HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL & IMPLEMENTATION

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: 13

SOP Title: RECRUITMENT, SELECTION AND COMPENSATION OF RESEARCH SUBJECTS

Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB Chairs, IRB Administrators, Protocol Navigators

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SOP 13 RECRUITMENT, SELECTION AND COMPENSATION OF RESEARCH SUBJECTS

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SOP 13 RECRUITMENT, SELECTION AND COMPENSATION OF RESEARCH SUBJECTS

13.1 PURPOSE

This policy outlines the responsibilities of NIH Institutes and Centers (ICs), Institutional Review Boards (IRBs), Principal Investigators (PIs) and other members of the research team related to recruiting, selecting and compensating research subjects.

These procedures are designed to assure:

A. The equitable recruitment and selection of subjects consistent with the DHHS Common Rule (45 CFR 46); and

B. Compliance with the NIH Revitalization Act of 1993 (PHS Act sec. 492B, 42 USC 289a-2)(see **References** below), aimed at ensuring women and members of minority groups are included as subjects in each project or research (except when inappropriate); NIH policy on the inclusion of children; and

C. That compensation, when it is given to research participants, is appropriate and fair.

13.2 POLICY

During the initial review (IR) of protocols, NIH IRBs will review and approve recruitment and compensation plans proposed by PIs. At the time of continuing review (CR), IRBs will evaluate whether the protocol has accrued subjects in accord with the IRB-approved selection criteria.

13.3 SELECTION OF SUBJECTS

13.3.1 GENERAL CONSIDERATIONS

Subjects should be carefully and equitably chosen to ensure that certain individuals, or classes of individuals, are not systematically selected or excluded, unless there are scientifically or ethically valid reasons for doing so. Special attention will be given to the enrollment of women, children and minorities in research (see

References below, and SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs), SOP 14A - Research Involving Vulnerable Subjects (General Considerations), and SOP 14D - Research Involving Children).

13.3.2 PI RESPONSIBILITIES

A. IR: PIs will include in the protocol section on the protection of human subjects, information on the rationale for subject selection as required in SOP 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols. The PI will also submit:

1. The following items to the IC Scientific Review Committee for review and approval:

   a. The scientific plan, which should include the basis for the inclusion or exclusion of women and minorities and children. For Phase III trials, the scientific plan should address valid design and analysis by sex/gender, race and ethnicity; and

      i. The Planned Enrollment Report (NIH Application Supplement P) when the research will involve the prospective enrollment of subjects.; and/or

      ii. The Cumulative Enrollment Report (NIH Application Supplement Q) when the research involves the use of existing data or materials;

      iii. Submit separate Enrollment Reports when the protocol includes domestic and foreign sites, as applicable.

   For more information on NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research and the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects, see **References** below.

2. The Intramural Initial Clinical Protocol Application must include the IC-approved Planned Enrollment or Cumulative Enrollment Report, as applicable, to be forwarded to the Office of Protocol Services (OPS) for tabulation.

B. CR: At the time of the CR the PI will submit the following information about the status of enrollment of subjects on the protocol as required by SOP 9 - Continuing Review by the Convened IRB which includes:

1. The PI will submit the Cumulative Enrollment Report (NIH Application Supplement Q) to his/her Laboratory or Branch Chief for review and approval. This report will include the cumulative number of subjects accrued by sex/gender and ethnic/racial category(ies) and any comments/justification if enrollment does not correspond to the original Planned Enrollment sample. The IC reviewer will examine the Cumulative Enrollment Report, compare it to the previously approved Planned Enrollment, and assess whether actual enrollment progress is satisfactory (see **13.3.2.A** above). As necessary, the IC reviewer will work with the PI to develop strategies to improve enrollment. The IC reviewer may refer the matter to the IC Clinical Director for evaluation of recruitment strategies and additional resources.

2. The PI will submit the IC-approved Cumulative Enrollment Report(s) to the IRB to be forwarded to the OPS to be tabulated and reported. When the protocol enrolls subjects at both domestic and foreign sites, the PI will submit a separate Cumulative Enrollment report for domestic subjects and for foreign subjects.

