1. Project title: "*Evaluation of the Current NIH Practice of Paying Research Subjects and Its Impact on Subject Recruitment, Compliance, and Informed Consent*"

2. Report title: same

3. Agency Sponsor: NIH/CC/ Department of Clinical Bioethics

4. Project Officer: Christine Grady

5. Status of Project: Completed
Report Attached

6. Start Date: August 20, 1998

7. End Date: July 2000

10. Project # CC98-10

12. Abstract: This project sought to evaluate current practices of financial remuneration to research subjects for their participation in research studies in the intramural research program of the NIH, and to evaluate the impact of payment on research subjects' motivations, knowledge and understanding of research risks, compliance with protocol requirements, and proclivity to withdraw. Funding was awarded in August 1998 to 1) address the underlying rationale of subjects for participation in a study; and 2) document current statistics on payment of subjects in Clinical Center studies.

Final Report for Evaluation project # CC98-10

"*Evaluation of the Current NIH Practice of Paying Research Subjects and Its Impact on Subject Recruitment, Compliance, and Informed Consent*"

Starting September 1998, we undertook an evaluation study with the following **objectives**:

1) address the underlying rationale of subjects for participation in research studies; and
2) document current statistics on payment of subjects in Clinical Center studies.

To meet these objectives, the following were completed:

Objective #1:

- A protocol for interviewing subjects consenting to participate in both paid and unpaid studies in the intramural HIV program was submitted for IRB review and approval.
- A focus group of enrolled subjects was conducted to discuss motivations for participation.
- An interview schedule was developed based on a review of the literature and information from the focus group.
- The interview questions were subjected to both cognitive and behavioral pretesting through a contract with the Center for Survey Research at University of Massachusetts.
- Subjects (20 from paid studies and 21 from unpaid studies) were recruited and interviewed by phone within one week of consenting to a clinical study. A follow-up phone interview was conducted 2-6 weeks later.
- Study was terminated because of difficulty recruiting subjects.
- Data were entered into an SPSS database and are currently being analyzed.

Objective #2:

- The database of all NIH intramural protocols newly approved from January 1, 1997-June 1, 1998 (n=319) was reviewed and those that offered compensation to subjects (86 or 27%) were selected.
- Each of the 86 research protocols and consent documents was carefully reviewed by one of two trained research assistants.
- Selected variables from each protocol were entered directly into a *Filemaker Pro* database via laptop computer.
- Variables included the type of study, type of subject, the number of clinic visits or overnight hospital stays required, and specific procedures and interventions involved.
- Additional data variables extracted were the total amount of payment offered to subjects, information about calculation of payment amount by time, visit or procedure, as well as pro-rating schedules, completion bonuses, and other details of payment.

- Data was also collected about the nature and extent of information about payment in the consent document
- The database was converted into a SAS data file and descriptive statistics were used to summarize the data. This was done through a contract with the Emmes corporation
- The NIH guidelines[1] for compensation of research volunteers by time and inconvenience units was compared to policies, guidelines and rules of thumb from 31 other research organizations.

The findings were:

Objective #1:

- Recruiting subjects for the interview was slow, labor intensive, and difficult.
- Data from the interviews that were conducted is still being analyzed.

Objective #2:

- About 27% of intramural protocols offer payment to subjects. These protocols include healthy volunteers alone (24/85), patient subjects alone (14/85) or both types of subjects (47/85).
- Of these protocols, 17 described calculation of payment based on time and inconvenience as per existing guidelines, 37 describes either time or inconvenience but not both, and 32 appeared to use neither time nor inconvenience units as the basis for amount of payment.
- Most of the ICDs (13/15) that have intramural clinical research programs had some studies that offered payment to subjects
- Across protocols (even within the same ICD) there was a range of inconvenience units and amount of payment for the same procedure , for e.g. payment for MRI ranged from $25-60/procedure; for PET (with arterial line) $50-125; for "Comprehensive exam", range 2 IU ($20) to 20 IU ($200)
- For 26% of the protocols, the total dollar amount that a subject might receive was not listed. For those in which it was listed, totals ranged from $20-2000. Of these, the total was more than $500 in only 10% (healthy subjects) and 12% (patient subjects) of the studies reviewed.
- Very few (9%) offered completion bonuses and less than 1% used escalating incentives
- Detailed information about payment was found on the consent form in 49 (57%) of the consent forms reviewed, but in 21 (24%) of the consent forms payment was not mentioned.

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[1] CRVP guidelines are: Mandatory inpatient $40 per diem; outpatient (on-site) $20 - 1st hour or part thereof; $10 - each additional hour or part thereof outpatient; escort fee: $25 in some cases
Number of inconvenience units assigned to procedure is totally optional and determined by the institute after considering the fiscal structure of protocol ($ allotted) and discomfort level of procedure. Procedures are assigned a numerical value that is multiplied by $10 per inconvenience unit

Conclusions:

Objective #1:

- Pending

Objective #2**:**

- The majority of ICDs in the Intramural Program currently pay participating subjects in some protocols. These protocols include patients and healthy subjects across a range of type of study.
- There is a wide range in the amount of payment for similar procedures and similar studies, and inconsistent application of the CRVP guidelines.
- About 75% of intramural NIH consent forms include any information about payment.

Utilization of Results

Objective #1:

- When data analysis is complete, results will be shared with relevant parties in the Clinical Center, and the Division of Intramural Research.

Objective #2**:**

- Results have been presented to the Medical Executive Committee, a special joint meeting of the Clinical and Scientific Directors, and to the Human Subjects Research Advisory Committee (HSRAC).
- Results have been discussed with the CRVP.
- HSRAC in conjunction with the MEC and Dr. Gottesman determined that an OHSR information sheet on payment should be developed in order to inform investigators and IRBs about NIH guidelines for payment. This information sheet is being finalized.
- Data from this evaluation study was presented at a Combined Clinical Staff Conference to the NIH community on April 26, 2000.