



DATE

Dear NeuroNEXT PI, Site PI, and Site Coordinator -

We are sending this document to provide guidance and instructions for study set up activities related to NN1XX – STUDY NAME. Below you will find some additional information about account set up, per subject fees, additional budget items and site payments.

A. Internal account set up

In order to have an account set up for this project at your site, you may need to submit a combination of the following to your Central Grants Office. Please check with your grants administrator to confirm what is needed.

- Master Clinical Trial Agreement – tied to NeuroNEXT (NN) Infrastructure grant at your site
- E-mail confirming selection of your site for NN1XX – STUDY NAME
- A proposed budget illustrating the anticipated number of subjects to be enrolled for NN1XX – STUDY NAME
- Per Subject Fee (PSF) Schedule
- E-mail confirming your CSS indirect tier level – *Your site belongs to Tier XXX which has XX% IDC*
- Award-specific information
 - Grant Number: 1 U01 XX
 - Budget Period: XX/XX/XX – XX/XX/XX
 - Project Period: XX/XX/XX – XX/XX/XX
 - CFDA #: XX.XXX

B. Per Subject Fee

- For enrolled subjects, reimbursable activities are outlined on page 3.
- For subjects who screen fail, you will be reimbursed for all work performed, so make sure you enter all information into the Case Report Forms (CRF’s).
- For fully enrolled subjects direct costs of all activities equal \$XX,XXX.XX
- NeuroNEXT Clinical Study Sites have been informed which tier they belong to

Tiers	Direct	Indirect	Total Cost
XXX – XX%	\$XX,XXX.XX	\$X,XXX.XX	\$XX,XXX.XX

C. Additional Budget Items

- None

D. Site Payments

- Clinical Coordination Center (CCC) Sr. Grants Administrator (GA) will send first quarterly invoice to sites 3 months after first subject is enrolled in the overall study. Subsequent invoices will be sent quarterly.
- Sites are paid for work performed as entered into the CRF’s at the fixed direct costs listed on the PSF.
- CCC Project Manager (PM) e-mails Clinical Study Site (CSS) 10 days before cutoff date of CRF is run.
- The Data Coordination Center (DCC) provides report to the CCC on the last 90 days of data entered.
- CCC Sr. GA reviews data and adds any additional reimbursable costs not on the PSF, i.e. Medicare coverage analysis and calculates indirect rates before generating invoices.



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- Invoices will include an itemization of work performed by subject by visit and will be e-mailed to the NN and CSS PIs and coordinators to review.
- CSS has 10 business days to follow up with the CCC Sr. GA and inform her of any discrepancies in the invoice.
- If no discrepancies are raised, the CCC Sr. GA will begin to process payment requests to CSS 11 business days after the invoice is sent to a CSS.

If you have additional questions, please direct your inquiries to the appropriate party below:

NAME

Project Manager

[e-mail](#)

NAME

Assistant Project Manager

[e-mail](#)

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SAMPLE