3. Information about the status of subject enrollment within the Memorandum of Progress for the IRB's review.

13.3.3 IRB RESPONSIBILITIES

A. **IR:** The IRB reviews and approves the protocol consistent with SOP 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols, including the rationale for research subject selection, the strategies and procedures for recruiting subjects (see **13.4** below) and any justification(s) for exclusion of women and/or individuals from particular population categories.

1. In determining if subject selection is equitable, the IRB will consider a variety of factors, including but not limited to: the purposes of the research; the inclusion/exclusion criteria; the setting in which the research will take place; whether prospective subjects are vulnerable to coercion or undue influence, recruitment/enrollment procedures (see

13.4.2 below), and the amount and timing of compensation, if any (see **13.5** below).

2. Exclusion of certain populations, such as children, should be justified based on the nature of the disease or condition being studied, or for other scientific, ethical or safety reasons (e.g., see SOP 14D - Research Involving Children and the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" in **References** below).

3. The IRB will forward the IC-approved Planned or Cumulative Enrollment Report, as applicable to the Office of Protocol Services (OPS) to be tabulated and reported.

B. **CR:** The IRB will review the Memorandum of Progress for the enrollment and retention of subjects to assess the consistency with the recruitment plan in the protocol, see **13.3.2.A** above and SOP 9 - Continuing Review by the Convened IRB.

1. If slow enrollment or loss of subjects on the study jeopardizes the scientific integrity of the research or no longer justifies the continued enrollment of subjects, and/or if the IRB finds that the cumulative enrollment is inconsistent with previously approved targets for subject selection (see Section **13.3.2.A**, above), the IRB has broad discretion in exercising its judgment on how to proceed. Its actions may include:

   a. Continuation of subject accrual, with or without a request that the PI provide a plan for improved accrual, or

   b. If necessary, referral of the matter to the IC Clinical Director for evaluation of recruitment strategies and additional resources, or

   c. Suspension or termination of the protocol for failure to meet the terms and conditions of IRB approval.

2. The IRB will forward the IC-approved Cumulative Enrollment Report to the Office of Protocol Services (OPS) to be tabulated and reported.

13.4 RECRUITMENT PROCEDURES AND MATERIALS

13.4.1. RECRUITMENT ACTIVITIES OR MATERIALS THAT DO NOT REQUIRE IRB APPROVAL

IRB review and approval is not required for basic descriptive information about a clinical trial website if the clinical trial information is limited to the following: title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for further information per the OHRP "Guidance on IRB Review of Clinical Trial Websites" (see **References** below). Descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information is not considered basic descriptive information, but part of the informed consent process and requires IRB review and approval. All other recruitment materials will be submitted to the IRB per **13.4.2** below.

13.4.2 PI RESPONSIBILITIES

A. The PI describes in the protocol who will participate in the identification and recruitment of prospective research participants.

B. The PI will provide the IRB with the materials to be used to identify participants, including recruitment activities/methods, advertisements, and/or other media announcements (such as internet sites), etc. The contents of advertisements/recruitment materials will be limited generally to information needed by prospective subjects to determine their eligibility and interest, such as:

1. The name and address of the researcher or research facility.

2. The condition under study and the purpose of the research.

3. A brief summary of the criteria that will be used to determine eligibility.

4. A brief list of risks and benefits, if any, to participants.

5. The time or other commitment required of participants, and

6. The location of the research and the contact person/office for more information.

C. If the PI intends to recruit subjects or obtain any identifying information *via* internet sites he/she must be compliant with NIH Policy Manual 2805 “NIH Web Privacy Policy”, and other NIH policies, (e.g., the Paperwork Reduction Act and the NIH Policy Manual 1825 “Information Collection from the Public” in **References** below), as applicable.

D. PI’s should also be aware of and comply as needed with the NIH Policy Manual 2809 “NIH Social and New Media Policy” and NIH Policy Manual 2809 Appendix 1, “NIH Office of Intramural Research (OIR) Guidance for Use of Social Media for Recruitment of Subjects to Clinical Trials” (see **References** below).

13.4.3 IRB RESPONSIBILITIES

The IRB will review and must approve recruitment materials before they are used. This includes the information contained in the materials, how the information is to be communicated, and the planned venue(s) for distribution (for example, newspaper, radio, or flyer). For audio/video tape, the IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The IRB will review the final copy of printed and/or electronic advertisements and the final version of audio- or videotaped advertisements and may use expedited procedures for final approval.

