Guidance for Human Subject Participant Payments on Sponsored Awards

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A. Getting Started

University research that involves humans, human tissue, subject surveys/tests, or the use of human subject records require Institutional Review Board (IRB) review and approval regardless of funding source. IRB protocols with funding provided by a sponsored award should be submitted as early as possible. In many cases, new protocols are submitted at the “Just in time” (JIT) notification when provided by sponsoring agencies, or at least 30–45 days prior to the anticipated award start date.

Prior to initiating any process for paying a human subject participant, both of the following items must have been approved and verified:

1. An IRB Protocol has been submitted, approved and linked with the awarded project’s aims and objectives.
2. Expected payment(s) to participants match the Informed Consent that has been approved by the IRB (which is typically signed by the enrolled participant, when applicable, as not all informed consent requires signature).

Additional guidance on the IRB process, may be found on the IRB website at research.uconn.edu/IRB.

B. Introduction: OVPR-SPS award setup activities for human subject payments

At time of award and setup of the sponsored project into the InfoEd and Kuali Financial System (KFS), the Office of the Vice President for Research, Sponsored Program Services:

a. Reviews the Internal Proposal Review (IPR) form to determine if the project includes human subjects.

b. Verifies an IRB protocol has been reviewed and approved by the IRB office in accordance with relevant regulations and linked to the sponsored award.
   
   o If an IRB protocol approval is not linked to the sponsored award, the subject incentive budget (if applicable) is withheld from the budget entry, and the department/PI is notified. Once the IRB protocol is approved and linked to the award within the InfoEd system, the subject incentive budget is loaded in the KFS financial system. No human subject research can occur until IRB approval has been obtained.

   o If the Human subject activities of the project are to occur at a later date (i.e., during second six months or year 2 of the project), the SPS Post-Award unit withholds the subject incentive budget (if applicable) and follows up with PI on the IRB status when applicable. No human subject research can occur until IRB approval has been obtained.
c. Reviews the approved budget to see if it includes human subject payments.

d. Reviews the proposal and/or reaches out to the department to identify how participants are planned to be paid. If cash payments are anticipated to be made using a research advance account or gift cards purchased on the PCard, SPS establishes a 4 ledger subject advance account at the time of the awards’ setup so that it will facilitate and be available to the department and Principal Investigator (typically, only one 4-ledger subject advance account needs to be established for an investigator who has multiple studies with participant payments). The advance may be requested on-line within the Kuali Financial System (KFS) by completing a DV and route to Accounts Payable. For more information on requesting a Research Advance, please refer to the Advance Guide and Training Video located on the Accounts Payable website.

C. Human subject participant payments and documentation standards

In most studies it is imperative that the institution protects the confidentiality of human subjects. Information and details that pertain to each subject participant must be maintained in the investigator’s records and stored in a safe and secure location that will ensure the confidentiality of the participant and their study record.

- For studies where participants are to be kept confidential, each participant enrolled in the study should be provided an enrollment number or code, which de-identifies the participant when referenced in any document that may be publicly accessible.

- Study logs should be created and securely maintained that cross-reference the name of the subject and their enrollment identification number and/or code.

- When applicable, signed consent forms must be obtained by the investigator from the subject participant and securely maintained as part of the investigator’s record.

- The PI or his/her designee must maintain proof of payments made to research subjects for both cash and non-cash payments. This proof can be in the form of a payment log, electronic payment list with unique identifier, or pre-numbered department receipts. Any participant receiving payment in person should sign a participant log or receipt to acknowledge receiving payment. These records are not to be submitted when documenting payment(s) for reimbursement but are to be made available to an auditor or university official for inspection, when requested. All documents are to be securely maintained as part of the investigator’s record. A log listing the participant’s identification number/code, number reference from the signed pre-numbered receipt and monetary value and date of the payment should suffice for backup documentation when submitting a DV.

Reminder: If there are any departures in the amount(s) paid to participants, please remember that you must obtain approval from the IRB for an amended human subject protocol and related informed consent forms prior to providing payment.

