

## GPSNJ-NETT Financial Plan

**Policy Overview:** This policy describes the financial operations, considerations, and restrictions of GPSNJ-NETT. Policies and procedures outlined within include an overview of GPSNJ-NETT funding mechanisms, considerations when creating budgets for trials conducted within the NETT, and mechanisms for expenditure and oversight of GPSNJ-NETT related funds. For general NETT SOPs, go to: [http://www.nett.umich.edu/nett/nett\\_standard\\_operating\\_procedures](http://www.nett.umich.edu/nett/nett_standard_operating_procedures).

**Participating individuals:** Any agent, study staff and investigators performing GPSNJ-NETT related activities within a NETT or GPSNJ-NETT network entity.

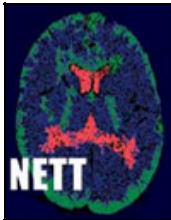
### 1. Definitions

- a) F&A costs. Facilities and administrative costs (previously termed indirect costs).
- b) GPSNJ-NETT entity: The Hub or any Spoke within the GPSNJ-NETT network.
- c) GPSNJ-NETT Hub. The University of Pennsylvania.
- d) Hosting. Providing food, drink, or entertainment outside of a meeting where technical or scientific information related to a specific project is being disseminated.
- e) Hub complex. The Hub institution and the spokes affiliated to the Hub.
- f) NETT entity. Any hub complex, affiliate hub, coordinating center, vendor, or subcontracted agent of the NETT network.
- g) Master agreement. A hybrid purchase service agreement between the GPSNJ-NETT Hub and Spoke.
- h) OMB Circular A-21. The Federal Government's Office of Management and Budget Circular A-21 that sets the principles for determining costs applicable to Federal grants, contracts, and other agreements with educational institutions.
- i) Over-arching agreement. A hybrid subcontract between the GPSNJ-NETT Hub and NETT Clinical Coordinating Center (CCC).

### 2. Financial Support of GPSNJ-NETT

- a) Investigator initiated trials. Costs of performing trials within GPSNJ-NETT will be supported by payments to the Hub from the NETT CCC, which receives trial funding from individual trial budgets. Investigator initiated trials within the NETT must undergo the NETT approval process before being initiated within the network.

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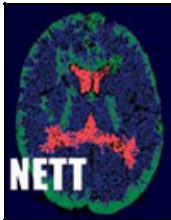


Neurological  
Emergencies  
Treatment  
Trials Network

Greater Philadelphia-Southern New Jersey  
Neurological Emergencies Treatment Trials  
(GPSNJ-NETT) Network  
Standard Operating Procedures

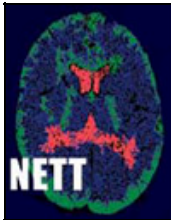
- b) Industry sponsored trials. Costs of performing industry sponsored trials within GPSNJ-NETT will be supported by payments to the Hub from the NETT CCC, which receives trial funding from individual trial budgets. For trials that are industry sponsored, NINDS will not support the infrastructure personnel costs as it will for investigator initiated trials funded through NIH grants. Industry sponsored trials will be assessed for the support of the NETT CCC, Statistical & Data Management Center (SDMC) and Hub personnel necessary to conduct the trial in addition to the other trial costs. Proposed industry sponsored trials within the NETT must undergo the NETT approval process.
  - c) NINDS support of the network. The infrastructure operations of the GPSNJ-NETT Hub will be supported through renewal of a competitive U-01 award.
3. Budgeting guidelines for trials to be considered by NETT
- a) These factors should be considered whether the proposed clinical trial will be the only or one of many trials conducted within the network.
  - b) Determinants of trial-related costs to be considered for each NETT trial are outlined below:
    - i NETT CCC, SDMC, Hub personnel costs
    - ii Benefit costs and F&A
    - iii Number of subjects
    - iv Involvement and number of spokes
    - v Complexity of intervention
    - vi Intensity of monitoring
    - vii Consent process required
    - viii Amount of data to be collected
    - ix Outcomes to be assessed
    - x Frequency and duration of follow up
    - xi Anticipated number of Adverse Events (AEs)
    - xii Funding for the trial PI and personnel at the PI's institution
    - xiii Travel funding for investigator meetings
    - xiv Unique training costs associated with the trial
    - xv Funding for trial specific costs including:
      - (1) Drug costs
      - (2) Regulatory fees and costs
      - (3) Pharmacy costs
      - (4) Costs of testing that is not considered routine (e.g. radiology, laboratory, functional testing, etc.)

