Reimbursement SOP

Version 1

SCOPE
These guidelines apply to new protocols and protocol revisions.

PURPOSE
The purpose of this SOP is to provide study teams information on how to handle reimbursements in the informed consent document (ICD) and protocol.

PROCEDURE
Per IRB policy, participants need to be informed of total amounts that may be reimbursed, such as travel expenses.

The options below indicate what reimbursement documents are required in the protocol, if any, depending on the study.

I. If there is NO reimbursement described in the protocol
No action is needed.

However, if you are made aware the sponsor will provide reimbursement anyway, resubmit the protocol to state that reimbursement will be provided. In the resubmission, also add the sponsor’s reimbursement forms, if any, or the appropriate Abbreviated form described below, and the consent wording described below.

II. If reimbursement IS described in the protocol
Use one of these options below, as applicable.

a.) If sponsor will use a 3rd party vendor, and dollar caps (maximum dollar amounts offered) and sponsor-provided forms ARE in the protocol, then:
   • Add the sponsor documents as appendices.
   • See below for resubmission instructions.

b.) If sponsor is NOT using a 3rd party vendor, then:
   • Add the Abbreviated form - Patient Disclosure/Acknowledgement for Reimbursement which utilizes Bank of America form as a consent information document (CID).
   • Add the other sponsor documents as CIDs.
   • See below for resubmission instructions.
c.) If sponsor will use a 3rd party vendor and there are NO sponsor-provided forms in the protocol, then:
   • Add the Abbreviated form – Patient Disclosure/Acknowledgement for Reimbursement not using Bank of America form as a CID. This form will only include the dollar caps.
   • See below for resubmission instructions.

d.) If sponsor will use a 3rd party vendor, and there ARE sponsor-provided forms in the protocol, but NO dollar caps, then:
   • Add the Abbreviated form – Patient Disclosure/Acknowledgement for Reimbursement not using Bank of America form in addition to the sponsor form(s) as a CID. The abbreviated form will only include the dollar caps.
   • Add the other sponsor documents as appendices.
   • See below for resubmission instructions.

IIa.) Resubmission Instructions
For a-d above, the consent will also need to include the following generic wording in the Costs and Compensation section:

   “The sponsor may reimburse you for costs that are a direct result of your participation, such as travel expenses. You will need to provide receipts for your expenses to be eligible for reimbursement. Please ask the study staff about this possible reimbursement.”

For revisions, include in your resubmission cover letter that you are adding this generic wording to the consent.

For new protocols that have already been submitted initially for scientific review, you should resubmit the other sponsor documents as described above, even if the consent is not yet finalized. (If you are not yet working with a consent editor, revise the consent and include the consent change in the resubmission cover letter. Otherwise just make your assigned consent editor aware if travel reimbursement is being newly added.)

2.) Resubmit the documents in PDOL as described in option a-d above. (Or add them to PDOL if you are creating a Version 00 new protocol.)

III.) Activation checklist
The consent editor will also ask you to confirm that the sponsor will in fact provide this reimbursement at our site.

IV.) For more information:
Contact Office of Human Subjects Protection (OSHP) Consent Editors at consenteditors@mdanderson.org

Contact CRF-ParticipantRemuneration@mdanderson.org

REFERENCES
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