

**OFFICE OF HUMAN RESEARCH AFFAIRS (OHRA)**

**COMPENSATION VS REIMBURSEMENT GUIDANCE**

Overview:

The terms compensation and reimbursement are often used when referring to human participant research. Both concepts are applicable for research and permitted, although, compensation and reimbursement may not cause undue influence or coercion and affect voluntary informed consent. The concepts are not interchangeable in the context of human participant research. If compensation or reimbursements are utilized, a detailed plan of use must be included in the informed consent, which will be reviewed by the IRB.

Definitions:

***Compensation*** refers to the payment given to the participant for their time, discomfort and inconvenience of participating in the study.

***Reimbursement*** refers to the payment given to the participant and/or family members for the additional expenses of participating in the study. (i.e. reimbursement of the out-of-pocket expenses made by the participant (e.g. travel expense, transportation, lodging, etc.)). This allows for greater diversity of participants from locations across the country.

* Reimbursement includes the off-set costs for certain studies where participants may need to purchase an item/device or be charged for participation in the study (e.g. co-pays). Reimbursements would be applied for any submitted costs as seen appropriate.

FDA Statement on Reimbursement:

In January 2018, the FDA released a statement ([FDA Reimbursement Statement](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects)) regarding their stance on reimbursement that encourages researchers to use reimbursement and compensation in their study but does so in a fair and just way.

IRB Review:

Compensation and reimbursements should never be classified as a benefit. IRB members will examine benefits and risks separate from compensation and reimbursement. Additionally, the IRB will review the monetary value as well as the timing of payment release to participants to assure no coercion and undue influence.