

UIC

2008 Bringing Administrators Together Conference

**The Recruitment and Payment of
Human Subjects**

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2:15 PM – 3:30 PM

Workshop Presenter(s)

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Please...

- Turn off cell phones.
- Avoid side conversations.
- [Insert your rules about asking questions:
Hold until the end or ask at any time?]
- Sign the attendance roster.
- Complete the evaluation at the end of the workshop.

Workshop Objectives

- Explain how recruitment fits in with the informed consent process
- Clarify UIC recruitment material requirements
- Discuss payment procedures for Human Subjects
- Discuss University tax reporting requirements on Human Subject payments
- Discuss special payment processing requirements for Nonresident Alien Human Subjects

Recruitment and Informed Consent

Belmont Report (1979)

- Basis of all human subjects protections
- Three principles basic to the protection of human subjects:
 - (1) Respect for persons*
 - (2) Beneficence
 - (3) Justice*



Respect for Persons

1. Individuals should be treated as autonomous agents; and
2. Persons with diminished autonomy are entitled to protection.

Practical Application

Principle - Respect for Persons

1. Regulation - Informed Consent Process and Document [45CFR46.116]
2. Protocol & Consent Forms - What will be said to subjects, when and where, assessing understanding, and voluntariness.

Practical Application

Principle: Justice

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved."

Principle: Justice (cont)

1. An injustice occurs when benefit is denied without good reason.
2. An injustice also occurs when a burden is imposed unduly.

Principle: Justice (cont)

1. Regulation - Selection of subject is equitable, vulnerable populations are protected [45 CFR 46.111(a)(3) and (b)]
2. Protocol - Recruitment, inclusion & exclusion criteria

Informed Consent

- (1) INFORMATION - disclosure**
- (2) COMPREHENSION- understanding (intelligence, rationality, maturity and language)**
- (3) VOLUNTARINESS – an agreement free from coercion and undue influence**



Informed Consent is a Process, not an Event

An information exchange that includes:

1. subject recruitment materials
2. oral instructions
3. written information
4. question/answer sessions
5. voluntary agreement in writing
6. continuing understanding/agreement

As such-

Subject recruitment is part of the informed consent process and must meet:

1. Ethical Guidelines (Belmont Report) and
2. Research Regulations (45 CFR 46.116)

UIC Recruitment Material Guidelines

Introduction-

Since recruiting materials (e.g., advertisements, flyers, phone scripts, newspaper ads, radio and television announcements, bulletin board tear-offs, Internet postings, and posters) are part of the informed consent process and the subject selection process, the IRB must review, approve and stamp all recruiting procedures and materials prior to their use by an investigator.

Appropriate Content and Format

- Recruitment materials are evaluated for the relative size of the type used and other visual effects. Therefore, materials should be submitted in their final format for review and approval.
- A description should be provided regarding the manner in which the materials will distributed/utilized and by whom (i.e. clinic staff will hand flyer to patients or e-mail announcement distributed through UIC Massmail).

Appropriate Content and Format

- Recruiting materials may state that subjects may be compensated or reimbursed, but specific dollar amounts should not be a major feature of the advertisement.
- For recruiting materials that are to be taped for broadcast, transcripts must be submitted for review and approval. The final taped message may be approved via expedited procedures.

Appropriate Content and Format

- The recruiting material must not be unduly influential in its approach and/or should not promise a certainty of cure or other benefits beyond what is outlined in the informed consent document and the research protocol.
- If investigational agents are involved in the research, no claims may be made (explicitly or implicitly) that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.

Appropriate Content and Format

- Recruiting materials may not use the terms "new treatment," "new medication," or "new drug" without explaining that the test article is investigational, i.e. not approved by the FDA. A phrase such as "receive new treatments" leads subjects to believe they will be receiving newly improved products of proven worth.
- Do not promise "free medical treatment," when the intent is only to say that subjects will not be charged for taking part in the research investigation.

Nine Items that Must Be Included in Recruiting Materials

1. Research project title or identifier (i.e. smoking cessation).
2. A description of the type of research and purpose of the research.
3. The word "research" must be included in the description. It is not enough to imply that the subject is being recruited for research by just using the word "study".

