



Office of Human Research Ethics Training Tips

Recruitment Incentives, SOP 26

October 2016

Payments to research study subjects

The IRB is responsible for reviewing:

1. the amount,
2. type of payment and
3. proposed method of disbursement in the context of the proposed subject population
4. course credit or goods with local monetary value are considered to be forms of payment to study participants.

Review Criteria:

- Amount not be based on degree of risk or discomfort associated with study participation;
- Amount is not be coercive,
- Appropriate level of payment is contingent upon a variety of factors, including:
 - the amount of inconvenience or time associated with participation,
 - local economic and cultural factors,
 - the socioeconomic status of prospective subjects and
 - any other circumstance that may affect subjects' ability to make a decision regarding their participation in the study
- Amount should be prorated, should not require subjects to stay in a study longer than they want,
- FDA-regulated research may not include compensation that involves a coupon from the sponsor for a discount on purchasing the product once it has been approved for marketing.

Finders' fees, enrollment bonuses, referral fees etc. **PROHIBITED**

And University employees may not accept gifts, payments or in-kind support (including but not limited to financial payments, gift certificates, books, conference attendance and payment of travel expenses)

Lotteries, raffles and door prizes

NOT Allowed

- Lotteries or Raffles (The terms used for these purchased chance distributions include "lottery" and "raffle." The prohibition is pursuant to State law and University policy.)

Allowed

- Door Prize for which there is no payment or donation
- Door Prize for which there is **NOT** a contribution of blood, tissue or significant time.
 - IRB review on a case-by-case basis
 - Minimal risk & of brief duration
 - Not coercive
 - The IRB should consult with the Office of University Counsel prior to approval of any incentive distributed by chance.
 - Include consent form language describing the incentive should avoid terms like "lottery" or "raffle" and instead include a reference to a "drawing based on chance in which each subject has equal odds of receiving [the incentive]."

Collection of Social Security Numbers for Research Purposes

The North Carolina Identity Theft Protection Act. The Act imposes new restrictions upon the collection and segregation of SSNs and upon the disclosure and security of SSNs and other personal identifying information (PII).

Personal Identifying Information (PII) consists of:

- 1) SSN, ITIN or Employer Taxpayer Identification Numbers (EIN)
- 2) Driver's license (unless appearing in a law enforcement record), State identification card, or passport numbers.
- 3) Checking account numbers.
- 4) Savings account numbers.
- 5) Credit card numbers.
- 6) Debit card numbers.
- 7) Personal Identification (PIN) codes, which are numeric and/or alphabetical codes assigned to the cardholder of a financial transaction card (FTC) by the issuer to permit authorized electronic use of that FTC.
- 8) Digital signatures.
- 9) Any other numbers or information that can be used to access a person's financial resources.
- 10) Biometric data
- 11) Fingerprints
- 12) Passwords

Conditions for use of SSN in research:

SSNs (or ITINs) collected for research:

- must be relevant to the purpose for which they are collected, and
- shall not be collected until and unless the need for the SSN (or ITIN) has been clearly documented and approved by the IRB.
- collecting the SSN (or ITIN), the investigator is required to provide a statement of the purpose or purposes for which the SSN (or ITIN) is being collected and used.
- the SSN (or ITIN) may not be used for any purpose other than the purpose stated.

IRB responsibilities: Review and Approval of Proposed Use

The IRB has been designated to serve in lieu of the Social Security Number Management and Advisory Committee to review and approve collection of SSNs (or ITINs) and/or PII when required within the context of a research project.

The IRB may approve such collection for the following purposes:

1. Tax identification and other purposes mandated by federal or State laws. Per University policy, investigators are required to collect and report SSN and related information when total payment(s) to an individual research subject will exceed \$200 per calendar year.
 2. Use as a unique identifier for a national registry or database where there is potential for duplicate registration and no other means of unique identification exists.
 3. Matching existing records or specimens to those contained in another data set (SSNs or ITINs should be destroyed prior to data analysis).
- Collection of the SSN (or ITIN) **may NOT** be approved for:
 - i. Use as an identifier when other means of unique identification would suffice.
 - ii. Labeling of stored biological specimens.
 - iii. Convenience.
 - iv. An identifier to facilitate future contact with subjects.
 - IRB Documentation: The IRB will document the justification for collection of the SSN (or ITIN) and whether disclosure of the SSN (or ITIN) is voluntary or required for participation in the research.

Investigator responsibilities

- Mechanisms for Processing Payments to Subjects
- SSN Collection Forms
- Submit for IRB Approval

➤ Storage and Disposition of Forms after SSN (or ITIN) Collection:

➤ **Confidentiality:**

➤ **Breach of Confidentiality:**

In the event of a security breach, as defined by the University's "[Protocol for Responding to Security Breaches of Certain Identifying Information](#)," the Office of University Counsel, and other University offices as appropriate, must be notified immediately.

➤ **Statement of Contractor Compliance:**

When the IRB approves collection and disclosure of an SSN to an outside entity (e.g., research sponsors or database administrators), the outside receiving party must complete a [Statement of Contractor Compliance with the North Carolina Identity Theft Protection Act of 2005](#). This signed form should be kept with the investigator's study records.

References:

UNC Material & Disbursement Services: http://www.unc.edu/mds/ds/help_hint.htm

NC Identity Theft Protection Act of 2005: <http://www.unc.edu/depts/legal/ssn>

NCGS §14-309.15 Raffles