A. Verification of information and institutional logos: The IRB will verify that all information included in the recruitment materials is consistent with the protocol. DHHS, NIH, and IC logos must be used consistently with NIH Policy Manual 1186, “Use of NIH Names and Logos” (see **References** below).

B. Recruitment Materials: As part of its review of recruitment materials, the IRB will ensure that materials do not:

1. State or imply a favorable outcome or other benefits beyond what is stated in the protocol and the consent document.

2. Include exculpatory language.

3. Emphasize monetary compensation or the amount to be paid by such means as larger or bolder type.

4. Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

5. IRBs should pay particular attention to risk and potential benefit information to ensure it is presented in a balanced and fair manner. If identifiable private information of prospective subjects is to be collected via a clinical trial website, the IRB should review plans for protecting the confidentiality of that information. The IRB should ensure that the website clearly explains how identifiable private information might be used. For further guidance, see OHRP “Guidance on IRB review of Clinical Trial Websites” (see **References** below).

C. Recruitment Materials related to FDA-regulated research: As part of its review, the IRB will ensure that recruitment materials are consistent with FDA regulations and applicable guidance, (e.g., “Recruiting Study Subjects - Information Sheet: Guidance for IRBs and Clinical Investigators”, see **References** below).

13.5 COMPENSATION OF RESEARCH SUBJECTS

13.5.1 GENERAL CONSIDERATIONS

At the NIH, compensation may be offered to persons participating in research protocols. Compensation is one way to acknowledge research subjects’ contributions; however, proposed payments should be commensurate with the expected contributions of the subject and should not be so much as to constitute (or appear to constitute) undue influence to participate. See **Appendix A - Guidance for Monetary Compensation for Clinical Research Volunteers** and **Appendix B - Worksheet/Tool for Calculating Estimated Compensation**, for more information.

A. **Who may receive compensation:** Generally, at the NIH, when compensation is offered for research participation, it is offered to healthy volunteers or to persons with diseases or disorders who participate in research that offers them little or no prospect of direct benefit. However, if justified by the PI and approved by the IRB, compensation may be given to patient subjects (persons with diseases or disorders who participate in research that offers them a prospect of direct benefit). For fairness reasons, all participants taking part in a particular research protocol should be offered the same amount of compensation for the same type of contribution. NIH

Institutes and Centers may have additional policy on this topic (see **13.6** below).

B. **Types and calculation of compensation:** Compensation may include check payments, gift cards, or other items. All forms of compensation must be specifically mentioned in the protocol and consent document (see **13.5.2** below). Such compensation may be given in addition to reimbursement for travel, meals, lodging, parking, or other expenses. See **Appendix A - Guidance for Monetary Compensation for Clinical Research Volunteers** for more information.

C. **Compensation amounts for healthy volunteers at the Clinical Center:** will be based on time, and in some instances, inconvenience of participating in the research using NIH/CC guidelines (contact NIH Program for Healthy Volunteers at 301-496-4763, see **References** below). NIH investigators at non-Clinical Center intramural sites will abide by site guidelines in addition to this policy's requirements. See **Appendix B - Worksheet/Tool for Calculating Estimated Compensation**, for more information.

D. **Tracking of compensation:** Compensation will be tracked and processed through the Clinical Research Volunteer Program (CRVP) for studies conducted in the Clinical Center and in accord with any required IC or outside site procedures for studies conducted at NIH non-CC sites.

13.5.2 PI RESPONSIBILITIES

A. The PI will make a preliminary decision about whether or not to offer compensation to the participants in his/her protocol. See **Appendix A - Guidance for Monetary Compensation for Clinical Research Volunteers** for more information.

B. Protocol-specific calculation of compensation: PIs will follow the recommended NIH/CC guidelines taking into account the time, and, in some instances, inconvenience required to participate in the protocol. See **Appendix A - Guidance for Monetary Compensation for Clinical Research Volunteers** for more information.

1. Deviations from these guidelines are permissible, but require written justification to and approval of the IRB (and possibly other IC/CC officials).

2. NIH investigators at non-Clinical Center intramural sites will rely on this policy and use site-appropriate guidelines as approved by the IRB.

