



Compensation of Human Subjects in Research	Document No.:	HSC-2021-004
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A. Purpose

This policy sets forth the expectations of the Human Subjects Committee (HSC) regarding the compensation of human subjects participating in research at Lawrence Berkeley National Laboratory (Berkeley Lab).

B. Persons Affected

- Principal Investigators, study coordinators, and anyone else involved in the experimental design of research proposals involving human subjects.
- HSC members performing review of human subjects protocols that include compensation.

C. Exceptions

Human subjects participating in Berkeley Lab research may be appropriately compensated unless they fall into one of the following exclusion categories:

- Employees of Berkeley Lab are prohibited from receiving incentive payments.
- Other possible groups *may* include employees of the funding source, other institutions performing the research, vulnerable populations, or other groups established on a case-by-case basis.

D. Policy Statement

The Human Subjects Committee’s review of proposed research includes an assessment of the amount of compensation/financial incentive proposed for participants in the study. Federal regulations do not give specific guidance regarding compensation; however, they do require that the investigator “minimize the possibility of coercion or undue influence.” [45 CFR 46.116, 21 CFR 50.20, 10 CFR 745.116] Compensation of research subjects is considered appropriate in many instances to account for the time and inconvenience of participation, however the amount must be reasonable and not considered to be exerting undue influence on the person’s choice to participate.

1. HSC Review

The HSC reviews the amount of payment, as well as the proposed method and timing of disbursement of payments to ensure that there is no undue influence being exerted.



Compensation can include monetary payments (cash, gift cards, etc.) or non-monetary rewards (gifts, course credit, etc.). All details regarding compensation must be described in detail in the study protocol, as well as in the informed consent. *Compensation is not considered a benefit to subject participation and is not taken into account when the HSC weighs the risks and benefits of the research.*

2. Allowability

In some cases, those in authority such as DOE program managers, will question the use of federal money to compensate subjects. Here are some notes from the Financial Office on the allowability of compensation to subjects:

- FAR subpart 31.2 does not exclude them;
- As long as the incentive cost follows the rules for allowability it is acceptable:
 - Reasonableness,
 - Allocability,
 - Applicable Cost Accounting Standards (CAS); otherwise, generally accepted accounting principles (GAAP) and practices appropriate to the circumstances,
 - The terms and conditions of Contract 31,
 - Any rules or limitations described in FAR subpart 31.201-2 as supplemented by DEAR subpart 970.31 and/or specific clauses in Contract 31.

3. Amounts

Generally, there are no hard limits to the amount (See Federal Employees section 6 below for an exception), but participation must remain be voluntary, based on the real risks and benefits of the research, and therefore compensation must not be so high as to coerce participation, nor to compel the individual to lie in order to meet inclusion criteria. Subjects should not see research participation as a way to make a living or regularly supplement their income. All compensation amounts should therefore be commensurate to the amount of time and effort participants commit to complete the study.

If the total compensation for the year exceeds \$600 you must report the name and contact information of the subject to the accounts payable office (Aphelp@lbl.gov) so that the subject can be sent an FW9 form for IRS purposes. This can be difficult because it removes the ability of the research to remain anonymous and makes protection of privacy much harder. For this reason, it is *highly recommended* that, when possible, the total amount within one calendar year paid to a single subject be kept below \$500 to avoid coming close to that mark. There are cases in which subjects (this is particularly true of students) participate in more than one study a year and cumulative compensation may approach that \$600 mark, or be over it. Thus, this question should be added to any screening/consent form where compensation is being added: “Have you participated in



another Berkeley Lab/LBNL study within this same calendar year? [yes/no] If so, how much have you been compensated?"

4. Timing and Method of Disbursement

In addition, it is recommended for studies that include multiple timepoints of participation, that compensation be prorated over the course of participation instead of given as one lump sum upon completion. This is to avoid compromising the perceived ability of the subject to withdraw from the research at any time. While total compensation should not be contingent upon completion of the entire study, it is acceptable to offer a small bonus to subjects who complete all scheduled study sessions.

Forms of payment may vary and include alternatives such as gift cards or prepaid online codes, however it is required that the method of payment be readily accessible to the participants and appropriate to the population.

Distribution of compensation should be performed directly by a person or entity performing the research. This can be completed in-person, via email, or mail, but cannot be done through a third-party. For example, a building management company cannot distribute payments to residents who participated if they are not contracted as performing the research. More details regarding distribution of research incentives can be found in Procurement's Customer Guide on the subject [*See implementing documents below*]. All processes regarding research incentives in the protocol are required to match subcontracts when the subcontractor is performing distribution.

5. Lotteries and Raffles

There are various federal guidelines as well as state regulations that are applicable to lotteries and raffles. Be aware that research conducted with Berkeley Lab funds in other states must follow that state's laws in addition to those of California.

California law (Penal Code §319) prohibits conducting lotteries. (Any person who prepares or operates a lottery, furnishes lottery tickets, or assists in conducting a lottery is guilty of a misdemeanor.) A "lottery" is defined as including three elements: (1) distribution of property/prize(s); (2) distribution of the property/prize(s) by chance; and (3) distribution of the property/prize(s) "among persons who have paid or promised to pay any valuable consideration for the chance of obtaining such property" (e.g., conditioning eligibility on purchase of an entry ticket or product). There is some question as to whether agreeing to participate in a research study constitutes "payment of valuable consideration." Consider this excerpt from the California Department of Consumer Affairs, "Courts have used certain rules to decide whether a scheme includes consideration because it is not always clear. If a person is eligible to win a prize without purchase, there is no consideration and the contest is legal. In such a case, if some people may pay money - for example, an admission charge or a product - there is not necessarily consideration if other people may enter without such a purchase. If eligibility to win a



prize is limited to those who have paid money, however, there is consideration. Alternatively, if some persons must pay in order to have a chance at a prize while others do not, there is consideration.”

