Budgeting Clinical Trials & RAMSeS IPF

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November 10, 2020
Grant vs Clinical Trial

**INDUSTRY TRIALS**

- Always negotiate
- Inflation of salary and procedure costs allowed
- Money paid as “earned” by recruitment
- Leftover funds can be used to fund other studies

**FEDERAL GRANTS**

- Low budget hard to negotiate
- Inflation of costs per year not allowed
- Lump sum payment at start of grant
- Leftover money often returned
Process of Building a Budget

1. Review most recent protocol and study activity listings (Protocol Feasibility)
2. List all other fees, direct and indirect
3. Identify procedures required and determine cost
4. Review Contract and current budget (if provided)
Initial & Ongoing

The Initial Payment - paid upon receipt and sponsor acceptance of:
- Initial IRB approval letter/notice
- Receipt of activation letter by Sponsor

Sponsor will pay Site for completed subject visits in accordance with Section 3.E – Per Patient Costs.
- A completed visit or milestone includes the proper completion of all protocol activities and delivery to Sponsor of complete and accurate CRF data for that visit.

The total amount of each payment will be determined by data entered into the Electronic Data Capture system (EDC).
- Payments are processed on a monthly basis, provided ten percent (10%) of each payment will be retained to be paid in accordance with the Final Payment as outlined.
**Clinical Trial Agreement:**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start up and Advance payment</td>
<td>• When and How much?</td>
</tr>
<tr>
<td>Payment Cycle</td>
<td>• How often will they pay?</td>
</tr>
<tr>
<td>Withholding %</td>
<td>• How much are they going to hold back?</td>
</tr>
<tr>
<td>Length of Storage</td>
<td>• 10-20-30 years?</td>
</tr>
<tr>
<td>Final Payment</td>
<td>• Timing of Payment?</td>
</tr>
</tbody>
</table>
Direct Costs

Labs
- Review Time and Event Schedule to determine when and how many times
- Know who will perform the test (UNC or a Central Lab)
- Obtain the cost from Integrated Billing

Procedures
- Know where they will be performed
- Who is doing them
- What all is included in the price
Effort Based Costs

• Informed Consent - Creation of CF & consenting subject
• Physical Exams, Vitals & History - Coordinator and PI Time
• Review of Labs - Coordinator and PI Time
• Drug Dispensing
• Recruitment
• Data Entry
• Monitor Visits
• Scheduling Patients - How long does it take to transport patient for CT Scan?
## Sample Budget Comparison

### Initial

<table>
<thead>
<tr>
<th>Visit Schedule</th>
<th>Payment Per Patient Per Visit Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1 (Screening)</td>
<td>$1,372.00</td>
</tr>
<tr>
<td>Visit 2* (Randomization)</td>
<td>$1,139.67</td>
</tr>
<tr>
<td>Visit 3 - Phone visit</td>
<td>$245.25</td>
</tr>
<tr>
<td>Visit 4</td>
<td>$600.50</td>
</tr>
<tr>
<td>Visit 5 - Phone visit</td>
<td>$245.25</td>
</tr>
<tr>
<td>Visit 6</td>
<td>$729.17</td>
</tr>
<tr>
<td>Visit 7 - Phone visit</td>
<td>$245.25</td>
</tr>
<tr>
<td>Visit 8</td>
<td>$679.50</td>
</tr>
<tr>
<td>Visit 9 - Phone visit</td>
<td>$245.25</td>
</tr>
<tr>
<td>Visit 10</td>
<td>$649.17</td>
</tr>
<tr>
<td>Visit 11 - Phone visit</td>
<td>$215.25</td>
</tr>
<tr>
<td>Visit 12*</td>
<td>$901.17</td>
</tr>
<tr>
<td>Visit 13 - Phone visit</td>
<td>$210.75</td>
</tr>
<tr>
<td>Visit 14</td>
<td>$640.50</td>
</tr>
<tr>
<td>Visit 15 - Phone visit</td>
<td>$290.25</td>
</tr>
<tr>
<td>Visit 16</td>
<td>$698.17</td>
</tr>
<tr>
<td>Visit 17 - Phone visit</td>
<td>$290.25</td>
</tr>
<tr>
<td>Visit 18</td>
<td>$640.50</td>
</tr>
<tr>
<td>Visit 19 - Phone visit</td>
<td>$290.25</td>
</tr>
<tr>
<td>Visit 20</td>
<td>$1,028.17</td>
</tr>
<tr>
<td>Visit 21 - Phone visit</td>
<td>$315.25</td>
</tr>
<tr>
<td>Visit 22</td>
<td>$530.50</td>
</tr>
<tr>
<td>Visit 23 - Phone visit</td>
<td>$290.25</td>
</tr>
<tr>
<td>Visit 24* (EOT)</td>
<td>$1,424.67</td>
</tr>
<tr>
<td>Visit 25 (Follow-up)</td>
<td>$471.00</td>
</tr>
<tr>
<td><strong>Per Patient Cost (inclusive of site overhead cost)</strong></td>
<td><strong>$14,487.94</strong></td>
</tr>
<tr>
<td><strong>Patients to be Enrolled/Randomized</strong></td>
<td><strong>7</strong></td>
</tr>
<tr>
<td><strong>PATIENT COSTS @ EXPECTED ENROLLMENT/RANDOMIZATION</strong></td>
<td><strong>$101,415.58</strong></td>
</tr>
</tbody>
</table>