Nine Items that Must Be Included in Recruiting Materials

4. A name of the person or office to contact and the number to call for further information.
5. The UIC research protocol number and the fact that the research is being performed at UIC.
6. The Principal Investigator's name, department, and address.

Nine Items that Must Be Included in Recruiting Materials

7. The specific location of the research.
8. A footer with version # and date.
9. Space for the UIC IRB approval stamp (approximately 2.5 x 1.5 inches).

Additional Information that May be Included in Recruitment Materials

- In summary form, the criteria that will be used to determine eligibility for participation in the research.
- A description of the time commitment and duration of the subjects' participation and number of visits required for the research.
- A brief description of the benefits of the research, if any (e.g., smoking cessation).

Lastly- What Does Not Require IRB Review

- Medical society newsletters.
- News stories (i.e. public service announcements).
- Publicity intended for other audiences, such as financial page advertisements directed towards prospective investors.
- Dear colleague/doctor letters - only those announcing the existence of the research.

Human Subject Payments and Taxation

***U.S. CITIZENS, PERMANENT
RESIDENTS, AND RESIDENT
ALIENS FOR TAX PURPOSES***

Non-Confidential Studies

- Cash or Gift Card/Certificate Payments
 - Total payments to each Human Subject (HS) may not exceed \$100 in a calendar year
 - Request funds by submitting a Program Advance to University Payables
 - Advance may be issued as a check to the employee, in cash through the Cashier's Office, or as a check made payable to a vendor

Non-Confidential Studies

- Cash or Gift Card/Certificate Payments (continued)
 - Maintain a schedule of payments issued to Human Subjects that includes HS name, address, signature, amount paid, and date
 - Attach schedule to Employee Reimbursement Voucher to close advance
 - Cash or gift card/certificate payments may not be issued to non-resident aliens

Non-Confidential Studies

- **Check-Issued Payments**
 - Payments to Human Subjects must be issued in the form of a check when:
 - Total payments to the HS in a calendar year exceed \$100
 - Payments are made to HS outside of the immediate vicinity, thereby requiring payment to be mailed
 - Submit an invoice voucher with an attached spreadsheet containing the HS name, address, Social Security number, and dollar amount of payment (acct code 141200)

Confidential Studies

- Cash or Gift Card/Certificate Payments
 - Total payments to each HS may not equal or exceed \$600 in a calendar year
 - Request of funds is the same process as described for non-confidential studies
 - To protect identity of HS, assign identifying code to each HS being paid; maintain a cross-reference of HS information in department for three years following the submission of final report

Confidential Studies

- Cash or Gift Card/Certificate Payments (continued)
 - Cross reference information must include the HS name, amount received, and date paid
 - This information is required to be available upon the request of internal or external auditors, or the Internal Revenue Service
 - Attach a listing of the identifying codes and the amounts paid to each to close the advance
 - Cash or gift card/certificate payments may not be issued to non-resident aliens

Confidential Studies

- **Check-Issued Payments**
 - Payments to Human Subjects must be issued in the form of a check when:
 - Total payments to the HS in a calendar year equal or exceed \$600
 - Payments are made to HS outside of the immediate vicinity, thereby requiring payment to be mailed
 - Information required on the miscellaneous invoice voucher includes the HS name, address, Social Security number, and dollar amount of payment (acct code 141200)

Tax Reporting of Payments

- The University is required to report to the Internal Revenue Service total amounts paid to Human Subjects receiving \$600 or more in a calendar year
- Human Subjects receiving \$600 or more in paid compensation during a calendar year will receive Form 1099-MISC from the University for reporting on his/her individual income tax return

Human Subject Payments and Taxation

NONRESIDENT ALIENS

All Studies -- Confidential & Non-Confidential

- All payments must be processed through University Payroll on the Foreign National Payment Form using acct code 215985
- Payments are subject to Federal and State tax withholding unless exempted by tax treaty and all necessary paperwork is submitted with the payment request
- No cash or cash equivalent payments allowed since all payments must be reported on Form 1042-S

Human Subject Payments to Third Parties

Third Party Contracts

- University departments/units may contract with a third party to provide support to HS studies by arranging access to participants
- May provide compensation to third party for their efforts
- Payments are not intended to serve as indirect participant fees to the HS
- Example: Contract with a homeless shelter to coordinate subjects for research. Pay the shelter for their efforts.

Questions / Concerns?