C. Contents of the written protocol: The PI will include a section on compensation containing the type, amount and conditions of payment.

D. Description of compensation in consent forms:

1. Compensation will be discussed in the consent document under a separate section labeled “Compensation.” It will not be listed or discussed as a benefit of participation in research.

2. Information will include what is being compensated, when and in what manner the compensation will be given, including the total amount the subject may potentially receive and how the amount will be prorated.

13.5.3 IRB RESPONSIBILITIES

A. General considerations: The IRB shall review the justification for compensation to ensure it is appropriate given the particular study and the population to be recruited, and that the compensation payments are reasonable, equitable, and do not constitute coercion or undue influence. In making this decision, the IRB should consider the potential vulnerabilities of the targeted subject population and the proposed methods for assessing subjects’ knowledge of risks and benefits and their ability to make voluntary, autonomous decisions. It should also take into account the amount, schedule, and method of disbursement of compensation payments.

B. Review and approval of the proposed compensation plan: The IRB reviews and determines that the amount of payment and the proposed method and timing of compensation is appropriate (does not present undue influence). In making that determination, the IRB shall verify that:

1. As appropriate, credit for compensation payments accrue as the study progresses and are not contingent upon the participant completing the entire study, and

2. Any amount paid for completion of the study is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

C. The IRB shall be satisfied that the NIH/CC (or local non-CC) guidelines for calculating amounts have been followed, or that justification provided for any deviation is appropriate. See **Appendix A - Guidance for Monetary Compensation for Clinical Research Volunteers** and **Appendix B - Worksheet/Tool for Calculating Estimated Compensation**, for more information.

D. Review and approval of the consent document language: The IRB shall assure that all relevant information concerning compensation, including the amount and schedule of payments, is set forth in the consent document.

13.6. ADDITIONAL COMPENSATION POLICIES

NIH Institutes or Centers (ICs) may have compensation policies specific to their research activities. Such policies may be in addition to, but may not conflict with, the policies described above.

REFERENCES

1. NIH Revitalization Act of 1993, PL103-43: http://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapIII-partH-sec289a-2.pdf

2. NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001: http://nih-extramural-intranet.od.nih.gov/d/nih/topics/inclusionwo_main.htm

3. NIH Policy and Guidelines on the Inclusion of Children as Participants In Research Involving Human Subjects: http://nih-extramural-intranet.od.nih.gov/d/nih/policies/children.htm

4. NIH Policy Manual 2805 - NIH Web Privacy Policy: http://oma1.od.nih.gov/manualchapters/management/2805/

5. NIH Policy Manual 2809 – NIH Social and New Media Policy: http://oma1.od.nih.gov/manualchapters/management/2809/

6. NIH Policy Manual 1186- Use of NIH Names and Logos: http://oma1.od.nih.gov/manualchapters/management/1186/

7. NIH Program for Healthy Volunteers: http://clinicalcenter.nih.gov/participate/studies/healthy_vol_prg.shtml#compensate

8. OHRP Guidance on IRB review of Clinical Trial Websites: http://www.hhs.gov/ohrp/policy/clinicaltrials.pdf

9. FDA guidance “Recruiting Study Subjects- Information Sheet: Guidance for IRBs and Clinical Investigators”: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

LIST OF APPENDICES

Appendix A - Guidance for Monetary Compensation for Clinical Research Volunteers
Appendix B - Worksheet/Tool for Calculating Estimated Compensation

APPENDIX A - GUIDANCE FOR MONETARY COMPENSATION FOR CLINICAL RESEARCH VOLUNTEERS

Purpose: To provide benchmarks that can serve as guidance for determining compensation rates for specified tests/procedures that are being implemented within a research study/clinical trial at the NIH Clinical Center. For further information refer to NIH HRPP SOP 13, “Recruitment, Selection and Compensation of Research Subjects”, section 13.5.1

Background: There has been a long standing need in IRP to provide Investigators and IRBs some benchmarks, reference points for compensation of research participants for certain procedures.

Scope: Compensation for time and inconvenience for participation in research. These can be applicable for both patients and healthy volunteers.

