Participant Reimbursement

Purpose

This policy describes the general expectations and procedures to be followed related to the reimbursement of participants in trials conducted in the SIREN network.

Responsible Individuals

SIREN coordinating centers
SIREN enrollment sites (hubs and spokes)

Definitions

Clinical trial visits – For the purposes of this policy, a clinical trial visit is a planned follow up outcome assessment occurring after discharge from the initial enrollment hospitalization.

Central Institutional Review Board (CIRB) – The single board (pursuant to NIH policy for multicenter clinical trials) serving as the IRB of record for SIREN trials and providing oversight of research (as described in 45 CFR Part 46).

Coordinating Centers - The network Clinical Coordinating Center, Data Coordinating Center, or any trial-specific Scientific Coordinating Centers for network trials.

Enrollment site - Network hubs and spokes as defined in the SIREN Hub Management of Spokes SOP

Background and Intent

This policy is designed to be consistent with FDA Guidance for Institutional Review Boards and Clinical Investigators. The FDA distinguishes between payment for participation and reimbursement for clinical trial visits. Payment for participation is intended as a recruitment incentive. Reimbursement for clinical trial visits, on the other hand, are intended to remove barriers that may adversely affect participant follow-up and retention in the study. Given the emergency conditions in which participants are generally enrolled in clinical trials conducted in SIREN, the network will **not pay patients for participation** in clinical trials conducted in the network. Reimbursements for clinical trial visits, however, are respectful of participants and the difficulties and expenses that they may incur while volunteering in clinical trials. Therefore, SIREN trial **enrollment sites may provide reimbursements for clinical trials visits** that consider costs associated with travel, parking, food, missed work, time and effort. Reimbursements for clinical trial visits in SIREN are intended to be fair and just. The total amount, disbursement, and timing of reimbursements for clinical trial visits in SIREN will not be coercive or present undue influence.

Procedure

1. **Payments allowed:** SIREN trials do not pay patients for participation. SIREN enrollment sites may offer participants reimbursements for clinical trial visits. Reimbursements for clinical trials visits may consider any incidental costs such as travel, parking, nourishment, missed work, and may be respectful of the time and effort of the participant or caregivers.
2. **Applicability and exception:** Unless otherwise stated, this policy is applicable to all clinical trials conducted in the SIREN network. If circumstances require modification of this policy for a specific trial, the procedures of that trial may override this policy with the approval of the SIREN executive committee. Variations from this policy for a particular trial also require individual approval of those procedures by applicable oversight bodies.
3. **Total payment amount:** Appropriate reimbursement amounts may vary by trial, type of visit, participant factors, and location of the enrollment site. To allow flexibility while preventing the reimbursement for a clinical trial visit from being coercive or presenting undue influence, payments will be capped at the US General Services Administration standard Per Diem Rates for the current year and the city in which the study visit takes place.
4. **Timing:** The timing of reimbursement for clinical trial visits will be proximate to the clinical trial visit. Reimbursement payments from multiple clinical trial visits should not be withheld or contingent upon completion of the entire study. Because SIREN does not intend reimbursements for clinical trial visits to ever be used as incentives for enrollment, and to prevent payments from coercing or influencing enrollment decisions, it is preferable to offer and explain reimbursements for clinical trial visits to participants when the clinical visits are being planned and scheduled, rather than at the time of enrollment.
5. **Budgeting and disbursement:** Disbursement of reimbursement payments to participants for clinical trial visits is at the discretion of the enrollment sites. The need for, or appropriateness of, payments for reimbursements for clinical trial visits in SIREN are determined by the individual enrollment sites. If needed, sites pay for reimbursements to participants for clinical trial visits from the overall per-participant payments the enrollment sites receive. Payments for reimbursements for clinical visits are not provided to participants directly from the coordinating centers, nor do enrollment sites receive separate additional payments from the coordinating centers to cover reimbursements for clinical trial visits. Sites may reimburse for itemized expenses or may provide reimbursement as a fixed per diem amount. The coordinating centers will not reimburse or require documentation from sites for itemized expenses for clinical trial visits, but sites should comply with their local institutional accounting requirements.
6. **Central IRB approval:** The SIREN Central IRB will be asked to approve application of this non-trial-specific policy separately for each SIREN trial. The policy will be appended to the trial parent application or a modification of the parent application. Approval permits enrollment sites to provide reimbursements for clinical trial visits in SIREN trials in accordance with this policy. The SIREN clinical coordinating center will submit this policy to the CIRB for comment and feedback at least every 5 years at the time of the CCC grant renewal.