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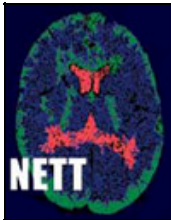
4. Funds flow
  - a) The direct costs outlined above for the proposed clinical trial should be awarded to the trial PI's institution.
  - b) The trial PI's institution should establish two subcontracts, one with the CCC and one with the SDMC.
  - c) The CCC will distribute funds to the Hubs through an already existing over-arching agreement.
  - d) The CCC will strive to waive F&A costs on the over-arching agreement with the Hubs on federally sponsored projects. Any additional costs needed at the SDMC will be paid directly to the SDMC.
  - e) The GPSNJ-NETT Hub will distribute funds to the Spokes through an already existing master agreement.
  - f) The GPSNJ-NETT Hub will strive to waive F&A costs on the master agreement with the Spokes on federally sponsored projects.
  
5. Expenditures of GPSNJ-NETT funds
  - a) Salaries supported by GPSNJ-NETT funding must comply with the Federal Government Office of Management and Budget Circular A-21, *Cost Principles for Educational Institution* guidelines. The circular can be found at <http://www.whitehouse.gov/omb/circulars/a021/a021.html>
  - b) The GPSNJ-NETT Hub complex must maintain an accurate system including certification of the percentage of effort that employees devote to sponsored projects or more than one functional activity.
  - c) If an institution has a method for ensuring compliance not clearly defined in the OMB circular, the method must be reviewed and approved by the NETT CCC.
  - d) GPSNJ-NETT related payments to Spokes from the Hub
    - i All conditions and requirements agreed upon prior to initiation of the trial must be satisfied before the payments for GPSNJ-NETT activities will be dispersed (e.g. entry of data related to a study visit, resolution of data queries, etc.).
    - ii Spokes will prepare and send invoices to the Hub for reimbursement of GPSNJ-NETT activities. The Hub will have fifteen (15) business days to review the invoices and determine whether or not the conditions of the Hub-Spoke Purchase Service Agreement have been satisfied for reimbursement of the activities listed in the Spoke's invoice.

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- (1) The Hub will request that the CCC review the CCC activity records and data provided by the SDMC for protocol related activities which qualify for reimbursement.
      - (2) The Hub will determine whether or not the terms for reimbursement have been satisfied based on the CCC report.
    - iii If there are any discrepancies, the Hub will work with the Spoke to reconcile the list of reimbursable activities. The Spoke will send a revised invoice with the reconciled list of activities.
    - iv The Hub will provide payment to the Spoke for the reconciled list of activities.
  - e) Purchase of capital equipment not specified within a funded proposal must be approved by the NETT CCC prior to purchase. Items purchased without prior approval may not be eligible for reimbursement.
  - f) Hosting is only allowed on federally-sponsored projects when the circumstances are stated during the proposal budgeting process, or when the study sponsor gives express consent. Hosting must be approved by the NETT CCC prior to the activity. Hosting expenses incurred without prior approval may not be eligible for reimbursement.
6. Reimbursement for expenditure of GPSNJ-NETT funds
  - i The Hub will review the list of reimbursable activities and items (subject visits, effort, equipment, etc.), which will be provided to the Hub from the CCC on no less than a quarterly basis.
  - ii The Hub will compare the list of reimbursable activities and items to the list of reimbursements made to the Spokes. If there are any discrepancies:
    - (1) The Hub will have ten (10) business days to inform the CCC of any discrepancies in the number, or nature, of activities included on the CCC list and record of activity maintained by the Hub complex.
    - (2) The CCC will work with the Hub to reconcile discrepancies in a timely manner.
    - (3) The Hub will develop an invoice based on a reconciled list of activities and return the invoice to the NETT CCC for processing and payment.
7. Oversight of NETT expenditures
  - a) Oversight of overall CCC project finances is the responsibility of the NETT Clinical Coordinating Center.
  - b) Oversight of overall GPSNJ-NETT project finances is the responsibility of the GPSNJ-NETT Hub.