### Final

<table>
<thead>
<tr>
<th>Visit Schedule</th>
<th>Payment Per Patient Per Visit Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1 (Screening)</td>
<td>$1,783.60</td>
</tr>
<tr>
<td>Visit 2* (Randomization)</td>
<td>$1,481.57</td>
</tr>
<tr>
<td>Visit 3 - Phone visit</td>
<td>$318.83</td>
</tr>
<tr>
<td>Visit 4</td>
<td>$780.65</td>
</tr>
<tr>
<td>Visit 5 - Phone visit</td>
<td>$318.83</td>
</tr>
<tr>
<td>Visit 6</td>
<td>$947.92</td>
</tr>
<tr>
<td>Visit 7 - Phone visit</td>
<td>$318.83</td>
</tr>
<tr>
<td>Visit 8</td>
<td>$883.35</td>
</tr>
<tr>
<td>Visit 9 - Phone visit</td>
<td>$318.83</td>
</tr>
<tr>
<td>Visit 10</td>
<td>$643.92</td>
</tr>
<tr>
<td>Visit 11 - Phone visit</td>
<td>$279.83</td>
</tr>
<tr>
<td>Visit 12*</td>
<td>$1,171.52</td>
</tr>
<tr>
<td>Visit 13 - Phone visit</td>
<td>$403.98</td>
</tr>
<tr>
<td>Visit 14</td>
<td>$832.65</td>
</tr>
<tr>
<td>Visit 15 - Phone visit</td>
<td>$377.33</td>
</tr>
<tr>
<td>Visit 16</td>
<td>$507.62</td>
</tr>
<tr>
<td>Visit 17 - Phone visit</td>
<td>$377.33</td>
</tr>
<tr>
<td>Visit 18</td>
<td>$832.65</td>
</tr>
<tr>
<td>Visit 19 - Phone visit</td>
<td>$377.33</td>
</tr>
<tr>
<td>Visit 20</td>
<td>$1,336.62</td>
</tr>
<tr>
<td>Visit 21 - Phone visit</td>
<td>$409.83</td>
</tr>
<tr>
<td>Visit 22</td>
<td>$689.65</td>
</tr>
<tr>
<td>Visit 23 - Phone visit</td>
<td>$377.33</td>
</tr>
<tr>
<td>Visit 24* (EOT)</td>
<td>$1,852.07</td>
</tr>
<tr>
<td>Visit 25 (Follow-up)</td>
<td>$612.30</td>
</tr>
<tr>
<td><strong>Per Patient Cost (inclusive of site overhead cost)</strong></td>
<td><strong>$18,834.37</strong></td>
</tr>
<tr>
<td><strong>Patients to be Enrolled/Randomized</strong></td>
<td><strong>7</strong></td>
</tr>
<tr>
<td><strong>PATIENT COSTS @ EXPECTED ENROLLMENT/RANDOMIZATION</strong></td>
<td><strong>$131,840.59</strong></td>
</tr>
</tbody>
</table>
Invoiced Items

