Developing a Budget

Considerations for Preparing a Budget

For studies that require a grant or contract, the Investigator or representative is responsible for generating and/or negotiating the budget with the sponsor.

Initiation costs and Personnel time for start-up

- **Determination of feasibility using electronic health record access core.** Potential eligible patients can be identified to ensure the study is likely to meet recruitment goals by applying to the Electronic Health Record Core.
- **Regulatory Document Preparation.** IRB application fee and personnel costs for preparation of documents for industry-sponsored trials.
- **Coverage Analysis.** The Finance Analyst is available to evaluate and verify conventional or "standard" care versus research costs and can or cannot be billed to a third party payer (either private insurance or Medicare). This is important for compliance as well as budgeting. Fees related to Coverage Analysis may be required; current rates may be found on the Clinical Research Center website.
- **Data Storage.** Data storage needs and costs vary with the type of data stored, HIPAA-compliant versus non-compliant, and duration. Consult the Research Information Technology Office (RITO) to develop a data storage plan and estimate. (phone: 402-559-9072)
- **Drug and Device.** Investigational devices may require additional clinical care costs for implantation. Devices with IDE must be submitted to Centers for Medicare & Medicaid Services (CMS) for a Coverage Determination.
- **Sample size analysis by a biostatistician.** Biostatistics consultation for study design, sample size calculation, and preparation of a biostatistical analysis plan can all be determined through consultation with the Center for Collaboration on Research Design and Analysis (CCORDA). Contact by phone: 402-559-9436.
- **Spanish language translation fees.** Spanish language translation of study materials is available through the NEMed Interpretive Services Office; however, if materials are needed rapidly, other translators may be contracted through the Center for Reducing Health Disparities .
- **Salaries.** The Clinical Research Center is available to contract clinical research support, contact the CRC 402-559-85555 for an estimate. Biostatistician salaries can be obtained from CCORDA as above.
- **Time from the Electronic Health Record Core** to obtain patient lists for on-going recruitment, contact the EHR director for an estimate.
- **Benefit rates** for each type of personnel can be found on the Sponsored Programs website.

Study related fees

Salaries and Effort

- **Investigator and Staff Time.** Principal investigators and key personnel are usually budgeted as FTEs.
- **Clinical personnel** who provide professional review services (e.g., Pathology or Radiology reviews) may require contracted professional fees. See Clinical Trial Professional & Technical Fee Billing Procedures Policy #8008 for guidelines on cost recovery for professional fees. Include salary and benefits, for all effort necessary (actual visits, preparation time, paperwork, queries, etc.).
- **Personnel time** needed to complete the study, including recruitment, study visits, preparation of IRB annual review, serious adverse event submissions, and changes of protocol.
- **Biostatisticians** and other collaborators.
- **Consultants.** This can include budgeted time and travel.
- **Research Pharmacy and Study Drugs.** The sponsor may provide the study drug whether the trial is investigator-initiated or not, however, the research pharmacy will charge for services provided. These could include consultation on obtaining the right drug or formula, submission of IND forms, subject randomization, study initiation, blinding, drug preparation or storage, and/or dispensing fees. The route of administration will determine if drug administration fees are required. Contact the research pharmacist at 402-559-5255 or download the price calculator.
- **Research IT Office or CCORDA** support of study database.

Supplies

- **Study drug or placebo** may be required for investigator-initiated study.
- **Study Devices.** Costs may be required related to obtaining, storing, maintaining, and/or training to use devices.

Travel

- **For the subject,** investigator or study personnel, or consultants.
- **Study personnel** may need to travel to the subject to obtain data or samples.
- **Subjects may require assistance** with travel to and from the study site, including bus passes or cab vouchers if local, or if distant, federally approved gas reimbursement or gas cards.

Other expenses

- **Core Facility Use and Equipment.** Fees for campus core facilities can be found on the individual core website. A full directory of core facilities is available on the VCR website. Include costs for device calibration requirements.
- **Clinical Research Center Use.** Fees for CRC facilities and staff are on the CRC website.
- **Biological Production Facility.** Fees for studies utilizing cell products.
- **Pathology Fees.** For studies requiring submission of pathology slides to a central reviewer.
- **Shipping Expenses.** If samples must be shipped in dry ice, additional shipping costs will be required.
- **Subject Stipends.** IRB typically allows up to $20/hour for participation in trials, which can include recovery or travel time. This can be provided by a check that is generated by the State of Nebraska or gift cards.
- **Postage.** Send follow-up messages or documents through the mail.
- **Record Retention Costs.** Costs of storing records during or after completion of study.