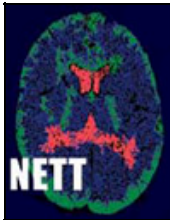
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- c) NETT funds will be identified in the following ways to provide clarity, verification, and ease of auditing:
  - i Protocol-specific funds will be identified by unique sub-project grant numbers.
  - ii The Hub complex will be assigned distinctive purchase order numbers and program codes.
  - iii The GPSNJ-NETT Hub will assign distinctive purchase order numbers for each trial to each Spoke.
  - iv Each activity within a Hub complex will be included on the NETT activity list which is reviewed and incorporated into the NETT financial tracking system.
  - v Each activity at a Spoke will be included on the GPSNJ-NETT activity list which is reviewed and incorporated in the GPSNJ-NETT tracking system.
- d) The CCC Administrator and finance specialists will review and reconcile overall CCC project finances on a monthly basis.
- e) The GPSNJ-NETT Project Manager and Hub Business Administrator will reconcile overall GPSNJ-NETT project finances on a monthly or as-needed basis.
- f) Activities to be reviewed on a regular basis include:
  - i Salary and effort allocation and changes.
  - ii Requests for payment to participating GPSNJ-NETT Hub and Spokes for clinical research activities.
  - iii Expenditures for study related equipment and supplies.
  - iv Unspent balances on obligated funds.
  - v Financial reports from the NETT CCC and GPSNJ-NETT Hub complex, when applicable.
  - vi Project/parent account balances.
- g) The GPSNJ-NETT Hub and Spokes will be responsible for tracking and maintaining OMB A-21 compliance with the expenditure of GPSNJ-NETT funds that are received from NINDS and dispersed through the NETT CCC or GPSNJ-NETT Hub.
- h) The CCC may request an expenditure report from the GPSNJ-NETT Hub complex at any time.
  - i The Hub will acknowledge the request within fourteen (14) business days and provide financial reports to the CCC within thirty (30) calendar days.
- i) The Hub may request an expenditure report from the Spokes at any time.
  - i Spokes must acknowledge the request with ten (10) business days and provide financial reports to the Hub within twenty-five (25) calendar days.

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These financial reports may be included in the expenditure reports which the Hub may submit to the CCC.

- j) The following practices are not allowed under federal guidelines:
  - i Rotating charges among projects.
  - ii Purchasing items simply to exhaust an unobligated balance or assigning charges to a project on the basis of the remaining balance to resolve availability of funding issues or simply to avoid the loss of carry-forward balances.
  - iii Changing the budgeted amount (in contrast to an amount based on actual usage), unless the project allows a fixed price or other type of approved reimbursement method that does not require tracking of actual charges to the project.
  - iv Assigning charges to an award before the cost is incurred.
  - v Charging an expense exclusively to a single award when the expense clearly has supported other activities (i.e. pens, telephone lines, paper, etc.).
  - vi Applying a unit "tax" to projects to distribute clerical and administrative expenses.
  - vii Transferring an overdraft from one sponsored project to another without express sponsor approval.
- k) The following purchases are considered F&A costs and cannot be charged as a direct cost to a GPSNJ-NETT related project unless the items were included in the budget approved by the sponsor:
  - i. Office supplies including computers under \$5,000, printers, monitors, fax machines, printer paper, toner cartridges, pens, pencils, legal pads, clips, rubber bands, post-it notes, books, individual subscriptions to journals, notebooks, binders, folders, diskettes, and departmental stationery.
  - ii. Postage costs associated with the normal administration of the project. The costs of overnight shipping and handling (e.g., Federal Express) are allowable assuming they are directly associated with the specific trial.
  - iii. The costs of local telephone lines, cell phones and prepaid long distance calling cards used to conduct routine business of the project. Charges for conference calls and toll free lines are allowable if they are directly related to project activities.
  - iv. Membership fees and dues to maintain individual memberships in professional and scientific organizations.

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