- Start Up Fee
- Advertising
- Document Storage
- Rent
- Screen Fails
- Adverse Events
- FDA/Sponsor Audits

- IRB/BCA Fee
- IRB Renewal
- IDS
- Dry Ice
- Protocol Amendment
- Monitoring Visit
# Invoiced Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Start Up Fee (Non-refundable)</td>
<td>$1,500.00</td>
</tr>
<tr>
<td><strong>Total Initial Costs</strong></td>
<td><strong>$1,500.00</strong></td>
</tr>
<tr>
<td><strong>Site Costs</strong></td>
<td></td>
</tr>
<tr>
<td>IRB Costs</td>
<td>Upon Invoice; See Section 3.C - IRB; payable upon receipt of proper documentation and approval of the appropriate Sponsor Trial Manager.</td>
</tr>
<tr>
<td>Advertising/Recruitment Costs: Sponsor agrees to reimburse Institution for Study-related advertisement and recruitment-related expenses if pre-approved by Sponsor in writing and, upon presentation of invoices and supporting documentation which may include IRB approval.</td>
<td>Up to $2,000.00; Institution may be eligible for additional reimbursement of advertising/recruitment expenses beyond the initial allotment of funds, if prior approval of advertisement plans/scope of work is obtained in writing from the appropriate Trial Manager before the spend occurs. Upon Invoice</td>
</tr>
<tr>
<td>SAEs and AEs requiring additional data collection <strong>(NON-JUDICATED EVENTS)</strong></td>
<td>$125.00 per reportable event. Payable upon verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each AESI/SAE event upon the Institution’s completion of all follow-up information and Sponsor’s acceptance of the documentation; Upon Invoice</td>
</tr>
<tr>
<td>SAEs &amp; AEs requiring additional data collection <strong>(JUDICATED EVENTS)</strong></td>
<td>$150.00 per reportable event. Payable upon verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each adjudicated event upon the Institution’s completion of all follow-up information and Sponsor’s acceptance of the documentation; Upon Invoice</td>
</tr>
<tr>
<td>Unscheduled Visit - Reasonable and medically necessary Unscheduled visits (conducted onsite)</td>
<td>Up to $240.00 for reasonable and medically necessary unscheduled onsite visits; payable upon receipt of proper Invoice and supporting documentation (source document and/or progress note of visit required to be submitted with invoice) as confirmation of work performed and subject to review and approval of the appropriate Sponsor Trial Manager. Upon Invoice</td>
</tr>
<tr>
<td>General Pass Through Expense</td>
<td>Up to $2,500.00; At normal/usual/customary reimbursement rates and receipt of proper documentation as confirmation of work performed. Upon Invoice</td>
</tr>
</tbody>
</table>
## Invoiced Costs

### Initial Costs

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Start Up Fee (Non-refundable)</td>
<td>$4,000.00</td>
</tr>
<tr>
<td>Pharmacy Start Up Fee (Non-refundable)</td>
<td>$1,000.00</td>
</tr>
<tr>
<td><strong>Total Initial Costs</strong></td>
<td><strong>$5,000.00</strong></td>
</tr>
</tbody>
</table>

