

Engaging with Sponsors about Financial Support Programs for Participants:



Checklist for Clinical Trial Site Staff

During budget negotiations, staff should ask trial sponsors these questions regarding support for non-medical, out-of-pocket participant costs.

1. Does the sponsor offer financial support for trial participants' non-medical, out-of-pocket costs?

☐ Yes ☐ No

if "no," there is no need to proceed with questions. If "yes," ask for the following information.

2. Are there eligibility requirements for patients seeking to access this support?

☐ Yes ☐ No

If "yes," please list:

3. What type of support is offered?

☐ Prepayment ☐ Reimbursement

If "prepayment":

3a. provide details including how much support is provided, at what interval (e.g., weekly, monthly), and how funds are dispersed (e.g., preloaded debit card, direct deposit to bank account, other):

If "reimbursement," proceed with the remaining questions.

3b. What is the procedure for submitting and approving reimbursements?

3c. What are the participant's responsibilities (list below with any applicable time limits):

3d. What are the site's responsibilities (list below with any applicable time limits):

3e. What expenses are considered reimbursable? Check all that apply and provide any limits (i.e., maximum amount reimbursable) and restrictions:

☐ Personal auto travel (including tolls and mileage)

☐ Taxi, rideshare service, public transportation

☐ Airfare, train fare

☐ Parking

☐ Lodging

☐ Meals (is this per meal or per diem allowance?)

☐ Childcare, elder care, pet care

☐ Lost wages

☐ Equipment, IT needs

3f. Are these same expenses covered for a caregiver or other person who must accompany the participant?

☐ Yes

☐ No

If "no," explain what is and is not covered for the caregiver:

3g. Provide other relevant information on the reimbursement program (e.g., whether the program is contracted through a third-party vendor, whether payments are sent directly to the participant or to the trial site, etc.):