The following is an excerpt from the NIH Guide for Grants and Contracts - Week Of March 18, 2005

Updated Instructions to the PHS 398 (DHHS Public Health Service Grant Applications) Now Available

Notice Number: NOT-OD-05-039

Key Dates
Release Date: March 16, 2005
Issued by: National Institutes of Health (NIH), (http://www.nih.gov)

Updated instructions to the PHS398 Application are now available at http://grants.nih.gov/grants/forms.htm. Since the November 2004 release of the new version, the instructions have been updated to reflect changes in policy and/or to provide better clarity. Not all updates are published in the Guide; however, all are noted on the web site. Applicants are reminded to periodically check this web site for the latest version. Notable changes in the instructions are marked in purple.
Instructions for the budget fields on the Face Page and the various Budget Form Pages have been revised to provide clearer guidance for applications that include consortium F&A costs.
Scenario #1 – Modular Budget

- When consortium/contractual costs are involved, the figures for each year in the "DC less Consortium F&A" row must be in $25,000 increments and < $250,000.
### Modular Budget Page

<table>
<thead>
<tr>
<th></th>
<th>Initial Period</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt;</th>
<th>3&lt;sup&gt;rd&lt;/sup&gt;</th>
<th>4&lt;sup&gt;th&lt;/sup&gt;</th>
<th>5&lt;sup&gt;th&lt;/sup&gt;</th>
<th>Sum Total (For Entire Project)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DC less Consortium F&amp;A</td>
<td>150,000</td>
<td>150,000</td>
<td></td>
<td></td>
<td></td>
<td>300,000</td>
</tr>
<tr>
<td>(Item 7a, Face Page)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consortium F&amp;A</td>
<td>22,500</td>
<td>22,500</td>
<td></td>
<td></td>
<td></td>
<td>45,000</td>
</tr>
<tr>
<td>Total Direct Costs</td>
<td>172,500</td>
<td>172,500</td>
<td></td>
<td></td>
<td></td>
<td>345,000</td>
</tr>
</tbody>
</table>

### Face Page

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7a. Direct Costs ($)</td>
<td>8a. Direct Costs ($)</td>
</tr>
<tr>
<td>7b. Total Costs ($)</td>
<td>8b. Total Costs ($)</td>
</tr>
<tr>
<td>$150,000</td>
<td>$300,000</td>
</tr>
<tr>
<td>$238,750</td>
<td>$464,250</td>
</tr>
</tbody>
</table>
Scenario #2 – Detailed Budget
Calculating Budget Totals – 7a

- Use the “Subtotal Direct Costs for Initial Budget Period” on Form Page 4.

<table>
<thead>
<tr>
<th>7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD</th>
<th>8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>7a. Direct Costs ($)</td>
<td>8a. Direct Costs ($)</td>
</tr>
<tr>
<td>$150,000</td>
<td>$300,000</td>
</tr>
<tr>
<td>7b. Total Costs ($)</td>
<td>8b. Total Costs ($)</td>
</tr>
<tr>
<td>$238,750</td>
<td>$464,250</td>
</tr>
</tbody>
</table>
Calculating Budget Totals – 7b

- Add together the “Total Direct Costs” from Form Page 4 and the F&A costs calculated for the initial budget period on the Checklist Page.
Calculating Budget Totals - 8a

- Total the “Subtotal Direct Costs” for all years on Form Page 5.

<table>
<thead>
<tr>
<th>SUBTOTAL DIRECT COSTS</th>
<th>150,000</th>
<th>+</th>
<th>150,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Sum = Item 8a, Face Page)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONSORTIUM/</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTRACTUAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COSTS F&amp;A</td>
<td>22,500</td>
<td></td>
<td>22,500</td>
</tr>
<tr>
<td>TOTAL DIRECT COSTS</td>
<td>172,500</td>
<td></td>
<td>172,500</td>
</tr>
</tbody>
</table>
Calculating Budget Totals – 8b

- Add together the “Total Direct Costs for Entire Proposed Project Period” on Form Page 5 and the Total F&A costs for all years calculated on the Checklist Page.

<table>
<thead>
<tr>
<th>TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>$ 345,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Amount of base</th>
<th>Rate applied</th>
<th>% = F&amp;A costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>$125,000</td>
<td>53.00%</td>
<td>$66,250</td>
</tr>
<tr>
<td>$100,000</td>
<td>53.00%</td>
<td>$53,000</td>
</tr>
<tr>
<td>$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$119,250</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chapter V of the PHS 398 has been revised to reflect that the modular budget format no longer applies to SBIR/STTR grant applications.

- pg. 65 SBIR/STTR 398, “The modular budget format no longer applies to SBIR/STTR grant applications. Applicants must complete and submit budget requests using Form Page 4 and Form Page 5.”
Who are Key Personnel?

- The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. Key Personnel must devote measurable effort to the project whether or not salaries are requested. "Zero percent" effort or “as needed” are not acceptable levels of involvement for those designated as Key Personnel.
Who are Other Significant Contributors?

- This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. These individuals are typically presented at "zero percent" effort or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.
Who are Key Personnel?

- Scenario – NIH’s designation of Key Personnel may differ from Key Personnel identified in WU application on Form Page 2.

<table>
<thead>
<tr>
<th>Name</th>
<th>eRA Commons User Name</th>
<th>Organization</th>
<th>Role on Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thomas S. Magnum, III, PhD</td>
<td>Magnum_Pl</td>
<td>Washington University</td>
<td>PI</td>
</tr>
<tr>
<td>Agatha Chumley, MD</td>
<td>agathac</td>
<td>St. Louis University</td>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Jonathan Q. Higgins, III, MD</td>
<td>Higgins</td>
<td>Washington University</td>
<td>Core Director</td>
</tr>
</tbody>
</table>
Who are Key Personnel?

