Coercion, Undue Influence, and Protections in Participant Recruitment

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Human subject regulations require investigators to design a consent process that minimizes the possibility of coercion or undue influence. The term “coercion” is often over-generalized to reference a broad range of practices that could occur in study recruitment. For instance, describing an excessively large stipend as “coercive” is technically not accurate.

-Coercion” is the use of real or perceived threats of harm that are intentionally presented in order to obtain compliance or achieve a result.

“Undue influence” by contract, occurs through an offer of an excessive or inappropriate reward which is impactful enough to cause someone to make a choice without adequate attention to the consequences.

Coercion vs. Undue Influence

While in most cases the practice of compensating research participants is ethically acceptable, investigators and IRBs are charged with determining fair compensation and making reasonable judgments about how payment might affect participation. Some factors to consider include the type of research (e.g., first-in-man vs. post-marketing), participant requirements, local norms, and study population (e.g., patients vs. healthy participants). Also consider potential vulnerability (e.g. children, impaired consent capacity); whether the participants feel free to refuse; and whether their situation could put them in a position that would impair their judgment.

At the University of Kentucky, the investigator describes the terms and schedule for incentives or monetary compensation offered to participants in the IRB Research Description. IRB’s are encouraged to consider whether payments are so high, they could cause someone to act against his or her better judgment or if payment is so low, it may be considered exploitative.4

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Many models and approaches exist for determining appropriate compensation. Research participants may be provided payment in appreciation for their effort and contribution in general or they may be reimbursed specifically for time, inconvenience, effort, and out-of-pocket expenses such as travel, childcare, parking, etc. Researchers and IRB members can gain a “first-hand” perspective on the time and effort involved by joining a study as a research participant.

UK recruitment guidance calls for all information concerning payment, including the amount and schedule of payments to be described in the informed consent document/process. Payment should not be contingent upon completion of the entire study. IRB policy requires partial or prorated payment be offered to preserve a participant’s decision to exercise his or her right to withdraw at any time.

The UK Office of the Treasurer policy, “Compensation to Research Subjects or Survey Participants” provides options, procedures, and required documentation for compensating participants at UK.

See links below for resources and additional detail.

References & Resources
1. FDA Information Sheet: Payment to Research Subjects
2. FDA Information Sheet: Recruiting Study Subjects
3. OHRP Frequently Asked Questions: Informed Consent
4. The Ethics of Compensation for Health Trail Participants, Quorum Forum, Fall 2015
7. University of Kentucky (UK) Office of the Treasurer Compensation to Research Subjects or Survey Participants policy

Transition to E Review: Incremental Steps

While ORI and Research Information Services (RIS) continue with the development of the electronic IRB submission program, ORI is implementing steps to shift to a paperless process.

The following are status updates and goals for implementing preliminary, incremental steps in advance of the eventual transition to a fully functional E-IRB submission system:

- **SharePoint Review & Electronic Submission Pilot:**
  Select departments and divisions are participating in a pilot project to submit PDF or electronic versions of initial IRB applications intended for review by the full, convened IRB.

- **Fully Electronic Exemption Application Submission:**
  ORI is in the process of transitioning to managing IRB EXEMPT protocol submission exclusively by email. This new process will be effective March 1, 2016. Instructions are available on the ORI website at [http://www.research.uky.edu/ori/human/HumanResearchForms.htm#XX](http://www.research.uky.edu/ori/human/HumanResearchForms.htm#XX)

In addition to being environmentally conscious and saving investigator time, these incremental steps will help the IRB reviewers begin to transition to reading and assessing IRB submission materials in an electronic format.