### Site Costs

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Costs</td>
<td>Upon Invoice; See Section 3.C - IRB; payable upon receipt of proper documentation and approval of the appropriate Sponsor Trial Manager.</td>
</tr>
<tr>
<td>Advertising/Recruitment Costs: Sponsor agrees to reimburse Institution for study-related advertisement and recruitment-related expenses if pre-approved by Sponsor in writing and, upon presentation of invoices and supporting documentation which may include IRB approval.</td>
<td>Up to $2,000.00; Institution may be eligible for additional reimbursement of advertising/recruitment expenses beyond the initial allotment of funds, if prior approval of advertisement plans/scope of work is obtained in writing from the appropriate Trial Manager before the spend occurs. Upon Invoice</td>
</tr>
<tr>
<td>SAEs and AES requiring additional data collection (NON-ADJUDICATED EVENTS).</td>
<td>$175.00 per reportable event. Payable upon verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each AESI/SAE event upon the Institution’s completion of all follow-up information and Sponsor’s acceptance of the documentation; Upon Invoice</td>
</tr>
<tr>
<td>SAEs &amp; AES requiring additional data collection (ADJUDICATED EVENTS).</td>
<td>$200.00 per reportable event. Payable upon verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each adjudicated event upon the Institution’s completion of all follow-up information and Sponsor’s acceptance of the documentation; Upon Invoice</td>
</tr>
<tr>
<td>Unscheduled Visit - Reasonable and medically necessary Unscheduled visits (conducted onsite)</td>
<td>Up to $240.00 for reasonable and medically necessary unscheduled onsite visits; payable upon receipt of proper invoice and supporting documentation (source document and/or progress notes of visit required to be submitted with invoice) as confirmation of work performed and subject to review and approval of the appropriate Sponsor Trial Manager. Upon Invoice</td>
</tr>
<tr>
<td>Re-Consenting Fee (per Consent)</td>
<td>$75.00; Upon invoice; payable upon receipt of proper documentation and approval of the appropriate Sponsor Trial Manager. Upon Invoice</td>
</tr>
<tr>
<td>General Pass Through Expense</td>
<td>Up to $2,500.00; At normal/usual/customary reimbursement rates and receipt of proper documentation as confirmation of work performed. Upon Invoice</td>
</tr>
</tbody>
</table>
Common Budget Mistakes

- Incorrect Overhead Rate
- Incorrect procedure costs
- Not including benefits
- Lack of inflation in costs
- No Start-up Fee
- Incorrect UNC Fees
- No Pharmacy Fee
Wow this is a great budget they gave us. So much more money than we need.

Said no one ever.
Internal Processing

- Electronic Internal Processing Form (eIPF) entered into RAMSeS
  - Includes personnel (role and effort), research subjects, research materials, subcontract (as applicable), detailed budget, budget justification, export control, intellectual property, community engagement, research locations, and project abstract
- Attachments required = internal budget & justification (totals must match Cayuse)
  - This is required for both federal AND industry budgets
- Office of Sponsored Research (OSR) or Sponsored Programs Office (SPO) review proposal and IPF to make sure all required elements are present
- OSR or SPO Submits to Grants.gov (or applicable sponsor portal)
RAMSES IPF

Initiating an IPF - Overview

1. Login to RAMSeS- [https://ramses.research.unc.edu/ramses/](https://ramses.research.unc.edu/ramses/)
2. From the Proposal Dashboard click “Start New Proposal”
3. Once the “General Info” screen has been completed and saved, the IPF number is generated by RAMSeS, along with a list of IPF screens

*FYI* The IPF number consists of the 2-digit Fiscal Year followed by 4 digits. IPF numbers are assigned in numeric order beginning on July 1st of the given fiscal year, e.g., the first IPF created in FY19 would be 19-4991, etc.

4. Complete the IPF “General Info” screen
5. Click down the Item List and complete each IPF Screen

**IMPORTANT!** IPFs must be received in OSR/SPO/OCT at least five (5) business days prior to the application deadline. Please allow ample time for preparation, submission, and routing of the IPF to accommodate this requirement.
RAMSES IPF

General Info

→ Always indicate both the Funding Agency and the Prime Funding Agency (where applicable)
→ Indicate appropriate Proposal Type - New, Supplement, Non-Competing Continuation/Progress Report, Resubmission or Amendment, Renewal (competitive), Revision (competitive) or Recurring Contract

The “Primary Award Contact” (required field) is the individual designated to work with OSR on award setup at the time the proposal is funded.

