NETT Financial Plan

Policy Overview: This policy describes the financial operations, considerations, and restrictions of the NETT. Policies and procedures outlined within include an overview of NETT funding mechanisms, considerations when creating budgets for trials conducted within the NETT, and mechanisms for expenditure and oversight of NETT related funds.

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

1. Definitions
   a) Affiliate Hub complex. A performance site that was not designated as a Hub complex by NINDS but will serve as a performance site for a specific trial. The affiliate Hub designation is restricted to a site at which the trial Principal Investigator is not affiliated with a Hub complex but would like to enroll subjects in his/her trial at his/her institution.
   b) F&A costs. Facilities and administrative costs (previously termed indirect costs).
   c) Hosting. Providing food, drink, or entertainment outside of a meeting where technical or scientific information related to a specific project is being disseminated.
   d) Hub complex. The Hub institution and the spokes affiliated the Hub.
   e) NETT entity. Any hub complex, affiliate hub, coordinating center, vendor, or subcontracted agent of the NETT network.
   f) 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.
   g) Over-arching agreement. A hybrid subcontract between the Hubs and NETT Clinical Coordinating Center.

2. Financial Support of the NETT
   a) Investigator initiated trials. Costs of performing trials within the NETT will be supported by payments to the Clinical Coordinating Center (CCC) and Statistical Data Management Center (SDMC) from individual trial budgets. Investigator initiated trials within the NETT must undergo the NETT approval process before being initiated within the network.

b) Industry sponsored trials. Costs of performing industry sponsored trials within the NETT will be supported by payments to the CCC and SDMC 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 CCC, 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 CCC, the SDMC and the Hubs complexes will be supported through renewal of competitive U-01 awards.

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 investigators 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.)

4. Funds flow
   a) The direct costs outlined above for the proposed clinical trial should be awarded to the PI's institution.
   b) The 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.

5. Expenditures of NETT funds
   a) Salaries supported by 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) Hub complexes 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) NETT related payments to Hubs from the CCC
      i All conditions and requirements agreed upon prior to initiation of the trial must be satisfied before the payments for NETT activities will be dispersed (e.g. entry of data related to a study visit, resolution of data queries, etc.).
      ii The CCC will review CCC activity records and data provided by the SDMC for protocol related activities which qualify for reimbursement.
      iii The CCC will provide a list of reimbursable activities and items (subject visits, effort, equipment, etc.) to the Hub complex on no less than a quarterly basis.
      iv The Hub complex 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. The CCC will work with the Hub complex to reconcile discrepancies in a timely manner.
      v The Hub complex will develop an invoice based on a reconciled list of activities.

vi The Hub will be responsible for returning the invoice to the NETT CCC for processing and payment.

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. Oversight of NETT expenditures

a) Oversight of overall CCC project finances is the responsibility of the Clinical Coordinating Center.

b) 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 Hub complexes will be assigned distinctive purchase order numbers and program codes.

iii 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.

c) The CCC Administrator and finance specialists will review and reconcile overall CCC project finances on a monthly basis.

d) Activities to be reviewed on a regular basis include:

i Salary and effort allocation and changes.

ii Requests for payment to participating sites for clinical activities.

iii Expenditures for study related equipment and supplies.

iv Unspent balances on obligated funds.

v Financial reports from Hub complexes, when applicable.

vi Project/parent account balances.

e) Each Hub complex will be responsible for tracking and maintaining OMB A-21 compliance with the expenditure of NETT funds dispersed through the CCC or received directly from NINDS.

f) The CCC may request an expenditure report from a Hub complex at any time. Financial reports for requested items should be acknowledged within 14 business days, and provided to the CCC within 30 calendar days.

g) 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.

h) The following purchases are considered F&A costs and cannot be charged as a direct cost to a 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.