Audience: This guidance has been developed for principal investigators, associate investigators, protocol navigators, protocol coordinators, research nurses, IRB administrators, IRB members, Office of Patient Recruitment (OPR) Staff, Clinical Research Volunteer Program (CRVP) Staff and other research support personnel.

Additional Points to Consider

Minors: Appropriate compensation of minor subjects involves additional considerations and may be viewed differently for children and adolescents. While it may be acceptable to compensate some adolescents monetarily, similar to adults, it may be more appropriate to compensate younger children in another manner. Although parents will have expenses for travel, babysitting for siblings, time off work to bring children in for appointments, it should be recognized that the children are the research subjects. They may undergo stress, discomfort or inconvenience as a result of participation in research studies, hence there should be some effort made to compensate the children directly and personally. Compensation for younger children can take the form of a gift certificate to a toy store or children's bookstore or other item of particular interest to the age group being studied if this is specified in the protocol/consent.

Steps to Take when Considering Providing Compensation

1. Decide if you want to offer money to research subjects within your protocol;

2. Use the worksheet in Appendix B to list the procedures and interventions that the protocol requires. For each procedure, designate a number of inconvenience units (each inconvenience unit=$10). The following list of ranges for common procedures is compiled from compensation levels provided by current NIH protocols. It provides benchmarks for determining a reasonable number of inconvenience units. Based on assigned inconvenience units, calculate the $ amount for each procedure. Sum the total for all of the protocol procedures;

3. Estimate the amount of time the participant will likely have to be at the NIH. Calculate the total expected dollar amount for time using the NIH formula;

4. Determine whether or not you want to offer a completion bonus

5. Add the dollar amounts based on inconvenience units, time, and completion for the total anticipated compensation. Include this in the protocol.

6. Plan how the amount will be prorated for those subjects who do not complete the protocol. Describe the prorating scheme in the protocol.

7. In the consent form, describe what payment is for, the possible total amount, and how the amount will be prorated.

Below is a formula for calculating compensation based on Inconvenience Units (ICUs) and adding in the amount of time required

Compensation Rates are based on time, inconvenience and effort required to participate in the research.

Inconvenience Units	
For calculating payment, Inconvenience units are assigned to procedures, whether inpatient or outpatient	• Number of inconvenience units assigned to procedure is totally optional and determined by the Institute after considering the fiscal structure of protocol (dollars allotted) and discomfort level or inconvenience of the procedure. • $10/inconvenience unit • Procedures are assigned a numerical value that is multiplied by $10. (Example: MRI may be assigned 5 inconvenience units or $50.).

***Time**	
Amount of payment for time depends on whether the participant is inpatient or outpatient; this is mandatory for protocols that provide compensation.	• Inpatient: $40 per night • Outpatient: $20 for 1st hour or part thereof, and $10 for each additional hour or part thereof

*Time includes access to campus/campus security

Escort fee: Compensation offered to one who accompanies a patient/subject **unable** to travel alone: may be paid for each visit

Inpatient	$25
Outpatient	$20

Baseline Compensation Rates for Common Procedures Conducted at the NIH Clinical Center

The compensation rates listed below were derived from several sources; primarily from data collected about amounts that have previously been offered by the Clinical Research Volunteer Program and from NHLBI, NIAID, NIDDK and CC. This includes data from FY 2011 (October 1, 2010 to September 30, 2011) and FYI 2012 (October 1, 2011 to September 30, 2012). It should be noted that the dollar amounts below are calculated using only inconvenience units and are general *guidance*. Time should be calculated separately. Each Investigator should also check with their individual Institute/Center (IC) for further standardization/institute specific guidance: Institute/Center (IC) Policy will supersede parameters for compensation in this document, as applicable.