D. Complying with IRS regulations

If compensation to any one human subject exceeds, or is expected to exceed, $600 in any calendar year, then the PI or his/her designee must obtain a valid and signed Form W-9 (www.irs.gov/pub/irs-pdf/fw9.pdf) from the Human Subject (noting, however, that certain Foreign Nationals will not be able to complete Form W-9. Please see below for further guidance regarding Compensation to Foreign Nationals.)

To ensure proper tax reporting, Form W-9s must be delivered to Accounts Payable, along with record of the date and amount of payment(s) to the Human Subject, by the second week of January immediately following the calendar year of payment.

Please note that compensation does not include properly documented reimbursements made in accordance with University Travel Policies and Procedures, if applicable. Accordingly, the $600 threshold described above is determined exclusive of such reimbursements.

Note: The University recognizes that there may be certain projects where the confidentiality of the subject is so great that the collection of these documents may not be possible.
Compensation to Foreign Nationals

Payments to Foreign Nationals for their participation in human research studies conducted in the United States may be subject to income tax withholding pursuant to Internal Revenue Code Section 1441(a) of the U.S. Income Tax Code. For research studies that involve only the participation of UConn students and/or employees, the nationalities and residency statuses of the participants are known by the University and, therefore, the University must determine if income tax withholding is required on the remuneration payments made to the Foreign National participants. It is advised that the PI contact the Tax and Compliance office (referenced in Section H below) prior to making a payment to a student or employee to determine if the person is a Foreign National and whether income tax withholding is required. In some instances, withholding will not be required because the Foreign National will meet one of several tax withholding exceptions.

When conducting studies where either the nationality of the participant(s) are known to be foreign or is self-identified by the participant to be foreign, income tax withholding is required on payments of cash and cash equivalents (i.e. gift cards). In the instance of these payments, the PI may be required to withhold tax from the gross payment amount due to the Foreign National at the applicable rate (generally 30%) as communicated by the Tax and Compliance office. The amount of cash withheld for income taxes will need to be credited to KFS Account # 9018324 (NRA Fed Inc Tax Whld) which will then be transmitted to the U.S. Treasury Department. In instances where cash has been provided to the student or employee before the PI realizes that the individual is a Foreign National or in the instance where a gift card was given to the Foreign National, the withholding tax on the remuneration must be paid out of other project funds.

Payments to Foreign Nationals for studies conducted entirely outside of the US are exempt from IRS tax withholding; however, payments being made to individuals or entities outside the U.S. does require a review and verification to ensure that financial assistance is not being provided to a blocked or sanctioned individual/entity. This verification is fairly routine and does not take long to perform. Contact Carol Connolly at ExportControl@uconn.edu for assistance or refer to section H below for additional contact information.

E. Current methods available for paying human subject participants

1. Research advance and corresponding 4 ledger advance account.
   
o Overview:

Currently at UConn, the majority of human subject payments are performed under this mechanism. An advance is considered a loan by the University to the investigator or requestor. The amount of funds requested and advanced is recorded in a unique 4-ledger subject advance account tied to a specific project and investigator. When the investigator/department submits the initial request for an advance (explained in the next bullet below), the request will route through SPS for approval. SPS verifies that the correct 4 ledger account is referenced and edoc contains all required documentation. Once verified, SPS approves and the DV routes to AP for processing. SPS personnel then records a corresponding encumbrance in the amount of the advance on the sponsored awards’ grant account to reflect a commitment exists against the human subject participant budget line-item.