Clinical Care costs

- **Facility Fees.** There may be room charges depending on where the study is performed.
- **Clinical tests or procedures** performed during the research study may be required (e.g., EKG, lung function testing).
- **Other supplies** needed (i.e., gowns, use of hospital owned equipment, glucose testing, IV fluids). One Chart-Price Inquiry can be used to locate these fees.

Overall budget considerations

- **Cost of Living Increases.** Prices often increase over the duration of the grant, 3-5% annually, although these cost of living increases may not be allowed in NIH grant applications depending on the funding agency.
- **Indirect Costs.** Current F&A rates can be found on the SPA website.

Who are my key contacts for questions about budgeting and sources for fee information?

- Your Department Administrator
- Clinical Trials Analysts, & Research Billing Senior Associate
- Sponsored Programs Administration
- One Chart-Price Inquiry
- UNeHealth, for industry-funded clinical research

What is the Clinical Trials Master Matrix/Billing Grid (CTMM)

Completion of the Clinical Trials Master Matrix/Billing Grid can assist you with budget preparation in that it sets up the budget table for the study.

A research billing “matrix” must be submitted for any study that includes clinical care conducted at Nebraska Medicine/UNMC clinics or facilities. The matrix/billing grid guides investigators through determining costs associated with a clinical trial; it is stored on a secure drive and access must be requested from the Senior Research Billing Associate.

Where do I find hospital-based charges?

Hospital-based charges can be found in One Chart, under the separate Price Inquiry tab. Instructions on using Price Inquiry can be found in the “Tips & Tricks” in the Epic modules of the Learning Center.

What requires a professional fee?

- Any hospital or clinic visit (office visit) where a physician, nurse practitioner, or physician's assistant would examine a patient
- Any consultation
- Any test that requires test review and a written report from one of the following departments, among others: Radiology, Cardiology, Pathology.

Are there fees for Children's Hospital & Medical Center facilities and services that I need for my study?

Yes. Questions regarding clinical research fees may be directed to the Pediatric Research Office.

How can I determine if study procedures, tests, items, which are "standard of care" can be billed to Medicare/insurance?

No costs for procedures completed solely for research purposes may be billed to insurance. Medicare Qualifying Criteria are outlined in NCD 310.1 "Routine Costs of Clinical Trials." If the study meets the qualifying criteria, routine costs and costs for diagnosis and treatment of adverse events can be billed to Medicare.

If the study does not meet the qualifying criteria, nothing can be billed to Medicare, not even routine care costs. Coverage analysis is performed to verify that research procedures listed as paid by insurance are "standard of care" and can be billed to a third party payer (either private insurance or Medicare).

Coverage analysis also compares the matrix/billing grid, informed consent document, and preliminary budget to ensure that all costs are known. This process ensures that the final study budget reflects the true cost of the research project. For additional information, see the SPA Clinical Trials Billing FAQ.

The coverage analysis makes a general judgement on insurance coverage for participation in clinical trials based on Medicare rules. When a patient is identified for potential participation in a clinical trial, insurance pre-authorization is put in place to review the patient's insurance policy and coverage. Information on the Insurance Pre-authorization process can be found at unmc.edu/cctr/resources.

Who initiates the insurance pre-authorization process?

It is the research coordinator or study staff's responsibility to initiate the insurance pre-authorization process with Nebraska Medicine patient financial counselors.

Coverage Analysis

Performing Coverage Analysis

Clinical Trials Analysts perform coverage analyses for drug/biologics related clinical trials. Faculty/Coordinators who have questions or would like assistance can contact the Clinical Research Manager or the Senior Clinical Trials Analyst at 402-552-7817.

Is a coverage analysis required for all industry sponsored trials?

A coverage analysis is required for all adult, full board clinical trials. It should be completed for any study involving billing of clinical care at the same time of the, trial regardless of funding. The IRB may also require coverage analysis for specific trials.

The results of the coverage analysis are shared with the IRB to determine if subjects will be placed at additional financial risk as a result of study participation.

Coverage Analysis Fees

There is a fee for coverage analyses for industry funded research. Contact the Clinical Research Manager for the fee amount.

What can be charged to the sponsor in an industry-sponsored trial?

Charge time and effort for activities, including all persons involved (investigator, coordinator, research assistants, etc.). Also include supplies needed to conduct the study. If hospital services are used you should charge for them. You can also meet directly with the manager of the CRC to discuss budgeting.

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