**NOTE** - At the time of funding, the Primary Award Contact may be changed if need be by your OSR Sponsored Projects Specialist
UNC personnel
→ completion of a COI disclosure and COI Training is required for the following roles: Lead PI, PI, Investigator, Postdoctoral Research Associate, and Clinical Research Coordinator
→ COI Training is required for all other roles, except Admin Contact

Non-UNC Personnel
→ When adding non-UNC personnel, checking “This individual is non-UNC personnel” triggers these questions:
  □ Does this person substantially contribute to the design of the study?
  □ Is this person conducting any experiments or activities?
  □ Is this person directly involved in/or have control over collection of data?
  □ Is this person involved in the analysis of the data?

→ Independent Contractors with any “Yes” responses are automatically assigned the role of “Independent Contractor (Investigator)” and will be required to complete a UNC-CH COI disclosure and UNC-Chapel Hill COI Training.
→ Independent Contractors with all “No” responses are automatically assigned the role of “Independent Contractor” and will not be required to complete a UNC-Chapel Hill COI disclosure or UNC-Chapel Hill COI Training.
### Preparing IPF for Submission

#### 3. “Research Subjects”
- Indicate whether or not human/animal subjects involved with research.
- Indicate if human/animal research is being conducted at UNC-Chapel Hill — if yes, indicate IRB or IACUC protocol, or the reason the protocol has not yet been submitted for approval (JIT or Not Yet Submitted).
- Indicate whether or not human/animal subjects research will be conducted by subcontractor(s).

#### 4. “Research Materials”
- Indicate whether or not the study involves radioactive, hazardous chemical and/or biological research materials. “Yes” responses trigger additional questions to be answered.
**RAMSES IPF**

**Subcontractors**

→ When adding a proposed subcontractor, search for/enter the subcontractor name, indicate whether the subcontract will involve human and/or animal subjects, and indicate what (if any) research materials will be involved in the proposed subcontractor’s scope of work.

→ If animal research is to be performed by the subcontractor, indicate (1) whether the subcontractor is a domestic or foreign institution, (2) if it is a subcontract, fee-for-service, or collaborating site, and (3) the animal species to be used.

For animal research performed at institutions other than UNC-Chapel Hill, for each institution upload the following:

☐ evidence of the institution’s IACUC approval;
☐ copy of most recent AAALAC accreditation letter;
☐ evidence of PHS Assurance
☐ If work involves USDA-covered species, the institution’s USDA Registration Number must be included.

**IMPORTANT!** If the IPF is not subject to "JIT," it is required to attach all of the above documentation at the time of the IPF submission.

→ For each subcontractor, the following must be attached via the IPF “Attachments” IPF screen:

☐ Statement of Work
☐ Budget Justification
☐ Letter of Intent (signed by an authorized official of the proposed subcontractor)
Subcontractors

**DHHS/NSF Sponsors only**
When a DHHS or NSF sponsor has been indicated as either the Funding Agency or the Prime Funding Agency via the “General Info” IPF screen and a subcontractor is being added, an additional Yes/No response must be provided for each proposed subcontractor: “The proposed subcontractor has a Conflict of Interest (COI) policy that complies with Department of Health and Human Services (DHHS) or National Science Foundation (NSF) standards, as applicable to this sub-award.”

**IMPORTANT!** It is recommended that the IPF Creator check with proposed subcontractors to verify that its conflict of interest policy is CFR-compliant. The following website is available to verify if the institution has reported that they are in compliance: [http://sites.nationalacademies.org/PGA/fdp/PDF_070596](http://sites.nationalacademies.org/PGA/fdp/PDF_070596). Delays may occur in the processing of an IPF if a CFR-compliant policy is not in place and/or cannot be verified.