In consideration of this statute, UC Office of General Counsel has provided the guidance outlined below.

- a) Researchers should use the term “drawing” or “sweepstakes” rather than “lottery” or “raffle,” since the latter terms imply purchase of tickets by participants.
- b) To further avoid the possibility that a drawing would be perceived as a lottery, the protocol should describe procedures for ensuring that all individuals who are contacted concerning the research will be allowed to enter the drawing. This would encompass individuals who are invited to participate but decline, prospective subjects who are ineligible, and subjects who enroll but later withdraw/are withdrawn by the researchers. Additionally, the protocol should affirm that the drawing may be entered by any individual who asks to be included.
- c) The protocol and consent document(s) should also include the following information:
 - i. Description of the prizes, including estimated value, and the total number of prizes to be awarded.
 - ii. The odds of winning a prize, if known, or explanatory language similar to this: “For any drawing, the odds of winning a prize depend on how many people are entered in the drawing. As we do not know how many people will participate in this study-related drawing, we cannot predict what will be the odds of winning a prize.”
 - iii. The approximate timing of the drawing (e.g., month/year).
 - iv. A fair method of determining the winner, and an explanation of how prizewinners will be notified.

6. Financial Incentives for Federal Employees

Federal employees have numerous restrictions regarding the receipt of compensation for outside activities. The use of research incentives for this group therefore has many barriers. The following 3 scenarios are the most likely, though exceptions may exist and can be brought to the HSC for determination.

- a) Compensation is strictly prohibited to employees of LBNL, or if the funding source for the study is the same as the employer of the subject.
- b) Compensation of a maximum of \$20 is allowed if the study population is recruited specifically because of their role as federal employees, or if the subject



of the study is directly tied to the job duties of the federal employee. This limited compensation amount is determined by 5 CFR 2635.204(a) which indicates that a gift of \$20 or less is considered exempt from the established restrictions on gifts from prohibited sources. The form of compensation is specifically prohibited from being any cash equivalent defined in the regulation as "... a gift card that is issued by a credit card company or other financial institution, because such a card is equivalent to a gift of cash."

- c) Compensation of a subject recruited entirely independently of their role as a federal employee *may* be considered appropriate under the 5 CFR 2635.204(e) exception regarding outside activities. It is likely that this incentive payment would need to be reported by the individual to their employer, and possible that prior approval may be necessary in order for the subject to participate. It is therefore expected that in the case of a subject population recruited from the general public that is likely to include federal employees, language be included in the consent forms and other materials to make the individuals aware of this potential conflict, and to collect verification of eligibility for compensation. These situations will be assessed on a case-by-case basis by the HSC and the Procurement office, and adequate justification of the need to include these subjects will be required.

E. Roles & Responsibilities

Role	Responsibility
Research Study Personnel	Accurately and thoroughly describe all compensation details in the protocol, informed consent documents, and (when appropriate) the recruitment materials. Maintain a Payment Log according to the requirements of the OCFO (see G. Recordkeeping below).
HSC Committee Members	Performing a thorough review of all compensation amounts and methods to protect potential subjects from undue influence.

F. Definitions/Acronyms

- a. **Compensation:** the act or state of compensating, as by rewarding someone for service or by making up for someone's loss, damage, or injury by giving the injured party an appropriate benefit.
- b. **Undue Influence:** (1) Influence by which a person is induced to act otherwise than by their own free will or without adequate attention to the consequences. (2) Undue influence [...] occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. (From The Belmont Report)



- c. **Lottery:** A lottery is any scheme for the disposition of property by chance among persons who have paid or promised to pay any value for the chance of obtaining the property, with the understanding that it will be disposed of by chance. As defined by California Department of Consumer Affairs.
- d. **Research:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition and do not fall under one of the exclusions at 45 CFR 46.102(l)(1)-(4) constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes.
 - i. **Systematic Investigation:** a study or examination involving a methodical procedure or plan.
 - ii. **Generalizable knowledge:** The information is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:
 - Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied. OR
 - Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
 - Usually includes results shared at conferences and public forums, included in abstracts, or published in journals or other literature, outside the institution.
- e. **Human subject:** A living individual about whom an investigator (whether professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. In clinical research, a subject is someone who becomes a participant in research, either as a recipient of the test article or as a control.
 - i. **Intervention** includes both physical procedures by which data or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
 - ii. **Interaction** includes communication or interpersonal contact between investigator and subject.

G. Recordkeeping Requirements

Documentation of all compensation details will be maintained as a part of the study protocol in the HARP system.

The Responsible Individual identified by Procurement is required to maintain a Payment Log



(for a 7-year period) that shall include: the unique project identifier, incentive information (date purchased, the dollar amount, the last 4 digits of the payment card (if applicable), the date delivered to the study participant), and the names of all personnel handling the incentive payment from purchase to distribution. In the case of studies without collection of identifiable information, some other format of identifying individuals is allowed, such as a code or number, however it must be clear how many individuals received incentive payments, and if a single individual received more than one amount so that totals can be accurately tracked.

H. Implementing Documents

Document Number	Document Title	Type
N/A	Human Subjects Committee	Website
N/A	Human/Animal Research Protocol Management System	Website
N/A	Customer Guide for Human Subjects Research	Guidance
N/A	Customer Guide for Research Incentives	Guidance
N/A	Approval to Purchase Research Incentives	Form

I. Contact Information

[Human and Animal Regulatory Committees Office](#)

HARC@lbl.gov

(510) 486-5399

J. Revision History

Date	Revision	By whom	Revision Description	Section(s) affected	Change Type