

AMENDMENT REQUEST FORM
(all fields are required)

PROTOCOL NUMBER:

TYPE OF AMENDMENT REQUEST (select one):

Protocol Amendment / Protocol Clarification Letters

- New Protocol Amendment Version/Date
- Is protocol amendment adding an arms/cohort? No Yes
 - If yes, please indicate what arms/cohorts we are participating in
 - If yes, please indicate if there are any new drugs added and who will be supplying them
 - If yes, will CTU be used for the new arms/cohorts? No Yes
- Is protocol amendment suspending an arms/cohort? No Yes
 - If yes, please indicate what arms/cohorts we are suspending

Other Information / Comments

Contract/Budget Amendment (please provide detail/information of amendment request)

Informed Consent Changes (affecting cost, injury, patient stipend and/or patient reimbursement)

- Is this a new ICF? No Yes
- What section is being modified (select all that apply): Injury Cost Stipend and/or Reimbursement
- If modifications are to stipend and/or reimbursement, please indicate modifications
- Is the responsibility for the stipend and/or reimbursement shifting (e.g. from a third-part vendor to site)? No Yes

PI Change **Current PI** **New PI**

Other (please provide detail information of amendment request)

Sponsor/CRO Contact Name:

Sponsor/CRO Contact Email:

Has Sponsor/CRO agreed to cover any services rendered relating to this amendment during the negotiation period to ensure continuity of care? IF YOU HAVE NOT REQUESTED THIS, PLEASE DO AND ATTACH EMAIL CONFIRMATION WITH YOUR AMENDMENT SUBMISSION.

Yes No Other

Submitted By:

E-mail/Contact:

Date: