Title: Payments to Research Participants (Human Subjects)

Additional References and Appendix Materials:
A.1. Authorization for the Purchase of Gift Cards/Gift Certificates, Incentives or Prizes Form at:
   http://www.ecu.edu/cs-admin/purchasing/index.cfm
A.2. Identity Theft Protection Committee (ITPC) disclosure language
   http://www.ecu.edu/cs-its/itssecurity/Sensitive-Data.cfm
A.3. Study Voucher Authorization Form; Study Participant Voucher Form; Study Cash Advance Request Form
A.4 Imprest Cash Fund
   http://www.ecu.edu/cs-admin/financial_serv/acc/Imprest-Cash-Funds-and-Change-Funds.cfm
A.5. Contractor Services
   http://www.ecu.edu/cs-admin/purchasing/contract/ContractHome.cfm
University & Medical Center Institutional Review Board (UMCIRB)
   http://www.ecu.edu/irb/
Clinical Trials Office
   http://www.ecu.edu/clinicaltrials/
OMB Circulars, A-133, A-21, and A-110 at
   http://whitehouse.gov/omb/circulars/index.html
Office of Civil Rights HIPAA Requirements
   http://www.hhs.gov/ocr/privacy/
Specific Sponsor Guidelines
ECU Business Manual

All forms attached are provided as examples and may be subject to periodic updates by their authorizing office. Before processing any requests, the appropriate website should be checked for the most current version of the necessary form(s).

1. PURPOSE:

The purpose of this policy is to outline the business practices and alternatives available to ECU Principal Investigators (PI) when compensating individuals for participation in either a sponsored research program or an independent research project.
1.1. Some sponsors authorize payments to human subjects participating in a research program. In accordance with sponsor guidelines, these may be in the form of monetary payments or as a reimbursement of costs or as a cash equivalent payment for services or goods. State and federal regulations, audit requirements, and good management practices also require that institutions maintain systems with adequate financial controls that minimize the risk of loss or fraud and that appropriate annual tax forms are issued when required by IRS regulations.

2. **PRIOR APPROVAL REQUIREMENTS:**

The anticipated need for compensation to human subjects for participation in a research program must be clearly described in the proposal to the sponsor and in the human subject protocol that is submitted to the University & Medical Center Institutional Review Board (UMCIRB) for approval. Payments to human subjects may not be made without prior UMCIRB disclosure, approval for incentives, and the completion of the subject’s informed consent document(s).

2.1. No human subject payment of any type may be made for a research subject without an approved UMCIRB protocol. (See additional information on the UMCIRB website.)

2.2. All costs charged to a sponsored project must be reasonable, allowable, allocable and necessary, and must be incurred within the award period. The Office of Grants and Contracts (OGC) will verify that subject payments are allowable under the specific sponsored agreement.

2.3. No payment of any type may be made to a research subject, from a sponsored project, without approval by OGC that subject payments are authorized under the specific award. OGC will review the award for general approval for payments, but will not necessarily need to review or preauthorize all individual transactions. OGC may issue an authorizing statement that the PI will attach to multiple transactional documents.

2.4. OGC may disallow costs when incentives have not been approved in the award or they are otherwise prohibited by sponsor terms or when there is no UMCIRB approval for human subjects.

2.5. For non-sponsored, internally funded research programs, the PI and an appropriate departmental administrator will determine the appropriateness of payments and will assure that there is UMCIRB approval before any type of payment is made.

2.6. To ensure that all purchases are in compliance with sponsor and university guidelines, prior approval should be obtained before making any purchases. An Authorization for the Purchase of Gift Cards/Gift Certificates, Incentives or Prizes form, found on the Materials Management (MM) website (See A.1) should be approved prior to making any purchases. The form is submitted for a single study, research project or event. A new study, project, or event will require submission of a new authorization form. Requests for approval should not combine multiple projects.