In general terms, the cash advance is disbursed to the participants as payments; those disbursed payments are then processed by either DV or Distribution of Income and Expense (DI) through the University’s financial system; the payment(s) made to the participants are recorded as an expense to the grant account, and the recorded advance amount in the 4 ledger account is either decreased by completing and routing a DI or replenished by completing and routing a DV for the amount(s) disbursed.

o Requesting a Research Advance:

To request a research advance, the department submits a DV e-doc request within KFS for the initial advance amount. Research advances are recorded in object code 1175 on the 4 ledger subject advance account; the 4 ledger accounts’ title should include a reference to the corresponding sponsored grant...
account number. *If a 4 ledger human subject advance account has not been established, please contact your SPS team member for assistance (Refer to section H below for contact information).*

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The initial advance request should include a copy of the:

i. Signed Promissory Note, obtained from Accounts Payable (AP); and  
ii. IRB protocol approval letter that corresponds to the sponsored awards’ activity; and  
iii. Copy of the subject incentive budget that details subject payment amounts and totals

The request, after submitted by the department, routes to the OVPR SPS post-award unit for review and approval, then to AP for processing and disbursement.

For detailed procedure and process information on requesting and submitting a DV for an advance, please refer to the *Accounts Payable Advance Guide* and *Training Video* located on the Accounts Payable website.

- **Q & A Guidance for using the Research Advance method:**
  - **i. How soon should I request an advance before funds are needed?**  
    Ideally, an advance should be requested approximately 4 weeks prior to the time needed.
  - **ii. How much money should be requested when I ask for an advance?**  
    Typically, the amount requested for the advance should *not* equal the total amount budgeted for participant payments on the award. Rather, the amount requested should represent an amount that will meet your needs until a *DV* is processed and your advance is replenished. To be safe, allow 10 working days for approvals, disbursement and replenishment to be completed. *For example*, if you submit a *DV* on a weekly basis, plan to have enough advance funds to last for approximately 3 weeks of participant payments.

Advances may be either spent down (*DI*) or replenished (*DV*). For studies and payments that span several months to several years, the replenishment method works the best. Conversely, one time activities such as out-of-country studies that occur only during the summer months, a lump sum amount to cover subject payments for the duration of the trip would most likely work best.

- **iii. How frequent should a DV/DI be submitted for recording the subject payments and replenishing my advance funds?**  
  A *DV* or *DI* to process payments made to participants on a sponsored account may be submitted and processed as often as daily but at a minimum should be performed no less than on a monthly basis.

- **iv. a. Can I pay non-U.S. persons or an entity while traveling abroad?**  
  University activities that involve the international payment of funds to non-U.S. persons abroad need to be verified to ensure that the university is not inadvertently providing financial assistance to a blocked or sanctioned entity. *Prior* to any payment, the PI or his or her designee must contact OVPR’s Export Control Officer at *exportcontrol@uconn.edu*, if their activity involves payment to persons or organizations outside the U.S.

- **b. Can I use my advance to pay for other out-of-pocket charges, including nominal payment for volunteers or individuals providing services that are associated with the same sponsored award?**  
  It is *not* advised to pay and submit these type expenses within your DV disbursement or replenishment request. Participant payments processed as part of the advance are coded in the financial system as subject payments, and any other type expenses processed in this
fashion are often miscoded and improperly recorded in the University’s financial system. The most appropriate method in reimbursing other related type project, non-participant payment, expenses is to set the individual(s) up in Payment Works as a vendor and request reimbursement by using a separate DV so that they can be coded appropriately and properly documented. By using this method, the step in iv.a. above is automatically performed as part of the vendor’s setup into the payment system.

v. **What type of documentation is required to be attached to a DV/DI when replenishing or depleting a research advance?**

A payment log containing participants assigned patient/participant number, pre-numbered receipt, amount, and date disbursed will be sufficient documentation to attach to the DV or DI e-doc.

Please keep in mind that payment logs containing the subject names and other personal identifiable information are not to be attached to the DV/DI request in order to maintain participant confidentiality. It is also important to remember that the information presented in the payment log (such as the patient/participant number) attached to the DV/DI should allow for a monitor or inspector to trace the payment(s) back to the following: an enrolled study human subject participant, a copy of the receipt signed by the human subject participant acknowledging receipt of payment and their signed consent form.