Procedure	*Inconvenience Units (IU)	Payment
Activity Monitor	1-5	$10-$50
Air Displacement Plesthymography	1-5	$10-$50
Apheresis	2-20	$20-$200
Arterial Blood Draw	15	$150
Arterial Blood Gas	20	$200
Arterial Line Placement	4-12	$40-$120

Procedure	***Inconvenience Units (IU)**	**Payment**
At Home Collection	1	$10
Auditory Tests	1-2	$10-$20
Behavioral Tasks	1-5	$10-$50
BIODEX	1	$10
Biopsy	2-40	$30-$400
Biopsy – Adipose Tissue	4-7.5	$40-$75
Biopsy – Bone Marrow Aspirate (Bilateral)	14-38	$140-$380
Biopsy – Bone Marrow Aspirate (Unilateral)	12.5-35	$125-$350
Biopsy – Breast	18	$180
Biopsy – Lip	2	$20
Biopsy – Liver	28	$280
Biopsy – Lymph Node	2-20	$20-$200
Biopsy – Skeletal Muscle	12.4-40	$125-$400
Biopsy – Skin	3-12	$30-$120
Blood Draw – 10 ML	1-2	$10-$20
Blood Draw – 20 ML	3	$30
Blood Draw – 50 ML	4	$40
Blood Draw – 80 ML	5	$50
Blood Draw – 120 ML	6	$60
Blood Draw Fasting	1-3	$10-$30
Blood Draw – Serial/Sampling through IV	1-40	$10-$400
Blood Draw Genetic	1-2	$10-$20
Blood Flow Study	10-40	$100-$400
Breath Holds	5	$50
Breath Sample	2	$20
Bronchoscopy	24	$240
Buccal Mucosa Sample/Swab	1-4	$10-$40
Cardiopulmonary Stress Test	2.4-5	$25-$50
Cardiopulmonary Stress Test, Walking	2	$20
Chest X-Ray	1-3	$10-$30
Cognitive/Psychological Testing	1-21	$10-$210
Colonoscopy	20-32	$200-$320
Contrast IC/Oral	2	$20
CT Scan, General No Contrast	1-3	$10-$30
CT Scan with Contrast	4-15	$40-$150
CT Scan – Abdomen	8-9	$80-$90
CT Scan – Cardiac	3-5	$30-$50

Procedure	***Inconvenience Units (IU)**	**Payment**
CT Scan – Cardiac with Contrast	5-13	$50-$130
CT Scan – Chest	10	$100
DEXA Scan – Bone Density Scan	1-10	$10-$100
Diary (24 hr)	.5-4	$5-$40
Diet Restriction	1-3	$10-$30
Drug Administration, General	2-5	$20-$50
Drug Infusion/Administration by IV	10-30	$100-$300
Drug Infusion/Administration, Phase I	10-50	$100-$500
Dry Eye Exam	2-2.5	$20-$25
Echocardiogram with Contrast	3-4	$30-$40
Echocardiogram – Doppler	4	$40
Echocardiogram Ultrasound	2-3	$20-$30
EEG (Electro Encephalogram), Routine	2-4	$20-$40
EEG Routine and Overnight	3-4	$30-$40
EGD (Esophagogastroduodenoscopy)	13	$130
EKG (Electrocardiogram), General	1-10	$10-$100
EKG Breath Hold	1	$10
EMG (Electromyography)	1-39	$10-$390
Endoscopy	20	$200
Endoscopy with biopsy	24	$240
Exercise Tolerance Test (ETT) (see cardiopulmonary stress test)		
Eye Movement	1	$10
Eye Test	4	$40
Faces Eye Tracking	5	$50
Food Monitoring	2.5	$25
GAIT	1-3	$10-$30
Glucose Tolerance Test (GTT)	1-10	$10-$100
Heparin Lock Insertion	1-4 (IU per attempt)	$10-$40
Heparin Test	1	$10
History and Physical	1-3	$10-$30
Holter Monitor (24 hr)	2-5	$20-$50
Intramuscular Injection	2	$20
Leukapheresis – 2 pass	10	$100
Leukapheresis – 4 pass	20	$200
Lumbar Puncture	1-5	$10-$50

