

POLICY AND COMMUNICATIONS BULLETIN

THE CLINICAL CENTER

Medical Administrative Series

M08-1 (rev.)

28 June 2016

MANUAL TRANSMITTAL SHEET

SUBJECT: Reimbursement of Travel and Subsistence Expenses
for NIH Clinical Research Protocol Participants

1. Explanation of Material Transmitted: This issuance transmits the policy and procedures of the Clinical Center on reimbursement of travel and subsistence expenses for participants in NIH Intramural Clinical Research Protocols. Specifically, all protocols are required to establish a protocol-specific reimbursement rate for travel (i.e., local and long-distance transportation) and subsistence (i.e., meals and lodging) and clinical research protocol participants are to be reimbursed in accordance with these protocol-specific reimbursement rates. The DRTS form, NIH 2868 (Appendix A) was updated with a correction: air/train travel is a percentage, not a dollar figure.
2. Material Superseded: MAS No. M08-1 (rev.), dated 13 August 2015
3. Filing Instructions: Ethics & Patient Rights Section

 Remove: No. M08-1 (rev.), dated 13 August 2015

 Insert: No. M08-1 (rev.), dated 28 June 2016
4. Distribution: NIH Institutes and Centers (IC), IC Clinical Directors, Principal Investigators, IC research coordinators, Institute Review Boards, Clinical Center (CC) Office of Protocol Services, CC Social Work Department, CC Voucher Office, and NIH Cashier's Office.
5. Additional Information: Additional information is available online at <http://intranet.cc.nih.gov/patienttravel> and links to relevant documents (where available) can be found in Reference section.

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SUBJECT: Reimbursement of Travel and Subsistence Expenses
for NIH Clinical Research Protocol Participants

PURPOSE

This chapter establishes a policy for reimbursement of travel and subsistence expenses for participants in clinical research protocols at all NIH intramural clinical research sites.

GUIDING PRINCIPLES

NIH will make every effort to assure fairness in reimbursing clinical research protocol participants for travel and subsistence by taking into account the scientific needs of the studies and the financial and/or medical needs of individual participants.

No U.S. citizen or permanent U.S. resident residing in the U.S. who otherwise meets eligibility requirements will be denied enrollment in clinical research protocols because of their inability to pay the costs of travel and subsistence.

POLICY

This policy establishes the requirement for each protocol to establish a protocol-specific reimbursement rate for travel (i.e., local and long-distance transportation) and subsistence (i.e., meals and lodging) ranging from zero up to the government rate. Participants will be made aware of the protocol-specific reimbursement rate as part of the enrollment process. Each participant will be provided reimbursement at the specified rate upon request.

Participants needing additional financial assistance will be able to receive supplemental reimbursement based upon need. Requests for supplemental reimbursement will be evaluated on a case-by-case basis for valid financial and/or medical need through a standardized process.

In establishing the travel and subsistence reimbursement rates for a protocol, Principal Investigators (PIs) must consider a set of objective factors, including reimbursement practices of similar protocols at the NIH, the rarity of the disease being studied, the benefit/burden being placed on the subject and family, and special needs of the participants. These factors will be used by the Institute Clinical Directors in approving the reimbursement rates to assure that proposed reimbursement practices are equitable.

In setting reimbursement levels for lodging, protocols must specify whether they will authorize use of The Children's Inn and The Edmond J. Safra Family Lodge. If use of these lodging facilities is authorized, full reimbursement at the current nightly rates will be required.

SCOPE

This policy applies to U.S. citizens or permanent U.S. residents residing in the U.S. (and parent/guardian for pediatric protocol participants or authorized attendant for adults) enrolling in research protocols that take place at NIH intramural clinical research sites, including protocols located on the NIH campus in Bethesda, Maryland, and at all other NIH intramural locations.

For participants whose home of record is outside the U.S., travel expenses from a U.S. port of entry may be covered.

The specific procedures for implementation will vary by site; however, all applicable travel guidelines outlined in the procedures section of this policy must be followed.

This policy does not address the issue of compensation that may be offered under a protocol other than reimbursement for travel and subsistence for participants.

DEFINITIONS

Protocol-Specific Reimbursement Rate: Amount of financial coverage provided to clinical research protocol participants (and parent/guardian for pediatric protocol participants or authorized attendant for adults) for travel and subsistence by the sponsoring Institute or Center (IC). This rate can range from zero up to the government rate. The parameters of coverage are detailed below (see “Parameters of Coverage”).

Supplemental Reimbursement: Additional financial assistance, above the protocol-specific reimbursement rate, made available by Institutes to clinical research protocol participants with valid financial and/or medical need. Generally, supplemental reimbursement extends coverage up to the full government rate; the amount is at the discretion of the IC and the IC may authorize supplemental reimbursement above the full government rate on an as-needed basis (e.g., a participant may require two airline seats for medical necessity).

Travel: Transportation of a person by car, bus, train or plane; refers to both local and long-distance. The parameters of coverage are detailed below (see “Parameters of Coverage”).

Subsistence: Refers to meals and lodging. The parameters of coverage are detailed below (see “Parameters of Coverage”).

PARAMETERS OF COVERAGE

The mode of travel approved will be the least expensive unless otherwise authorized.

NIH will pay for expenses that involve travel from the home of record to the NIH site. Unless medically indicated, NIH will not pay for expenses that involve alternate routes. Unnecessary stops or delays along the way for sight seeing, visits, vacations, or to increase frequent flyer miles will not be authorized, even if it makes the travel less expensive.

NIH will not pay for expenses that are incurred beyond the approved time period of the visit.

Local Travel: Protocol participants who live within 50 miles of the NIH clinical research site are eligible for reimbursement of local travel at the protocol-specific reimbursement rate. The approved modes of local travel are as follows:

- *Car:* The government will reimburse participants for car mileage. Reimbursement for rental cars will not be allowed beyond the car mileage reimbursement rate.
- *Taxi/Train/Bus/Metro:* Participants traveling by taxi, train, bus, or metro will be reimbursed if authorized.

Long-Distance Travel: Protocol participants who live more than 50 miles from the NIH clinical research site are eligible for reimbursement for long-distance travel at the protocol-specific reimbursement rate. The approved modes of long-distance travel are as follows:

- *Air:* The government will pay for air transportation from the airport nearest to the home of record to the least expensive airport near the NIH clinical research site.
- *Train:* The government will pay for train tickets.
- *Car:* The government will pay for car mileage provided the cost of the round trip does not exceed a round trip government-rate airline ticket. Reimbursement for rental cars will not be allowed beyond the car mileage reimbursement rate.
- *Bus:* The government will pay for bus tickets provided the cost of the round trip does not exceed a round trip government-rate airline ticket.

NOTE: If a protocol participant arrives by any other modes of travel, reimbursement for travel will not exceed the government rate for one of the approved modes of travel.

Lodging: Participants will be provided reimbursement for lodging expenses in accordance with the protocol-specific reimbursement rate for participants living greater than 50 miles from the NIH clinical research site. If the hotel cost is less than the protocol-specific reimbursement rate, NIH will only reimburse for the actual cost of the lodging.

Meals: Protocol participants who live greater than 50 miles from the NIH clinical research site are eligible for reimbursement in accordance with the protocol-specific reimbursement rate for meals at a daily rate.

PROCEDURES

1. ESTABLISHING THE PROTOCOL-SPECIFIC REIMBURSEMENT RATE

During the development of a new protocol or at the time of renewal for existing protocols, the PI will complete the “Designation of Reimbursement of Travel and Subsistence (DRTS) Expenses for NIH Intramural Clinical Research Protocols” (Form NIH 2868). In completing the DRTS form, the PI will consider the disease characteristics, benefit/burden to participants, scientific need and the reimbursement practices of similar protocols and will determine a protocol-specific reimbursement rate

for travel and subsistence expenses. The protocol reimbursement rate can range from zero up to the government rate.

The DRTS form (Appendix A) can be accessed from the CC Office of Protocol Services (301-496-0744) at <http://intranet.cc.nih.gov/ops/> and at <http://intranet.cc.nih.gov/patienttravel>. Investigators can query protocols to identify protocols with similar disease characteristics identified on the DRTS Form, as well as by reimbursement, protocol number, or PI at http://pqs.cc.nih.gov/protocol_query/pi_institute_search.

The PI or designee uses the NIH CC template that will ensure that each protocol consent document includes the following statement:

“Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.”

The PI will sign the completed DRTS form and submit it to the IC Clinical Director as a part of the protocol package.