For more information and guidance on the documentation standards necessary for the payment of human subject participants, please refer to section C of this document titled: **Human subject payments and documentation standards.**

2. **Gift Cards**

Gift cards used to compensate human subject participants can be issued in various forms and formats. They may exist in the form of physical cards, certificates, email vouchers, HuskyBucks, or credits on merchant web sites. Gift cards are typically purchased with the procurement cards (PCard) issued by UConn procurement office; however, **the purchase of gift cards using the PCard is by prior approval only**. Please contact the PCard Administrator or submit the PCard/Gift Card Pre-Approval form in HuskyBuy before any purchase of gift cards (refer to section H below for contact information). **As a general rule, gift card purchases should not be charged directly to a federal sponsored award until after the cards are provided to participants for their involvement in the study.** Similar to the research advance disbursement process described above, the costs associated with the payment of subjects should be charged to a 2-ledger or 4-ledger discretionary account and processed, after payment(s) are made to the human subject participant, by preparing a DI form in KFS transferring the expense to the sponsored award.

For physical cards, maintaining a strict and rigorous inventory control monitoring and disbursement system for gift card management can often be challenging, especially when there are multiple interviewers and disbursement agents involved in the study. The information presented below represents general guidance for the management, documentation and disbursement of gift cards at UConn.

**Gift Card Purchase and Management:**

- First, purchase the number of gift cards that is anticipated to be disbursed over the next one to two months. Additional cards can be purchased as needed, but it is difficult to return them.
  
  - Gift Cards can be purchased using the UConn procurement card with prior approval by the PCard Administrator only as outlined in the **Procurement Card User Manual, Section 1 – Restricted Purchases.**
  
  - Gift cards should be charged to a non-sponsored, discretionary, account. As cards are distributed to participants for payment, the cost associated with those distributed cards may be transferred via a DI form in KFS to the grant account.
Second, after purchasing and receiving the gift cards,:
  i. Create a gift card inventory control log by making a complete list of the cards purchased that includes their unique card number and additional columns to record participant information as cards are disbursed that includes:
    a. the identification number or code (not the name of the participant) given to the participant whom receives the card, and
    b. the number of the receipt or gift card number/code of the distributed card(s), and
c. the date that the gift card was provided to the human subject participant.

  NOTE: A copy of the gift card inventory control log, containing no personal information of the participant, will be attached as support documentation to the DI when charging the sponsored grant account (refer to the fourth step below).

ii. Make sure to store the undistributed gift cards in a locked and secure location with access limited to the investigator or designated staff.

iii. Purchase of on-line certificates for web based studies are to be purchased on a 4 ledger subject advance account until the certificates are distributed to the participants. PI and researchers should maintain a list of all participants, along with their corresponding de-identified study ID or unique identifier, whom enrolled and received payment. A DI to transfer the cost of the distributed certificates can be performed as frequently as daily, but should be performed no less frequently than monthly.

Third, when disbursing the card to a participant in person, have each participant sign a pre-numbered receipt that acknowledges receipt of the card and records: the date the participant received the card, the last 5 digits of the card number given to the participant, and the gift cards’ monetary value.

Fourth, prepare and submit a DI to charge the disbursed gift card(s) to the sponsored grant accounts’ human subject participant object code and credit the non-sponsored discretionary account where the cards were originally charged when purchased. Remember to attach a copy of the completed gift card inventory control log for each card disbursed that includes the participant’s identification number/code and receipt number so that the cards can be easily accounted and tied to the study.

Fifth, when possible, segregate the duties associated with the purchase, storage, payment, and DI processing of the gift cards to strengthen internal control management and oversight.

3. Standard Disbursement Voucher (DV) through UConn Accounts Payable

This method is rarely used and is only used for those studies that do not require the confidentiality of the enrolled human subject participants to be maintained. In addition, payment is provided by mail after participation is complete. This method requires two basic steps:
  o First, the individual must be setup as a vendor in the Accounts Payable vendor file.
  o Second, the investigator or department submits a DV within KFS to issue a check to the individual after their participation.

