exempt category, and six agreed that the study would be in an educational setting but would not involve normal educational practices. In all of these cases, the IRB deemed the studies to be within the range of acceptable practices for exempt status. Here again, clarification in the Wizard might help achieve consensus. For each of these situations, we plan to clarify language in wizard 2.0 to help the investigators better select appropriate answers.

Flagged Set (278 Studies)

The mechanism to identify studies that could not easily be assessed by the wizard worked effectively but also suggested that there is room to fine-tune the wizard. Roughly half of the studies that were entered into the Wizard were flagged due to particular answers that suggested the need for additional review by the IRB. Figure 2 displays the results of our examination of the different reasons for this review.

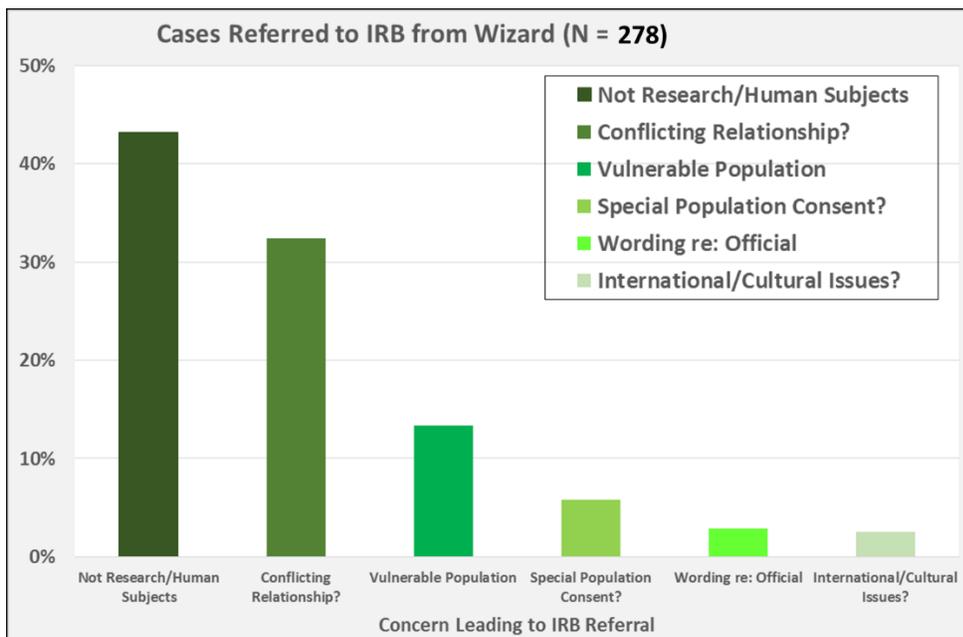


Figure 2. Reasons Studies Were Flagged in Wizard for Additional IRB Review

Over 40% of referrals were caused by what seemed to be trouble interpreting the federal definitions of “research” and “human subjects.” In over 100 studies, investigators’ answers suggested that their projects were not research or did not involve human subjects, despite that fact that this determination was made for only one study by the IRB. Because this suggests that these OHRP definitions can be hard to interpret, we plan to add clarifying questions to the wizard 2.0 to assist investigators in properly

determining whether or not their study meets the federal definitions of “research” and “human subjects.” Thus, we believe many of these studies can be successfully processed within the wizard.

There are some cases, however, that may not be appropriate for self-review. These make up the remainder of cases that were flagged by the wizard for IRB review. About 30% of the cases were referred to the IRB because the investigator reported some type of relationship with the study participants (e.g., instructor–student, healthcare provider–patient, staff–client). The remaining cases were referred for IRB review because the study might be sensitive due to its international or cultural context or participants included potentially vulnerable populations, special populations wherein consent might be needed, or officials requiring special considerations. For wizard 2.0, we plan to ask questions that will exclude these kinds of cases early on, so that investigators become aware of which considerations make a study unsuitable for self-review even if it may be eligible for exempt status. This will also increase efficiency by flagging the concern before completing the bulk of the wizard items.

Conclusion

As a proof of concept, our results suggest that the wizard pilot is a success. The pilot demonstrates the promise of a self-determined, automated system for allowing investigators to determine exempt status, at least for a large subset of projects. The wizard also shows promise for identifying studies that require additional oversight, either because they cannot be exempted, or because the judgment requires sophistication not yet incorporated in the wizard. The wizard also has potential to be a quick and user-friendly method for researchers to use, reducing administrative burden for both investigators and staff, while providing a detailed record of responses leading to any exempt determination. With the help of the IRB community, we hope to continue to refine the wizard to create a useful tool for gaining efficiency in the review of low risk human subjects studies.