The Office of Protocol Services will assure that the Federal travel rates listed are current by updating the electronic database upon changes in the Federal travel rates.

2. APPROVING THE PROTOCOL-SPECIFIC REIMBURSEMENT RATE

The IC Clinical Director will ensure that the protocol review package includes a completed DRTS form and a new consent document as referenced in Section 1.

The IC Clinical Director will review the DRTS form as part of the protocol review package to ensure that the PI has considered the relevant factors in establishing the protocol-specific reimbursement rate.

The protocol-specific reimbursement rates will be considered effective as of the date of the final IRB approval of the complete protocol package.

3. INFORMING PARTICIPANT OF THE POLICY, PROTOCOL-SPECIFIC REIMBURSEMENT RATE AND REIMBURSEMENT OPTIONS

The PI or designee will inform prospective and current protocol participants of the policy on *Reimbursement of Travel and Subsistence Expenses for NIH Clinical Research Protocol Participants* and the protocol-specific reimbursement rate (for air/rail travel, car mileage, meals and lodging). The PI or designee may opt to send written documentation to prospective and current protocol participants describing this policy and the protocol-specific reimbursement rate. A sample generic notification memorandum is available at <http://intranet.cc.nih.gov/patienttravel>.

The PI or designated IC research coordinator will explain the three reimbursement options to the participant and will ask the participant to select one:

- a. Accept protocol-specific reimbursement

- b. Decline reimbursement
- c. Request supplemental reimbursement for financial or medical need

4. ENTERING THE REIMBURSEMENT OPTION SELECTED BY PARTICIPANT

Once a reimbursement option is selected by a protocol participant, the PI or designated IC research coordinator will document the participant's selection in the Admissions/Travel/Voucher (ATV) system. If applicable, the PI or designated IC research coordinator will initiate a request for a financial or medical needs assessment in the ATV system which generates a service request to the CC Social Worker or the CC Patient Travel Coordinator, respectively.

5. EXPLAINING TRAVEL PLANNING STEPS TO PARTICIPANT

The PI or designee will explain the travel planning steps that correspond with the selected reimbursement option:

a. Participant ACCEPTS protocol-specific reimbursement

IF THE PROTOCOL-SPECIFIC REIMBURSEMENT RATE IS SET AT (OR ABOVE) THE GOVERNMENT RATE FOR AIR/RAIL TRAVEL:

The PI or designee will direct the participant to contact the Patient Travel Office to have air or rail travel arranged and paid by the government. The PI or designee will instruct the participant to arrange and pay for his/her own lodging. The PI or designee will inform the participant to keep receipts for reimbursement of lodging and other travel expenses.

IF THE PROTOCOL-SPECIFIC REIMBURSEMENT RATE IS SET **BELOW** THE GOVERNMENT RATE FOR AIR/RAIL TRAVEL:

The PI or designee will instruct the participant to arrange his/her own air or rail travel and lodging at his/her own expense. The PI or designee will inform the participant to keep receipts for reimbursement of these and other travel expenses. The participant may contact the Patient Travel Office for assistance with air/rail travel planning.

b. Participant DECLINES reimbursement

The PI or designee will inform the participant to arrange ALL travel and lodging at his/her own expense. The participant may contact the Patient Travel Office for assistance with air/rail travel planning.

c. Participant REQUESTS supplemental reimbursement

IF THE REQUEST IS FOR **FINANCIAL** NEED:

The PI or designee will inform the participant that he/she will be contacted by the CC Social Worker who will conduct an in-person or phone interview to evaluate financial need using a standardized assessment tool that was developed by the Social Work Department. Within three days of the interview, the CC Social

Worker will evaluate the participant's responses and record the results of financial assessment in the ATV system. The PI or designee will check the results of the financial assessment in the ATV system and inform the participant of the decision.

If the participant is approved for supplemental reimbursement, the PI or designee will then instruct the participant to follow the appropriate travel planning steps from Section 5a. If participant is denied supplemental reimbursement but accepts instead the protocol-specific reimbursement rate, the PI or designee will then instruct the participant to follow the appropriate travel planning steps from Section 5a.