3. **SUMMARY OF ALTERNATIVES:**

There are no exceptions to the payment alternatives listed below or the procedures outlined in this policy without prior written approval from both the Director of the Office of Grants and Contracts and the Director of Materials Management or the Director of Accounts Payable (AP).
3.1 ECU supports alternative methods of compensating individuals for participation in a research study based on the needs of the study and sound accounting practices. These methods are:

1. Check to the individual;
2. Cash, via the University Cashier's Office (UCO - east campus), Health Sciences Depository Services (HSDS – west campus) or a petty cash replenishment (Imprest Fund);
3. Gift card or gift certificate (includes gas cards); and
4. Non-monetary item or service typically purchased on behalf of the participant through an ECU ProCard or processed as a reimbursement to an ECU employee who made the original purchase.

3.2. Because of significant internal control and administrative advantages, the best method of compensating individuals for participation in a research study is with an ECU check processed through the Direct Payment Form (see AP website) or the Contractual Services Payment Request Form process (see MM website). Under specific circumstances and with prior approval, compensation via cash, gift card or a non-monetary item may be appropriate.

3.3. Regardless of the specific method of payment, a record of a subject’s signed receipt acknowledging the type and value of the payment received should be kept. In addition, the PI must keep a record/log of all payments (of whatever type) made on behalf of the research subject.

3.3.1. All information about human subjects should be maintained in a secure location and data, logs, receipts, etc., whenever possible, should be maintained in a de-identified manner (e.g., participant code used - not name or social security number; electronic data encrypted). The Identity Theft Committee (ITPC) website has information available about securing identifying information and the use of social security numbers.

3.4 All methods of payment are potentially taxable income to the recipient. If the participant receives $600 or more per calendar year identifying tax information will need to be maintained and reported. For each study, the PI must maintain cumulative documentation/logs of all payments or other incentives made to each individual. On a calendar year basis, Jan-Dec, the PI must review payment documentation to determine if any individual received $600 in payments from the study. If any subject receives $600 or more from the project the PI must report this information to AP by no later than December 20th of each year.

3.4.1. IRS regulations require that ECU issue a 1099 to any individual who receives $600 or more in compensation (including incentives for research participation). It is the responsibility of the recipient to report these payments on their annual tax return.

3.4.2. For those projects where it is anticipated the participant will receive more than $600/year, the PI must obtain social security number information and a home address for 1099 reporting. It is strongly recommended that these participants receive all of their compensation/incentives/reimbursements by check.
3.4.3 The ITPC has established disclosure language to be used for protocol development and consent documents when it is necessary to document that social security numbers and other identifying information from human subjects. (See A.2)

4. PAYMENT ALTERNATIVES/DESCRIPTIONS:

4.1. Payment to Individual Via Check:

Subjects may be compensated for their research participation by check payment processed through ECU Financial Services. Although this method may require incremental administrative effort, payment via check substantially reduces the potential for loss or misappropriation of funds and helps assure compliance with IRS regulations. Any payment by check will require securing SSN and other identifying information from the subject.

4.1.1. Payee information should be transmitted to Accounts Payable (AP) using the Direct Payment Form or to Materials Management (MM) using the Contractual Services Payment Request Form. A completed W-9 should be attached to the payment form.

4.1.2. A check must be issued whenever payments to the individual exceed $600 per calendar year; either as a unit payment or as a cumulative payment to that individual. The PI records should track all payments to study participants on a cumulative basis.

4.1.3. In order to maximize participant privacy and to minimize administrative burden, the PI may choose to only request payment by check whenever payments to an individual are projected to exceed or are at the $600 threshold or when by the nature of the project or the participant’s circumstances other alternatives are not viable for the study.

4.2. Payment to Individual Via Cash:

4.2.1. Voucher Authorization Form:

Participants may receive payment through the Cashier’s Office (CO) or the HS Depositary Services (HSDS), utilizing the Voucher Authorization process. (See A.3.) The voucher process may be utilized either to give the payment directly to a participant who can access HSDS/CO or as a cash advance on behalf of the study. When used as a cash advance form, the PI must submit reconciling receipts and/or a refund within 2 business days from the payment date.

4.2.1.a The Study Voucher Authorization form is used to establish cash services for the study as a whole.
4.2.1.b The Study Cash Advance Request form is used when the PI wants a cash advance in order to directly distribute payments to participants.
4.21.c The Study Participant Voucher form is given to the participant and is used when the participant will go to HSDS/CO to receive cash payments.
4.2.2 **Imprest Cash or Change Fund**

Payments to research participants may be made using funds obtained through an Imprest Cash or Change Fund (petty cash) process (see A.4). Research programs that anticipate a very high number of low dollar payments to non-employees or for which payments via check or through the cashier process are impractical (e.g. research subjects are unable to negotiate checks due to status as minors, transients without bank accounts or payments/subjects are at field sites off campus, etc.) may use a petty cash process to pay participants. Establishment of such funds must be pre-approved by OGC and Financial Services. Because of the potential for loss or misappropriation of funds, this process is discouraged and will normally only be approved when there are mitigating circumstances for the study’s success. Imprest funds must be reconciled monthly.

4.2.3 **Employee Reimbursements on Direct Payment Form:**

On rare occasions, an ECU employee may personally provide the cash payment and be reimbursed through the Direct Payment Form process. This procedure should not be a common practice and should only be used under unusual or emergency circumstances when there is no viable alternative. In such cases, it will be extremely important to have adequate justification documents and signed receipts included as part of the payment request.

4.3 **Payment to Individual Via Gift Card or a Non-Monetary Item:**

For some studies, it may be appropriate to distribute gift cards or non-monetary items (e.g. memorabilia or supply items) to research subjects, in exchange for participation in the program.

4.3.1 **Examples:**

a. A PI conducting a study on drug addiction may prefer to issue gift cards or provide an item such as a tote bag, rather than checks or cash, based on concerns about the ultimate use of funds by study participants.

b. A PI conducting a study with teenagers may prefer to issue gift cards to a shopping mall or provide non-monetary items rather than checks or cash, based on the perceived preference of the recipient population.

4.3.1.1: In order to minimize any related administrative problems, the use of gift cards or non-monetary items should be considered and discussed, in advance, with UMCIRB as part of the protocol review, and with OGC and MM at the time purchase is anticipated. Requests should be submitted via the Authorization for the Purchase of Gift Cards/Gift Certificates, Incentives or Prizes form (A.1).

4.3.2 **ECU ProCard:**
Gift cards and non-monetary items may be purchased using an ECU ProCard with prior approval. An Authorization for the Purchase of Gift Cards/Gift Certificates, Incentives or Prizes form (A.1) must be completed and approved prior to making the purchase. The form will be used to establish an eligibility item and an estimated level of payment/cost for the study. The authorization form will need to be resubmitted for additional approval if the items to be purchased change or if the amount requested needs to be increased. For any ProCard purchase for gift cards or other incentive items, the original itemized receipts for the items purchased and the approved Authorization for the Purchase of Gift Cards/Gift Certificates, Incentives or Prizes form must be provided with the monthly cardholder statement. The PI must maintain a reconciling log identifying all cards/items distributed.

4.3.3. Employee Reimbursement - Direct Payment Form:

On occasion it may be appropriate for an ECU employee to purchase gift cards and non-monetary items and then be reimbursed using the Direct Payment Form process. Reimbursement to employees for purchases of gift cards and incentive items should be minimized and only used under mitigating circumstances. An authorization for the Purchase of Gift Cards/Gift Certificates, Incentives or Prizes form should be submitted and approved prior to making the purchase.

a. Any employee reimbursement for gift cards requires prior-approval by the Department of Materials Management. Approval may be requested via email to the Director of MM (taylorn@ecu.edu) before the purchase is made.

b. Any reimbursement request for gift cards or incentive items must attach appropriate documentation of the items purchased (e.g., receipts, a copy of the de-identified distribution log and program description and the approved Authorization for the Purchase of Gift Cards/Gift Certificates, Incentives or Prizes form, etc.).

4.3.4. The maximum value allowed for a single gift card is $100.00.

4.3.5. All gift cards and incentive items must be retained in a secure location with access limited to only appropriate project personnel. Gift cards and other incentive items must be treated with the same security concerns and cautions as cash.

4.3.6. At no time may the PI or any ECU employee use the gift cards or incentive items for personal use. All items must be used for legitimate purposes for the project. At the end of the award period or at the end of human subjects incentives for the project, any unused items must be refunded to the project fund (FOAP that made the purchase) and/or returned to Materials Management for alternate use approvals or refunds. Materials Management may authorize the department to retain the items for alternative uses for other university business but the sponsored project must be credited for the value of the item(s) not used.
4.3.7. If not received before the end date, OGC will require that reconciling logs and/or other appropriate documentation for gift cards and incentives be submitted to OGC for final financial reconciliation of the project fund.

5. UNIVERSITY & MEDICAL CENTER INSTITUTIONAL REVIEW BOARD:

5.1. Potential research subjects for whom compensation for participation will be appropriate should be told before signing a consent form that identifying information (subject’s name, mailing address, social security number) may be required as a prerequisite to payment by ECU. A subject may waive his/her right to payment if he/she does not want to provide the requested information. (See sample disclosure language A.2.)

5.2. As part of the UMCIRB protocol review, information must be provided on the anticipated methods and amounts of payment for participation in the research study. See UMCIRB procedures for additional information on protocol review for projects with human participants.

5.3. Incentives and reimbursements should be reasonable. Subject payments should not be so large that they provide an undue influence or inducement for subject participation in a study.

5.4. All appropriate disclosure forms must be signed by the research subject prior to receipt of any form of compensation, reimbursement, or incentive payment.

6. PARTICIPANT CONFIDENTIALITY:

HIPAA regulations, sponsor guidelines and university procedures mandate that patient and subject confidentiality be protected at all times during participation in a research program. This requirement may sometimes appear to be in conflict with IRS regulations which may require tax reporting for subject payments. When designing an incentive program, PIs must plan their project to both protect subject confidentiality and assure compliance with IRS requirements.

6.1. For subject payments less than $600 (or anticipated to be less than $600 annual cumulative) the PI may submit payment requests (for petty cash reimbursements, cash payments, gift cards or non-monetary items) with tracking logs or other information where the participant is de-identified and personal information such as name and social security number are not included as part of the backup documentation for the payment requests.

6.2. Whenever possible, the PI should submit payment requests without personal, identifying information of the individual participant. If the appropriate backup documentation includes some portion of identifying information (e.g., name or social security #) that portion of the document may be blacked out when attached to the payment request.

6.3. The PI should take into consideration the $600 threshold for tax reporting requirements when developing the protocol. Whenever possible, the incentive program should be designed so that no individual meets the $600/calendar year threshold.

6.4. It is the PI’s responsibility to secure name, social security numbers, and addresses from all participants (when necessary) and to maintain this information in secure project/program files. Although such information may not always be required as backup for each payment.
transaction submitted, it must be maintained when required for IRS or other program reporting purposes and it is subject to review and audit by sponsors and auditors. Failure to maintain adequate information on participants may result in disallowed costs, IRS audit, or other sanctions.

6.5. It is the PIs responsibility to maintain a log of payments to all study participants and to track cumulative payments for each participant to assure that the participant is not paid $600 or more, per calendar year, without receiving a 1099 for tax reporting purposes. If a subject does receive $600 or more in payments, this must be reported to AP by December 20th of each year. AP will need the full name, social security number, and address of the subject in order to issue the 1099. For projects where the sponsor budget period does not coincide with the calendar year, the PI may need to maintain cumulative records from multiple sponsor budget periods in order to track the calendar year payments for tax reporting purposes.

6.6. If a participant is anticipated to receive $600 or more in incentive payments, all the payment(s) should normally be made by check. If a participant is initially compensated through non-check methods, once the participant receives near or at $600 cumulative value, in a calendar year, all additional payments for that year must be made by check.

6.7. The PI must notify Accounts Payable that the participant has met the $600 threshold so that the university can issue a 1099 with the appropriate value (even if some payments were not made by check).

6.8. Costs may be disallowed if the PI does not maintain an adequate log and tracking system to identify subjects receiving incentives and the cumulative amounts paid to individuals.