- Notice of Grant Award (NGA) arrives with the following statement under Section III:
  - KEY PERSONNEL: In addition to the PI, any absence, replacement, or substantial reduction in effort of the following individual(s) below, requires the written prior approval of the National Institutes of Health awarding component.
  
  AGATHA CHUMLEY, MD

- NIH did not consider Dr. Higgins Key Personnel.
Who are Key Personnel?

- When addressing SNAP Question #2 "Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Grant Award from what was approved for this project?" use key personnel listed on NGA (e.g., Thomas S. Magnum, III & Agatha Chumley).

- The Personnel Report (2590 Form Page 7) should address WU designated Key Personnel (e.g., Thomas Magnum, III, Agatha Chumley & Jonathan Q. Higgins, III).
Mandatory Use of New DHHS Instructions & Forms

- NOT-OD-05-043
  - Use of the revised instructions and forms (9/04) for the PHS 398 and PHS 2590 are mandatory for receipt/submission on or after the following dates:
    - May 10, 2005 for the PHS 398
    - May 1, 2005 for the PHS 2590
Testing of NSF Submissions Via grants.gov

- **Purpose:**
  - To identify problems and solicit feedback to NSF
  - To determine how the grants.gov system may integrate with our internal systems at WU

- Made available to research entities on a volunteer basis.

- Testing ran April 4 through April 15.
Testing of NSF Submissions Via grants.gov

- Both successes and failures in testing
  - 28 institutions participated
- No time frame for when it will be mandatory to submit NSF applications on grants.gov
What should I do when I learn an application has been rejected by the agency?

- It is not necessary to inform G&C of rejected applications. We have a system in place that notifies us of older proposals that have not been funded.
Human Studies Committee Issues

School of Medicine
May ’05

Presented by Sarah Frankel
Significant revisions have been made primarily in Part II, Human Subjects Research Supplement, to further address NIH implementation of OHRP Guidance on research involving coded private information or biological specimens.

- Please see Part II for complete instructions
- Contact the Human Studies Committee with any questions or concerns
Under HHS regulations to protect human subjects from research risks, certain research areas are exempt. (See Exemption Categories). Nonetheless, with the exception of research projects that meet the criteria for Exemption 4, studies that are exempt from the human subjects regulations must still address the inclusion of women and minorities and children in the study design. Therefore, applications will be evaluated for compliance with this policy. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable to the investigator(s) are also to be included within the term “research involving human subjects.”
Federal requirements to protect human subjects would apply to research on human specimens (such as cells, blood, and urine), residual diagnostic specimens and/or medical information, when these specimens and/or medical information are from living individuals who are individually identifiable to the investigator(s).
From R-News Dated 3/21/05 – Changes in Part III

Exemption Categories

- Although Exemptions 1 and 3-6 apply to research involving children (see Subpart D), Exemption 2 can only be used for research involving educational testing or observations of public behavior of children when the investigator(s) do not participate in the activities being observed.
  - Must still be submitted to the IRB to receive Exempt status
Summary reports of adverse events must be provided to the NIH funding institute/center and to individual IRBs in order for them to address reports related to the site for which they have responsibility. Grantees should address questions on this subject to the NIH Program Official.
From R-News Dated 3/21/05 – Changes in Part III

- Prior to award, applicants will be required to provide a description of education completed in the protection of human subjects for all Key Personnel. While NIH does not endorse specific programs, there are curricula available that can provide guidance or that can be modified to provide training in this area.

- Title of D. is now “NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research”
Education in Protection of Human Subjects

WU Research Education Policy

- Key Personnel
  - Any individual responsible for the design, conduct or reporting of research that is “engaged in human subject research.”
    - WU employee
      - IRB of Record
      - Biomedical Research Team track of CITI
    - Non-WU employee
      - Auspices of another IRB
      - Education from other institution is acceptable
Key Personnel and HSC Paperwork

- **Scenario 1**
  - Predoctorial student, fellow, etc. with a funding source other than that of his/her mentor
    - **Form 19 – Identical To**
      - Allows for the addition of funding sources
      - Allows you to list predoctorial student as PI
Key Personnel and HSC Paperwork

- **Scenario 2**
  - Pre or postdoctorial student, fellow, etc. without a funding source being added to a mentor’s protocol
    - Form 5 – Revision/Amendment
    - Student is being added as a collaborator
      - *Any individuals listed as authors on the project meet the criteria for collaborator per the WU Authorship Policy*
Key Personnel and HSC Paperwork

○ Scenario 3
  ● Same research participants are being asked for something additional, e.g. blood, information. There is no new funding and no additional participants will be recruited.
    ○ Substudy
    ○ Form 5 – Revision/Amendment
Key Personnel and HSC Paperwork

○ Scenario 4
  ● Fellow, pre/post doc, etc. wants to ask a new research question – related or unrelated to the mentor’s research question.
    ○ New Protocol
Key Personnel and HSC Paperwork

Scenario 5

- Trainees are being added to a training grant
  - Form 8 – Review of Training Grants
  - List
    - Faculty Supervisor
    - Agency Grant Number
    - Trainees
    - Full Board or Expedited Review
    - HSC #
    - Reviewing Committee
    - Approval Date
Questions?

Please feel free to contact G&C with any questions, comments or concerns.

Thank you.