4. Providing incentives (t-shirt, book, Huskybuy, etc.)

Incentives other than cash payments should be specifically spelled out in the proposed budget to the sponsor and should identify what item is planned to be provided in order to incentivize enrollment. It is important to remember that when purchasing any incentive(s), Procurement Policies and Procedures must be followed.
  o Typically, incentives are treated similar to gift cards. However, incentives such as t-shirts and books do not often have unique identification numbers. Emphasis is placed on the study participant logs and/or pre-numbered receipts with signatures or unique identifier, of the participants for documentation support (refer to the gift card purchase and management section above).
Nominal valued incentives such as a pencil or candy provided to participants should be documented in the budget, and the quantity purchased should be reasonable for the number of participants enrolled.

F. Donations to Charities on Behalf of or In-Lieu of Human Subject Participant Payments

Federal Uniform Guidance Section 200.434, Contributions and Donations state “Costs of contributions and donations, including cash, property, and services, from the non-Federal entity to other entities, are unallowable.”

For non-federal sponsors - unless the terms of the grant or contract clearly authorize a usage not consistent with University policy titled “Use of University Funds for Gifts, Social Functions, Sponsorships & Donations”, Donations are not permitted.

For University or Institutional funds – University policy titled “Use of University Funds for Gifts, Social Functions, Sponsorships & Donations” identifies under section IV that Donations of University Funds are not permitted. Exceptions to this policy may be approved on a case-by-case basis by the President, Provost, and their authorized delegates.

G. Monitoring, review and closeout of the Advance and 4-Ledger account

Monitoring & Review

- SPS approves the advances and replenishments when the DV is submitted through KFS. SPS will review the DV to make sure on the initial advance that the IRB approval and Promissory Note match the sponsored project and the correct object code (1175) is being used.
- UConn Accounts Payable monitors the activity of all the advances issued on 4 ledger accounts that correspond to a sponsored project. UConn Accounts Payable informs SPS if a DV to either replenish or DI to reduce the advance is not submitted within 30 days. SPS will contact the department for a status on the advance to ensure proper monitoring.
- Departments and Principal Investigators must monitor the disbursement and reconciliation of the 4-ledger advance and charging of payments to the sponsored account; Ensure confidentiality of subjects are maintained by preparing de-identified DV/DI requests that properly charge human subject participant payments to the sponsored award on a timely basis, no more than 30 days from disbursement, and submit replenishment as needed or a research advance closeout request once human subject participation is complete.
- When receipts are submitted to reduce an advance, SPS will prepare and submit a corresponding entry to unencumber the grant account by the same amount as the submitted receipts.

Closeout of Advance

- When the project is complete, or human subject participation on the project is complete, unused subject advance funds should be returned to Cash Operations. Before returning funds to Cash Operations, the department/principal investigator should process a Cash Receipt (CR) e-Doc in KFS to return the excess cash to the University crediting the corresponding 4-ledger subject advance account, object code 1175. For more information on completing and processing a Cash Receipt e-doc, please refer to the KFS Cash and Accounts Receivable Guide for a step-by-step procedure. A final reconciliation should be done by the department by submitting a DI to reduce the advance. Please refer to the Accounts Payable Advance Guide and Training Video located on the AP website for information on how to submit a DI e-doc in KFS.
- SPS will perform a final reconciliation to ensure that the receipts submitted match the expense recorded on the grant and that the cash advance line 1175 has been reduced to “0”.

H. Contacts

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### Offices of the Vice-President for Research

#### Sponsored Program Services

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<th><strong>Accounts Payable</strong></th>
<th>Telephone: (860)486-4137</th>
<th>Email: <a href="mailto:travel@uconn.edu">travel@uconn.edu</a></th>
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<th>SPS Team Lead in Sponsored Program Services: Telephone: <strong>(860)486-3619</strong></th>
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