Compensation and Advertising

Compensation

The federal regulations require that the Institutional Review Board (IRB) review and approve the methods used to recruit participants, including compensation, to ensure that they do not include coercion or undue influence. However, the regulations do not set specific limits on payment of research subjects or offer definitive information to guide the IRB in their review. International codes are similar to the federal guidelines and include statements such as the World Medical Association’s Declaration of Helsinki which indicates that “researchers should provide information regarding incentives” for IRB review.

The Office for Human Research Protections (OHRP) IRB Guidebook discusses several payment models such as payment based upon the number of visits or procedures to be performed, time involved, anticipated discomfort or inconvenience, etc. Models proposed by Dicker and Grady include: the market model (i.e., supply and demand), wage payment (i.e., compensation based upon standard wages for unskilled labor), and the reimbursement model (i.e., compensation for gas, parking, etc.).

The International Ethical Guidelines for Biomedical Research Involving Human Subjects provide the most definitive statement regarding compensation:

> Subjects may be paid for inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research; they may also receive free medical services. However, the payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment (“undue inducement”).

The Food and Drug Administration (FDA) requires prorating payments based on duration of participation in the research so that subjects are able to receive compensation even if they don’t complete the entire study. The FDA also indicates that payment to research subjects should be considered an incentive to participate rather than a benefit. Therefore, the IRB does not consider compensation in their assessment of the risk benefit analysis for the proposed research.

Based on these guidelines, the ISU IRB requires the amount of compensation provided to participants to be described in the Human Subjects Review Form and communicated to participants during the consent process. As noted above, compensation should not be described as a benefit to participants. If applicable, a clear description of how prorating will be handled must be included.

Advertisements

The IRB must also review advertising used to recruit participants to assure that it does not create undue influence and is not misleading. This is of particular importance in studies involving people who are economically or educationally disadvantaged or who suffer from severe physical or mental illness.

Advertisements used to recruit study subjects should state only the information needed for prospective participants to determine their interest and eligibility. The following items may be included in the advertisements:
1. The name and address of the investigator and/or research facility
2. The condition under study and/or the purpose of the research
3. A summary of the criteria that will be used to determine eligibility for the study
4. A brief list of participation benefits, if any (e.g., a no-cost health examination)
5. The time or other commitment required of the subjects
6. The location of the research and the person or office to contact for further information

The amount of compensation for participation may be included in the advertisement but should not be overly emphasized (e.g., by placing the dollar amount in larger font or bold letters, placing prominent dollar signs throughout the ad, including statements such as “Do you want to earn extra cash?” etc.). Rather, a simple statement such as, “You will also receive up to $XX for your participation in this research,” may be included.

References

- 45 CFR 46 Protection of Human Subjects (Department of Health and Human Services)
- 21 CFR 50 Protection of Human Subjects (Food and Drug Administration)
- Council on International Organizations of Medical Sciences “International Ethical Guidelines for Biomedical Research Involving Human Subjects”
- FDA Information Sheets
- Institutional Review Board Management and Function, Bankert and Amdur
- Office for Human Research Protections IRB Guidebook
- World Medical Association Declaration of Helsinki “Ethical Principles for Medical Research Involving Human Subjects”