Procedure	*Inconvenience Units (IU)	Payment
Magneto Encephalography (MEG)	2-30	$20-$300
Metabolic Chamber Testing, Resting	4	$40
Metabolic Stress Test	5	$50
Motion	3	$30
Motor Testing	3	$30
Movement Restriction	1	$10
MRI	1-10	$10-$100
MRI – Abdomen	2	$20
MRI – Brain	3-5	$30-$50
MRI – Cardiac	4-6	$40-$60
MRI – Cardiac Catheterization	50	$500
MRI – Cardiac with Contrast	6-8	$60-$80
MRI – Carotids	4	$40
MRI – Functional	1-10	$10-$100
MRI – General	2-10	$20-$100
MRI – Knee	4	$40
MRI – Neck	4	$40
MRI – Pelvis	4	$40
MRI – Shoulder	4	$40
MRI – Whole Body	4	$40
Nasal Lavage	4	$40
Nasal Swab/Scraping	4	$40
Near Infrared Spectroscopy	2	$20
Nerve Stimulation	1-1.5	$10-$15
Neurological Exam	1	$10
Neuropsychological Exam	2-3	$20-$30
Nitric Oxide Inhalation (NOI)	2	$20
Nitric Oxide Pulse Therapy (24 hr)	12	$120
Nuclear Stress Test with Contrast	5-6	$50-$60
Peripheral IV	1-4	$10-$40
PET Scan	1-65	$10-$650
Plasmapheresis	20	$200
Photography	2.5	$25
Physiological Monitoring	1	$10
Psychological/Cognitive Testing	1-21	$10-$120
Pulmonary Function Test	1	$10

Procedure	*Inconvenience Units (IU)	Payment
Pulse Oximetry	1-2	$10-$20
Questionnaire	1-4	$10-$40
Radioactive Tracer	8	$80
Return of Equipment	1-3	$10-$30
Saliva Collection/Sampling	1-2	$10-$20
SCID – Structural Clinical Interview for DSM	1-5	$10-$50
Screening	3-15	$30-$150
Sensory Testing	2	$20
Six Minute Walk	1-2.5	$10-$25
Sleep Study	1-8	$10-$80
Study Diary/Log	.5-4	$5-$40
Speech Language	2.5-3	$25-$30
Suture Removal	1	$10
Telephone Follow-up/Interview	1	$10
Tilt Table Testing	2	$20
Transcranial Magnetic Stimulation (TMS)	2	$20
Treadmill Exercise Test (see cardiopulmonary testing)		
Ultrasound, General	1-5	$10-$50
Ultrasound – Heart (see echocardiogram)		
Ultrasound – Vascular	2.5	$25
Ultrasound – Transcranial	2	$20
Urine Sample/Urinalysis	1-3	$10-30
Valsalva Maneuver	1	$10
Vascular Studies	5	$50
Vasodilator Stress	2.5	$25
Venipuncture (see blood draw)		
Video Recorded Interview	3-6	$30-$60
Videofluroscopy	2-21	$20-$210
X-Ray, Chest (see chest X-ray)		

For Disbursement of Funds: Refer to the Clinical Research Volunteer Program (http://clinicalcenter.nih.gov/participate/studies/healthy_vol_prg.shtml).

APPENDIX B - WORKSHEET/TOOL FOR CALCULATING ESTIMATED COMPENSATION

Key

Per Subject Enrolled:

- **IU - Inconvenience Unit**
- **IU = $10**
- **Outpatient Visit - $20.00 for the first hour and $10.00 for each additional hour or portion thereof**
- **Frequency - Number of times subject has test/procedure/# of nights/# of outpatient visits**
- **Total $$ = $ X Frequency**
- **TT- Time Total: Compensation for Time**
- **IT- Inconvenience Total: Compensation for Inconvenience**

TIME: *(As applicable. It is NIH policy to compensate for time in all instances when compensation is provided.)*

		$	**Frequency**	**Total $$**
INPATIENT		**$40/Night**		
OUTPATIENT- Ist Hour		**$20**		
OUTPATIENT TIME- Per Additional Hour		**$10**		
ESCORT FEE- INPATIENT				
OUTPATIENT				
TIME TOTALS				

INCONVENIENCE: *(As applicable. There is no NIH policy requirement to compensate with inconvenience units.)*

Procedures	**IU**	**$**	**Frequency**	**Total $$**
Completion Bonus?				
INCONVENIENCE TOTALS				

FOR IC USE ONLY (*as applicable)*

Total Estimated Compensation Expenditures Per Protocol

TIME + IU= Amount of Compensation Per Subject ($$$ X Total # of Subjects Enrolled = $$$$)

Compensation/Subject= $$$	**Total # of Subjects to be enrolled**	**Total Compensation for Study $$$$**
(TT)+ (IT)= $$$ per subject		