IF THE REQUEST IS FOR MEDICAL NEED:

The PI or designee will determine if supplemental reimbursement for medical need should be provided to the participant. This determination is based on individual participant need and the scientific/recruitment needs of the protocol. As a management control, the CC Patient Travel Coordinator will review supplemental reimbursements for medical necessity to ensure that patient travel funds are the appropriate funding mechanism to cover the request. If patient travel funds are not the correct funding source, the CC Patient Travel Coordinator will contact the PI or designee to determine alternative resources. The PI or designee will specify the supplemental reimbursement amount in the ATV system and inform the participant of the decision.

If the participant is approved for supplemental reimbursement, the PI or designee will then instruct the participant to follow the appropriate travel planning steps from Section 5a. If participant is denied supplemental reimbursement but accepts instead the protocol-specific reimbursement rate, the PI or designee will then instruct the participant to follow the appropriate travel planning steps from Section 5a.

6. EXPLAINING THE REIMBURSEMENT PROCESS TO PARTICIPANT

The PI or designee will explain the following information to participants who pay up-front for travel, lodging and/or meal expenses that have been approved for reimbursement:

- The participant can receive a travel voucher for reimbursement of approved travel-related expenses from the CC Voucher Office.
 - Hours of Operation: Monday – Friday 7:30 am – 5:00 pm
 - Proof of payment (receipts) is required for lodging and travel expenses (not required for meals or mileage)
- The CC Voucher Office will prepare a voucher in accordance with the protocol-specific reimbursement or supplemental reimbursement rate for the dates authorized on the ATV request.
- The participant has two options for receipt of payment:

- Obtain voucher from the CC Voucher Office and take it to the NIH Cashier's Office and receive cash or a check (picture identification is required to receive funds).
- Request at the CC Voucher Office to have the reimbursement check mailed to participant's home of record.

SUMMARY OF RESPONSIBILITIES

1. The Medical Executive Committee, in conjunction with the CC Director, will:
 - Conduct an annual assessment of the policy, including but not limited to, policy compliance; IC-specific and overall NIH expenditures on patient travel; and any unforeseen administrative or patient-associated impacts related to the process.
 - Provide the Deputy Director for Intramural Research an annual summary of above assessment.

2. The Principal Investigator (PI) will:
 - Complete, sign and submit a "Designation of Reimbursement of Travel and Subsistence (DRTS) Expense for NIH Intramural Clinical Research Protocols" (Form NIH 2868) to the IC Clinical Director with every new protocol review package.
 - Inform prospective and current protocol participants of the policy on *Reimbursement for Travel and Subsistence Expenses for NIH Clinical Research Protocol Participants* and the protocol-specific reimbursement rate.
 - Notify the Office of Protocol Services of any changes to the DRTS form (i.e. any changes to protocol reimbursement amounts, CAN, etc.).
 - Ensure that each protocol consent document includes the following statement:
 "Reimbursement for travel and subsistence will be offered consistent with NIH guidelines."

3. The Institute Clinical Directors (CD) will:
 - Ensure that their Institute is in compliance with this policy.
 - Monitor monthly reports from the Clinical Center of their Institute's expenditures on patient travel.
 - Ensure that the protocol review package includes a completed DRTS form.
 - Review the DRTS form as part of the protocol review package to ensure that the PI has considered the relevant factors in establishing the protocol-specific reimbursement rate.

4. The Institutes' or Centers' (IC) research coordinators will:
 - Communicate this policy and protocol-specific reimbursement rates to new and existing clinical research protocol participants and provide instructions to participants.
 - Notify the CC Patient Travel Coordinator of any participant or IC concerns and/or issues.
 - Serve as a liaison between participants, the CC Patient Travel Coordinator, the CC Admissions Office, the CC Voucher Office and other stakeholders.
 - Generate participant travel requests in the Admission Travel Voucher (ATV) system.

5. The Clinical Center will:
 - Serve as the primary point of contact for resolution of any participant or IC concerns and/or issues related to travel.
 - Evaluate requests for supplemental reimbursement.
 - Assist with training IC research teams.
 - Serve as a liaison between participants, IC research coordinators, the CC Admissions Office, the CC Voucher Office and other stakeholders.
 - Provide ICs with monthly summary reports of IC expenditures on patient travel (by CAN and protocol).
 - Maintain a website that permits investigators to query protocols by disease characteristics, reimbursement amount, protocol number, or PI.
 - Will process vouchers for participant reimbursement.