**“Subcontractor Personnel” IPF screen (DHHS/NSF IPFs only)**
- When adding a subcontractor to an IPF with a DHHS/NSF sponsor, a “No” response to the CFR-compliant COI policy question automatically triggers the addition of a “Subcontractor Personnel” screen to the IPF Item List.
- For each subcontractor added without a compliant COI policy, it is required to add at least one (1) individual from the subcontractor who will be involved with the project via the “Subcontractor Personnel” screen.
Subcontractors

Subcontractor personnel indicated with the following roles will be required to complete a UNC-Chapel Hill COI disclosure: PI, Investigator, Postdoctoral Research Associate, and Clinical Research Coordinator. (It is not possible for the Lead PI role to be assigned to subcontractor personnel.

Additional personnel added at time of award for subcontractors without a compliant COI policy will also be required to complete a UNC-Chapel Hill COI disclosure.

**IMPORTANT! For COI disclosure and COI Training purposes, subcontractor personnel will be identified by the email address entered via the “Subcontractor Personnel” screen.**

- The email address cannot be revised once it has been added and saved. The only way to revise an incorrectly added subcontractor personnel email address prior to IPF submission is to remove the individual via the Subcontractor List of Personnel, and re-add him/her with the correct email address.
- After the IPF has been submitted, subcontractor personnel added with incorrect email addresses will have to be removed and re-added by either the Proposal Specialist or the Program Administrator.
- When completing COI Training, subcontractor personnel must log in to UNC-Chapel Hill’s COI Training system using the same email address indicated on the “Subcontractor Personnel” IPF screen. If the email address indicated on the Subcontractor Personnel IPF screen and the email address indicated via COI Training system aren’t identical, COI requirements will not be reflected as complete in via the RAMSeS COI grid.
RAMSES IPF

Budget

Complete the Budget screen by entering both Initial and Total Budget Details

→ Enter Cost-Sharing/Cash-Matching information (as appropriate)
→ Personnel/Space/Equipment information (as appropriate)
→ If the IPF’s F&A Rate is not 55.50% and/or cost sharing or cash matching is being requested, please include a note via “Submission Notes” IPF screen stating where to find this in the agency guidelines.
→ Budget and Budget Justification must be attached

If “F&A Sharing” screen is triggered only if Lead PI’s department is different than the IPF’s Admin Award department or if PIs/Investigators listed on the “Personnel” screen are from departments other than the Admin Award department. **FYI** F&A distribution indicated via the “F&A Sharing” screen represents the intention of the collaborating units to share F&A recoveries from a resulting award. It does not transfer any funds automatically - implementing F&A transfers remains the responsibility of the administering unit. If you have special circumstances, include it via “Submission Notes.”

**IMPORTANT!** If budget includes a reduction in F&A, an F&A waiver request (found on OSR Information Sheet) must be submitted/approved before IPF is approved.
Answer Export Control questions as directed
Questions may be directed to Judy Culhane Faubert (faubert@email.unc.edu) or visit one of the following export control websites:
- http://www.unc.edu/campus/Export_Control/

3. Some types of research may have export control implications even if all work is conducted within the U.S. Do you anticipate that the project work may involve:

a) Non-commercial encryption or information security software?
- Yes  No

b) Any equipment, technology, materials or software specifically designed, modified, or adapted (even slightly) for a military purpose or that may involve national security?
- Yes  No

c) Any classified materials, equipment, technology or data?
- Yes  No
Provide information re: Intellectual Property as indicated:
- research disclosed to the Office of Technology Development (OTD)
- filed or issued patents
- materials obtained from a third party under a transfer agreement granting ownership rights in inventions and/or data out of the use of the material
- Will this research use any material, patented or otherwise, which is owned by UNC-CH and licensed to a commercial entity?
- SBIR (Small Business Innovative Research Program)
- STTR (Small Business Technology Transfer Program)
Community Engagement

→ Indicate if some or all of the proposed project activity can be considered community engagement, and if yes, indicate what percentage, and distribution by location (in NC, outside NC but within the US, or internationally—must total 100%)

→ Indicate if some or all of the proposed project budget will be used for community engagement, and if yes, indicate what percentage, and distribution by location (in NC, outside NC but within the US, or internationally—must total 100%)
→ Indicate the locations where the research budget will be expended (UNC-CH, In-State/County, Out-of-State and/or Internationally) and assign a percentage of the budget to be expended to each location.

