Chapter 24
Payment to Research Participants

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Payments to research subjects help alleviate the cost of time and resources for participation. Payments can come in the form of money, gifts, free medical care, or travel reimbursement. Compensation can have positive effects. Compensation has been shown to increase survey response rates and willingness to participate [1]. The United States has a longstanding tradition of paying human subjects, with famous surgeons such as William Beaumont in the 1800s and Walter Reed in the early 20th century providing monetary compensation to study their subjects [2]. The National Institutes of Health has regularly paid "normal" healthy volunteers for participation since the 1950s.

The U.S. Food and Drug Administration permits advertisements of payment to subject participants, however payments and the amount must not to be emphasized (such as with larger or bold type) [3]. The Council of Organizations for Medical Sciences advises that payments not be so significant that volunteers "take undue risks," as this violates free choice [4]. A distinction needs to be made between coercion and inducement. Coercion is an extreme influence controlling a person's decision violating autonomy and is hence inherently unethical. An inducement is a motivating factor that is not inherently coercive but can become so in certain negative circumstances; thus, an inducement is not necessarily unethical. The distinction also depends on the socioeconomic status of the subject, as one person's undue inducement may hardly solicit the interest of someone with higher means. Macklin attempted to clarify the ethical ambiguity of the term inducement by

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separating it into two different types: due versus undue inducement. Due inducements are usually based on an established, reasonable fee-for-service schedule, often at minimum hourly wage with additional small compensation amounts for providing laboratory samples or to participate in a more unpopular study. Undue inducements cause subjects to lie, deceive, or conceal [5]. An example of undue inducement would be monetary recompense far exceeding a wage the subject would earn with other gainful employment. Emanuel highlighted four key features of undue inducements: that they produce a positive good, are irresistible, produce bad judgment or they cause an action causing substantial risk of serious harm [6].

Several concerns arise when considering payments to research participants. Participants may conceal information for concern of possible disqualification from the study. Some argue against all inducements that expose patients to risks under concern that they lead to inequity in the research process [7]. A skewed sample may occur when money attracts lower income individuals [8]. Furthermore, payments for research involving children should be approached with extra caution. Payments may alleviate the cost and inconvenience of allowing children to participate in research, but they may also sway parental decision-making [1].

Dickert and Grady proposed three models for payment. The market model is based on the economic model of supply and demand, with payment justified by the need to pay subjects for recruitment. The wage payment model is based on standard wage payment for unskilled labor, compensating for time and effort. The reimbursement model provides compensation for expenses incurred and lost wages, but is problematic in leading to unequal payments of subjects depending on their income. The wage payment model is the most ethically favorable option as it reduces undue inducement and standardizes payment [3].

In keeping with the ethical principle of nonmaleficence–that is, to avoid harming others–if harm comes to research subjects due to their participation in a clinical trial, the International Ethical Guidelines for Biomedical Research Involving Human Subjects recommends “free medical treatment for such injury” and compensation for any disability. In case of death, the research participant’s dependents are ethically entitled to compensation. Research subjects should not be asked to waive their right to compensation. Whether the pharmaceutical company, organization, institution, government, or investigator is liable for these costs should be determined when designing the study [4]. However, these are ethical rather than legal mandates [9]. In 2012, only 16% of academic medical centers in the United States compensated research participants injuries, and none did so for lost wages or suffering [10]. Personal health insurance still remains the main source of compensation in the event of injury. Although other countries, the NIH Clinical Center, and the University of Washington have transitioned to “no fault” schemes of payment for injured subjects, the vast majority of medical centers are still laying the burden of compensation on the individual researcher [11]. It is incumbent on every researcher to be fully aware of the compensation plan at his or her institution and research subjects must be fully informed of what options for compensation will be available in the event of a research-related injury.

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