6. The NIH Cashier's Office will provide cash or checks to protocol participants.

REFERENCES:

The "Designation of Reimbursement of Travel and Subsistence (DRTS) Expense for NIH Intramural Clinical Research Protocols" (Form NIH 2868) can be accessed from the CC Office of Protocol Services (301-496-0744) at <http://intranet.cc.nih.gov/ops/> and at <http://intranet.cc.nih.gov/patienttravel>.

Investigators can query protocols to identify protocols with similar disease characteristics identified on the DRTS Form, as well as by reimbursement, protocol number, or PI at http://pqs.cc.nih.gov/protocol_query/pi_institute_search.

Government Travel Rates

Government rates for round trip airfare are available at www.gsa.gov/citypairsearch

Government rate for car mileage is available at www.gsa.gov/mileage

Government rate for meals is available at www.gsa.gov/perdiem (Search for DC Metropolitan rate.)

Government rate for lodging is available at www.gsa.gov/perdiem (Search for DC Metropolitan rate.)

Appendix A

DESIGNATION OF REIMBURSEMENT FOR TRAVEL AND SUBSISTENCE (DRTS) FOR NIH INTRAMURAL CLINICAL RESEARCH PROTOCOLS

Protocol Number: _____ Institute/Center: _____

Principal Investigator: _____ CAN (Common Accounting Number): _____

Protocol Title: _____

Points to Consider in Establishing Reimbursement for Protocol

In determining the reimbursement, the following factors affecting recruitment are considered applicable to this protocol.

Disease Characteristics: Check all that apply.

- Rare disease Common disease
 Sick participant population Healthy participant population Mixed participant population (sick & healthy)

Benefit/Burden to Participants: Check all that apply

- Direct benefit possible (Direct benefit possible with treatment) No benefit
 Demanding protocol regimen Easy protocol regimen Varied protocol regimen
 Participant disability No participant disability

Scientific Need: Check all that apply

- Participants would likely not participate unless reimbursed
 Geographically dispersed participant population required Local participant population

Does the Protocol Provide Travel Reimbursement? Yes No

Reimbursement Practices of Similar Protocols:

- The following protocols with similar characteristics or treating a common diagnosis have been considered and reimburse at a similar rate (insert protocol numbers or IC-specific standard rate) _____

Identify the Government Rate or Protocol-specific Reimbursement Rate for each category: A link to the Government rates can be found on the Patient Travel Web site: <http://intranet.cc.nih.gov/patienttravel/index.html>

Air/Train Travel	<input type="checkbox"/> Government rate for air/train. <input type="checkbox"/> Luggage fee for # _____ checked bags <input type="checkbox"/> Protocol-specific rate for air/train: _____ % per round trip. (View Government airfare rates at www.gsa.gov/citypairsearch)
Local Transportation (≤50 miles from home)	<input type="checkbox"/> Government rate for car mileage per mile <input type="checkbox"/> This protocol will cover taxi/train/bus/Metro costs. <input type="checkbox"/> Protocol-specific rate for car mileage: _____ ¢ per mile
Long Distance Transportation (>50 miles from home)	<input type="checkbox"/> Government rate for car mileage per mile <input type="checkbox"/> This protocol will cover taxi/train/bus costs. <input type="checkbox"/> Protocol-specific rate for car mileage: _____ ¢ per mile
Meals for long distance travelers (>50 miles from home)	<input type="checkbox"/> Government rate for meals per day <input type="checkbox"/> Protocol-specific rate for meals: \$ _____ per day
Lodging	<input type="checkbox"/> Government rate for lodging per night <input type="checkbox"/> Protocol-specific rate for lodging: \$ _____ per night <input type="checkbox"/> This protocol will cover friend/family lodging at \$ _____ per night Children's Inn: <input type="checkbox"/> This protocol will cover costs of The Children's Inn. Family Lodge: <input type="checkbox"/> This protocol will cover costs of The Family Lodge.
Guardian Coverage	Air/Train Travel: <input type="checkbox"/> Government rate or <input type="checkbox"/> _____ % Meals: <input type="checkbox"/> Government rate or <input type="checkbox"/> \$ _____ per day Lodging: <input type="checkbox"/> Government rate or <input type="checkbox"/> \$ _____ per night
Screening Visit	<input type="checkbox"/> Reimbursement will be provided at the above rate. <input type="checkbox"/> Reimbursement will not be provided. <input type="checkbox"/> Not applicable
Comments	

PI Signature: _____

Date: _____

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