PERSONNEL COSTING HANDOUT

1. For help with your budget, contact the Office Clinical Research....567-0651 (Leo Nosser)
   a. Refer to Excel Cost-Estimator and Grid Template on the OCR website
   b. Final budget must be consistent with 4 things:
      i. Billing grid for separating sponsor funding from standard of care
      ii. Informed Consent Cost Section
      iii. Clinical Trial Agreement (CTA)
      iv. Certificate of Proposal to OSP
   c. Attach supporting documentation – notes on how did you arrive at the costs associated with the personnel who will be executing the study? There should be an auditable trail for this information.

2. Calculating Direct Costs for Personnel (Workload Load Analysis)
   - To determine with some certainty the number of personnel required for a study, or a number of studies, you need to do an adequate time and effort estimate for each study. For each member of the study team follow these steps to calculate the cost of their work:
     1. Identify all visit related activities for 1 study subject to complete the study from screening to closeout.
     2. Estimate the amount of time required for each visit and related activity to calculate the total amount of time required for 1 study subject.
     3. Multiply the total amount of time required for 1 study subject by the total number of subjects to yield the total time for all subjects.
     4. Total the amount of time required for all other study related activities to be handled by the applicable team member and add to the total from #3 above to arrive at total time and effort for the study.
     5. Calculate the total time period for the study by adding the duration of the recruiting period to the length of time 1 subject will be "on study". For example, 3 year recruitment period plus 1 year of study participation equals 4 years total time period.
     6. Divide the total from #4 by the total from #5 to equal the percent of time and effort required.

3. Costing HINTS (these do not have to be itemized to the sponsor during budget negotiation, they can be rolled into Hourly Fees or other sponsor-covered categories)
   a. Activity-based Personnel Costing for Study Execution and Activities
      i. Based on smallest increment of work, for example:
         1) Informed Consent preparation
         2) Informed Consent process & delivery to participant
         3) Screening and inclusion/exclusion criteria applied to each participant
            a) Physical exam
            b) Clinical or Research Measurement/scoring
            c) QOL questionnaire administration
         4) Baseline, Randomization, Follow up data collection and forms entry/completion
      ii. Examples of “hidden” activities to include in costing personnel (See Budgeting handout-Personnel Costing):
         1) Training and certification on protocol-specific measurement tools
         2) Attending initiation visit
         3) Investigator and/or coordinator travel to investigator meetings (this is for time not travel expense reimbursement)
         4) Managing adverse events – clinical and research-regulatory-reporting time
         5) Attending monitoring visits
         6) Processing Central Lab specimens for shipping
         7) Close out - Add time for cost of:
            a) Data queries and correction
            b) End-study visit activities such as patient education and or referral;
            c) Reconciliation of budgets, invoices, institutional accounts
            d) Reports to sponsor
            e) Preparation for records retention and storage

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