→ Percentages should reflect the portion of the total budget which would be expended in that location, and must total 100%
Many projects are associated with a particular geographic location. For example, for projects involving or affecting human or animal populations (collecting new data or analyzing existing data), these geographic locations would be where the humans or animals live. For environmental studies, these geographic locations would include the site(s) of the phenomenon under study.

Indicate geographic location(s) relevant to your project, ensuring that all pertinent locations are reflected.

This information allows UNC-CH to accurately map the areas relevant to this project and is invaluable in demonstrating the broad reach and impact of UNC’s work.
Application Abstract


→ The abstract will be used for the UNC-CH Research Abstracts Database (RAD), a database designed to match faculty researchers with potential collaborators and funding resources and to help identify expertise and areas of research interests on the UNC-CH campus.

→ The abstract should be plainly written and in sufficient detail to summarize: (a) the purpose(s) or problem(s), (b) the hypothesis(es) or objective(s), and (c) the method(s) of the project(s).

→ All abstracts in the RAD will be available to the public, unless indicated otherwise via the “Application Abstract” IPF screen.
RAMSES IPF

Attachments

→ Proposal Announcement Guidelines
→ Budget (in Excel)
→ Subcontractor documentation (letter of commitment, budget, budget justification, scope of work)
→ Representations & Certifications (when applicable)
→ For industry-sponsored clinical trials, please attach the following documents:
  □ Sponsor Protocol
  □ Final Sponsor Budget
  □ Final Internal Budget
RAMSES IPF

Approving Departments

→ Departments required to review/approve the IPF are automatically added to the routing list (based on information provided on various IPF screens) and may be reviewed via the “Approving Depts” screen.

→ If desired, additional departments may be manually added to the routing list via “Add Approving Department”.

→ The “Role” column (via “List of Approving Departments”) indicates the reason each department has been added to the routing list, e.g., Award Dept, Lead PI, Rollup from sub-department, etc.

→ One of the following offices will authorize the IPF on behalf of the University and will automatically be added to the routing list as appropriate. It is not necessary to add one of these departments to the routing list.
  - Office of Sponsored Research (OSR)
  - Sponsored Programs Office, Medicine (SPO) or
  - Office of Clinical Trials (OCT)
Routing Order - Approving Departments

The Admin Award department is required to be first in the routing order and cannot be changed. Departmental routing of the IPF does not begin until the Admin Award department has signed off on IPF.

- Sequential Routing (1, 2, 3, etc.) is the default routing order – one department at a time reviews the IPF (in the order designated via the “List of Approving Departments”). Approval by the Admin Award department triggers the approval notification email to the second department on the routing list, approval by the second department on the routing list triggers an email to the third department, etc.

- Concurrent Routing – to expedite the review/approval process, the routing order for departments (other than the Admin Award department) may be designated to be reviewed/approved concurrently (at the same time). For example, indicating “2” for all departments after the Admin Award department will result in all “2” departments being notified at the same time to review/approve (upon approval by the Admin Award department). → When indicating Routing Order via “List of Approving Departments,” ensure that sub-departments route ahead of their respective parent departments, and that Colleges/Schools are indicated last in the routing order.
NOTE - Upon submission of the IPF, the actual routing order may vary somewhat, based on institutional routing requirements.

“Submission Notes” IPF screen
→ Add notes related to IPF screens i.e., F&A, cost sharing etc.
→ Indicate if proposal package was prepared in Cayuse

IPF Submission Confirmation / Submission
→ After completion of all screens on the IPF Item List (green check mark on each screen), the IPF may be submitted by clicking the “Submit” button located at the bottom of the IPF Item list.
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