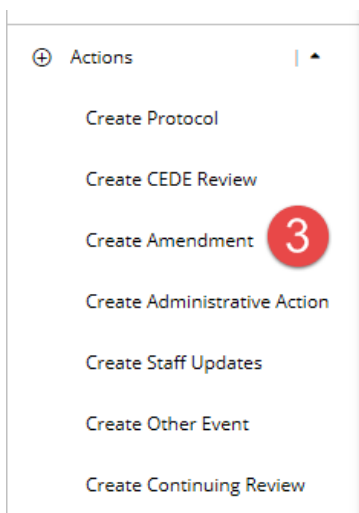


### Introduction

The Amendment function in Humans module under Actions menu is used to funding source to an existing protocol and submit to Partners Institutional Review Board (IRB) for review.

### STEPS

1. Click **Humans**
2. Select an existing active protocol from the landing page for which you would like to create an Amendment
3. Select **Create Amendment** under Actions menu on the left navigation panel
4. The entire protocol gets unlocked for modifications
5. Complete the Amendment Form and click the **Save** button.
6. At the top of the Amendment Form click on **+ Add new form** link on the right corner.
7. Upon clicking on + Add new form link, a type ahead drop-down box is displayed. Type in “Add Sponsor/Funding” form and click the **Add** button.
8. Navigate to the Add Sponsor/Funding form in the left navigation under Forms.
9. Select an option. Search Insight Agreements will allow you to link to existing Agreement records.
10. Search for an Agreement by Agreement Number, Fund Number or PI Name. Click the Search button. Note that only funded record types are returned as part of this search.
11. Select a returned result by clicking the radio button. Note that you will not be able to select an Agreement already linked to the record.
12. Click the Save button.
13. Complete all the the sponsor funding form. Submission Checklist on the right panel helps in identifying the incomplete information within the page that needs to be completed
14. When all the mandatory fields are answered in a section, a green check mark (✓) appears next to the page title.
15. When all the sections are complete, Submit button gets enabled at the bottom right corner of the screen
16. Click **Submit**
17. Upon submission, a transaction status bar is displayed which represents the future flow of transaction progression.
18. The Related Records page will show the status of the link until the Amendment is approved. For more on the Related Records page [click here](#).
19. Once the Amendment is approved the protocol will be listed on the Compliance page of the select Agreement record.



Sponsor / Funding

None

Intervention

Conflicts of Interest

Study Details

Clinical Trials Registration

Study Population

Performance Sites / Facilities

Recruitment

Remuneration

Informed Consent

Diaries

Privacy / Confidentiality

Instruments / Questionnaires

Ancillary Drugs

Ancillary Devices

Non-Intervention / Non-Interaction Group

Nursing Planning & Implementation

Nursing Implementation and Planning

Drugs / Biologics / Dietary Supplements

Bupivacaine

Amendment

Amendment

Staff

Attachments

Related Records

Summary Notes

Actions

Create Protocol

Protocol Info

Forms

Staff

Attachments

Related Records

Superior hypogastric plexus block during laparoscopic hysterectomy: a randomized controlled trial.

AMET1

Draft

v11.1

Protocol #: 2017P001804

Overall Status: Active, Enrolling Subjects

Expiration Date: 10/17/18

PI/Institution: Aguirre\*, Amy L, PHS

Type: Intervention/Interaction

Protocol Admin: Pennington\*, Marisa J

Download

TURN TRACK CHANGES OFF

Amendment

5

6

+ Add New Form

Central IRB Performance Sites

Is this a NeuroNEXT or STRIDE network protocol?

Note: The Partners IRB is the Central IRB for the NeuroNEXT and Stride networks.

☐ Yes
 ☐ No

Sponsor Amendment

Is there a sponsor amendment number?

☐ Yes
 ☐ No

Change in Protocol Status

Does the study involve an intervention / interaction with human subjects?

Note: Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject (45 CFR 46.102(f)).

☐ Yes
 ☐ No

Briefly describe the proposed changes:

Provide rationale for the proposed changes:

< Previous

Next >

### Amendment

spons

SPONSOR / FUNDING

Add Sponsor/Funding

Add

Cancel

7

Is this a NeuroNEXT or STRIDE network protocol?

# 2017P001804 AME11

Forms MOD

**Initial Questionnaire**

✓ InitialReview

**Sponsor / Funding** 8

✓ None

Add Sponsor/Funding ADD

**Intervention**

✓ Conflicts of Interest

✓ Study Details

✓ Clinical Trials Registration

✓ Study Population

Sponsor/Funding + Add New Form X Delete

**Instructions**  
Select fund type etc etc

☒ Search Insight Agreements for the funding proposal (pending or awarded) supporting the research below 9

☐ No funding proposal in Insight Agreements

☐ NONE – There is no external sponsor/funding, institutional award or sundry funds supporting this research

Agreement # 2018A054352 Fund # PI Name Search by PI nam... Search 10 Actions

Agreement #	Fund #	PI Name	Record Type	Sponsor	Project Period
2018A054352	232284	Noble*, Darrell D	Innovation – SRA	Leap Therapeutics	03/06/18 - 12/05/18

11

Draft

Instructions

Submission Checklist

All validations in this area have been completed

Notes

Submitter Actions

Please complete the submission checklist 12

DELETE APPLICATION Cancel SAVE SUBMIT

HUMANS

Leap Therapeutics [Industry] 13

Select the source of funding that will be used to support the proposed research:

☒ Government / Foundation / Other Non-Profit

☒ Corporate

☐ Institutional Award

☐ Department Funds

☐ None

Select the type of corporate funding:

☐ Corporate sponsored clinical research

☐ Funding for investigator-initiated clinical research

**NOTE: When the corporate sponsor designs the study, the corporate sponsor's protocol must be submitted to PHRC for review. Before the research can begin, PHRC must approve the sponsor's protocol and Partners Clinical Research Office must execute the Agreement with the sponsor.**

Enter contact name at sponsor:

Enter telephone number of contact:

Sponsor protocol # (if known):

Insight Agreement proposal number (read-only field): 2018A054352

Enter Principal Investigator name (if different): Noble\*, Darrell D

< Previous Next >

Draft

Instructions

Submission Checklist

You must select the type of corporate funding. You must enter the contact name at sponsor. You must enter the telephone number of sponsor contact. You must indicate if the protocol for this study will involve any items or services that will be billed to Medicare/private insurance, including study-specific procedures or those considered usual and customary care ("standard of care") outside the t. You must indicate if the funding will cover all subject study-related drugs, devices, procedures, tests, and visits.

Notes

Submitter Actions

Please complete the submission checklist

DELETE APPLICATION Cancel SAVE SUBMIT

HUMANS

Action Required2

Notifications7

Administration

# 2017P001804 AME11

FormsMOD

Staff

Attachments

Related Records18MOD1

Summary Notes

Actions

Create Protocol

Create CEDE Review

Related Records

Funding/Support Agreement Records (1)

Record #	Fund #	Project Period	PI Name	Sponsor	Record Type	Process	Link Date	Link Status
2018A054352	232284	03/06/18 - 12/05/18	Noble*, Darrell D	Leap Therapeutics	Innovation – SRA	AME11	18	Draft Added

Other Agreement Records (0)

Record #	Fund #	Project Period	PI Name	Sponsor	Record Type	Process	Link Date	Link Status
No data found.								