6.9. Costs may be disallowed if the PI does not provide information for 1099 processing for study participants receiving $600 or more in payments within a calendar year.

6.10. All receipts signed by the subject should be maintained with the program log or other program documents and are also subject to review and audit.

7. PAYMENT FOR SERVICES OR GOODS:

7.1. Occasionally, the nature of the research project or the needs of the participant may make it necessary to purchase services or goods (e.g., babysitting, gas, transportation) rather than provide direct payment to the individual. In those cases, payment must be made directly to a vendor (via check/PORT/ProCard) or by reimbursement to an ECU employee, using a Direct Payment Form, with all receipts attached. Any payment for services or goods must have a valid receipt or invoice for the purchase.

7.2. If it is anticipated that there will be recurring services (e.g., babysitting, transportation) from an individual the PI should process a Contractor Services Form and process payments through that process. (See A.5)

7.3. When services or goods are procured for the participant the payment request should de-
identify the participant. However, as with other payments, the PI must maintain an appropriate program log and must track subject services provided. As with gift cards and cash payments, IRS 1099 reporting may be required for payments that exceed a value of $600/year.

8. **PAYMENT TO AN ECU EMPLOYEE:**

If the human subject is an ECU employee, all payments must be made by check through the payroll supplemental/incidental pay process. ECU employees may not receive cash or gift cards or non-monetary items as incentives for participation in a sponsored project.

9. **EXCEPTIONS:**

9.1. Occasionally, the nature of the research project (e.g., working with the homeless) may make it impossible to secure all necessary identifying or tax-related information from the participants. In such cases, the PI should contact OGC prior to making any payments and OGC will assist the PI in developing an appropriate tracking log and will coordinate with MM or AP to determine the most appropriate methods and procedures for providing subject incentives.

9.2. In all cases, the PI must make a good faith effort to collect the identifying data (when necessary) even when it is anticipated that this will be difficult to achieve.

9.3. Occasionally, due to the nature of the project or the circumstances of the participant, it may be necessary to provide payment to a third party (e.g., relative, friend or caretaker) on behalf of the participant (e.g., gas money for transportation). This should be avoided, whenever possible, and payments should normally be made directly to the participant or to a vendor. However, when that is not possible, the payment may be made to another individual with appropriate documentation and justification. The third party may be subject to tax reporting requirements if payments meet the $600/year threshold. In those cases, the identifying information (name, social security #, address) of both the third party recipient and the subject participant must be maintained. The service provided must be tracked as part of the log for the participant.

9.4. Both the subject and the third party must be informed and give consent prior to making payment to a third party. The subject and the third party may waive payment if they do not want to provide identifying information.

9.5. The form, documentation and approval requirements for a third party payment are the same as for the participant; based on the method of payment (check, petty cash, gift card, etc.).

10. **ADDITIONAL REQUIREMENTS:**

10.1. Advance purchases of gift cards, gas cards, or goods and services should be limited to the amount projected to be needed for a reasonably short period and based on anticipated subject participation. Gift cards and goods should not be stock piled and all purchases must be for a reasonable amount based on realistic project needs. Purchases should only be made on an as needed basis.

10.1.1. For example: A project anticipating 6 participants per month may reasonably purchase 6-12 gift cards in advance. The gift card stock would be replenished
every month or two or as needed by actual distribution. It would be inappropriate to advance purchase more than the projected need for 2 months of subject participation.

10.1.1.a The anticipated purchases plan (i.e., how many of what, at what value, how often) must be approved by OGC and MM. A copy of the authorization must be attached to each transactional request for payment. A new request must be submitted/approved if the maximum is exceeded.

10.1.2. The PI may negotiate for the provision of vendor services (e.g., babysitting or transportation) on an advance basis. However, no advance payment may be made for services. Any payment for services must be made only after or when such services are performed. All payment for services must have an appropriate receipt or invoice.

10.2. Prior to or at the end of the sponsored project budget period, any remaining gift cards or goods and services must be reconciled and liquidated. Unused items may not be charged to the sponsored fund or stockpiled and retained for some future use. The cost of the unused items must be transferred to another appropriate fund and credited to the sponsored fund. The cost of the unused items may not be reported against the sponsored project budget for reporting or invoicing purposes.

10.2.1. OGC or MM may require a certification and reconciling statement from the PI concerning remaining items as part of the fiscal year or project closeout process. OGC, MM, or AP may disallow costs if adequate documentation of incentive distributions is not provided.

10.2.2. If the cost of the unused items is to be transferred to another university fund, it cannot be transferred to another sponsored project fund without an approved incentive plan for the receiving study.

10.2.3. Materials Management must approve retention of the unused items by the PI/Department for other legitimate university business purposes. Unused items may not be retained or distributed for personal use unless the individual reimburses ECU for the costs. In the event the PI/Department has no business use for the unused gift cards or other items, they must be forwarded to MM. Materials Management will attempt to secure a refund from the vendor or transfer the items to another university project.

10.3. All non-electronic payment forms processed (Voucher, Petty Cash, Direct Pay, ProCard, etc.) must have original signatures in blue ink. Forms may be returned if not complete or inappropriately signed.

10.4. Subject payments, regardless of type, are subject to periodic internal and external audit review. ECU financial services, OGC, Materials Management, internal audit or UMCIRB may periodically contact PIs and inspect/audit/review documentation, logs, procedures, etc., related to subject activities and payments. Costs may be disallowed if activities, documents, and approvals are not maintained in conformance with this procedure statement and other university or sponsor requirements.
Insert A1 Form
*SAMPLE DISCLOSURE LANGUAGE TO INSERT IN RESEARCH STUDY PACKAGE*

**Social Security Number Disclosure Statement:** The University will require you provide your Social Security Number (SSN) if you are to receive a study participation payment by check or a study participation payment totaling $600.00 or more for this study. If provided, your SSN will be used solely for tax reporting purposes or issuance of a University check. If you meet this stipulation, the University will require you complete the SSN Disclosure Form (attachment #) requesting your SSN and signature. If when requested to provide your SSN for this purpose and you do not provide it, the University cannot issue you a study participation payment by check or for payment totaling more than $600.00 per tax year for participating in this study.

I have read the SSN Disclosure Statement above and understand if I am to receive a study participation payment by check or study participation payment totaling $600.00 or more, I must provide my SSN to the University.
*SAMPLE DISCLOSURE FORM FOR RESEARCH STUDIES*

STUDY SUBJECT REIMBURSEMENT FORM

For Payments by Check or for $600.00 or More

[STUDY NUMBER ____________________]

In order to receive a study participation payment by check or totaling $600.00 or more for this study, you are required to provide your Social Security Number (SSN) to the University so that the University can comply with its tax reporting obligations. The University will use your SSN solely for this tax-related purpose or for issuance of a check. If you do not provide your SSN, we cannot issue you a study participation payment. However, you may still choose to participate in this study by checking the second box below.

☐ I am willing to provide my SSN in order to receive the study participation payment by check or the study participation payment totaling $600.00 or more. (ONLY PROVIDE YOUR SSN IF THIS STATEMENT APPLIES TO YOU)

My SSN is: _________ - _________ - _________

☐ I am not willing to provide my SSN. I understand that I will not receive a study participation payment by check or a study participation payment totaling $600.00 or more unless I provide my SSN.

_________________________________________________________
Printed Name

_________________________________________________________
Signature

_________________________________________________________
Date
EAST CAROLINA UNIVERSITY
Study Cash Advance Request

To: Cashier Office

From: ____________________________

Date: ____________________________

Reference:

<table>
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<th>Fund</th>
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Please dispense $__________ cash payment to be distributed to study participants on

Date

Principal Investigator/Department

I verify that I was dispensed a $__________ study cash advance payment from the Cashier Office.

Received by: ____________________________ Date Signed: ____________________________

Signature of Cashier ____________________________ Date Signed: ____________________________

*This cash advance payment must be reconciled with the Cashier Office (receipts and supporting documentation submitted) within 2 business days of receipt of this payment. No more than one cash advance per study can be outstanding at any given time.

**ID will be required for the individual receiving the cash advance.

Prepared by EECG Grants Office May 2010