

IRB NEWS

Brought to You by the Harvard University Area IRB
Committee on the Use of Human Subjects



October 2019

In This Month's Issue!

- AAHRPP Highlight – Institutional Policies: Finders Fees
- Mechanical Turk (“MTurk”) Attention Checks
- Key Tips for IRB Submissions
- Do You Speak IRB? Broad Consent



AAHRPP Highlight – Institutional Policies: Finders Fees

Yes, we know, we've been mentioning the Human Research Protection Program (HRPP) plan a lot lately. Well, how could we not? It's a great document that provides a comprehensive overview of not only what constitutes our HRPP, but also the scope of our IRB's purview, an overview of the key players in the HRPP, as well as the various regulations that the HRPP and IRB take into consideration.

One aspect of the HRRP that is just as important as the federal regulations are local policies and guidelines. That's right – in addition to the various federal regulations (e.g., Common Rule, HIPAA, FERPA, to name just a few), the Harvard University Area IRB (HUA IRB, that's us) must enforce Harvard institutional policy and guidance.

One such Harvard institutional policy outlined in the HRPP plan pertains to "finder's fees". Specifically, from page 6 of the HRPP, "This Institution prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees") and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments")" as such payments may increase the likelihood that the person referring potential subjects may be influenced by the promise of compensation and not act in the best interest of the individual.

Interested in other Harvard institutional policies? Check out the HRPP plan [here](#) – *just be certain to be logged into ESTR before clicking on the hyperlink.*



Key Tips for IRB Submissions

Did you know that the Harvard IRB office provides tips on how to speed up the review of your IRB submission? Yep, that's right. And, that one of the main culprits for a longer than usual review is inconsistent or incomplete information? It's true! To find out what some of these other tips are, check out our website [here](#). Interested in knowing more IRB secrets? Check out the "Guidance" tab on our [website](#). Its located smack-dab in the middle of our main page.



Mechanical Turk ("MTurk") Attention Checks

No, we are not talking about the fake chess-playing machine that was constructed in the late 18th century but rather, the online crowdsourcing marketplace platform developed by Amazon. Amazon refers to this platform as "MTurk". The MTurk platform is very popular among researchers as they can post various Human Intelligence Tasks (HIT's) on the platform to be completed by individuals (known collectively as "Turkers" or "crowdworkers") who complete these tasks for compensation.

Turkers are a very connected community and when one Turker comes across an issue with a HIT, it is very quickly shared with others in the community. One such issue that has been a popular topic among Turkers is the use of "validity checks" also known as "attention checks" in HIT's. So, what is a validity check? A validity check is a method to ensure that the responses provided by the Turker are legitimate and not just randomly generated responses. Often only those responses that pass a validity check (if used) are compensated. However, not all HIT's include a validity check and when they do and a Turker

is not paid, someone will know about it, often the IRB office.

If you plan on using a validity check in your MTurk study, here are some suggestions from our IRB colleagues, courtesy of the IRB Forum blog:

- Include language in the informed consent form or information sheet (depending on the IRB review level for your study) that says something along the lines of, “This study will contain a number of attention checks. If you fail these checks, your HIT will be rejected.”
- Indicate in the HIT posting that validity checks are embedded in the survey.
- Explain the use of validity checks in the IRB Protocol and whether or not someone will be compensated according to the validity check.



Do You Speak IRB? Broad Consent

The concept of **broad consent** has been in existence for quite some time. This concept rests on the idea that there may be uncertainty about how an individual’s data or biological specimen may be used in the future. This is how it works: An individual will consent to their sample being used once at the beginning of a research experiment. If additional analyses need to be performed or new experiments are designed, the individual isn’t contacted again, provided the new research isn’t a significant deviation from what was agreed to initially.

How the IRB reviewed the downstream use of the data or specimen largely depended on the identifiability of the material. If the material was identifiable (and therefore considered a [“human subject”](#)) when distributed to others, an IRB would need to consider whether the individual consented to that use. For

example, did the original consent state that the sample would only be used for cancer research and now it is being used for Alzheimer's research?

With the revised regulations that were implemented earlier this year, the above 'concept' has now been codified into regulation. Specifically, **broad consent** may be obtained in lieu of the standard informed consent process for the secondary use of identifiable material. **Broad consent** is not a waiver of consent, but an alternative method of obtaining permission.

So how does **broad consent** work? Well, **broad consent** is only to be used for repositories, biobanks, or other "banking" models that qualify under some very specific exempt review level categories: Category 7 (45 CFR 46.104[d][7])[[1](#)] and Category 8 (45 CFR 46.104[d][8])[[2](#)]. When an individual is approached to place their data or specimen in the bank, under the new regulations, a **broad consent** form may be used. Unlike other informed consent requirements, there are many additional specific criteria that must be included in the **broad consent** form.

Broad Consent does sound cool but there is a downside. In fact, this downside is why our federal regulators have given IRB's the option of implementing **broad consent** at a local level. Okay, here it is: If an individual is asked to provide broad consent and the individual "refused to consent," an IRB cannot waive consent for the storage, maintenance, or secondary research use of that person's identifiable private information or identifiable biospecimens as long as that data or specimen are in existence. Basically, a researcher would need to keep track of an individual's wishes ad infinitum. Given the challenges of ensuring compliance with this requirement, Harvard has decided not to implement **broad consent**. In fact, it is uncertain if there is any institution that has implemented **broad consent**.

If you would like to learn more about **broad consent** (the good, the bad, and

the ugly), check out what the Secretary's Advisory Committee on Human Research Protections (SACHRP) had to say [here](#).

[1] Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

[2] Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.