

Summary of Proposed Changes to the PHS398 (2004 Version)

ERA Implications

Format Changes

- This edition of the PHS 398 has been *extensively* rewritten with a focus on clarity and special emphasis on simplicity and plain language.
- It has been reorganized into three distinct parts, each of which is available as a separate file:
 - **Part I: Instructions for Preparing the Application**
 - Efforts have been made to keep Part I instructional material only
 - See Part III for information pertaining to policies, assurances, definitions and other information
 - Instructions reorganized to pull all the “general information” together in the “Forward”
 - **Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan**
 - New approach—all instructions and related policies related to Human Subjects Research (Research Plan Section e.) are now in their own section
 - New approach—“Plain Language” questions to help better guide application writers through the decision making process re: use of Human Subjects
 - This section is still a work-in-progress. A “subgroup” of the PHS 398 working group and other NIH/OHRP staff will continue their discussions to resolve some outstanding issues
 - **Part III: Policies, Assurances, Definitions and Other Information**
 - Separate section now with links from “Instructions” as necessary
 - Incorporates all policy changes since the 5/01 revision
 - Definitions have been harmonized with those used in the NIH Grants Policy Statement

Specific Changes of Interest

Form Changes

- **Face Page**
 - **Item 3h.** NIH Commons User Name field has been added. This data item is currently optional. **ERA Implications—This is a step towards harmonizing the electronic and paper processes. R&R may need to be modified to enter this data item. However, this will actually be a positive step in the long run since it should greatly reduce the need to search for the correct PI Profile.**
 - **Item 4.** Human Subjects Research box has been modified as follows:
 - 4a: No/Yes check boxes for “Research Exempt”
 - 4b: Human Subjects Assurance Number

- 4c: No/Yes checkboxes for Clinical Trial (*New Data element under discussion*)
ERA Implications—If this stays as a separate data element, this would need to be added to the database. Currently (I believe) only one field exists and it is for Phase III designation only.
 - 4d: No/Yes checkboxes for NIH-Defined Phase III Clinical Trial
- **Form Page 2:**
 - **Description/Abstract:** Instructions have been added to regarding projects that involve human embryonic stem cells. Applicants must include the registration number of the specific cell line(s) as part of the “Description”. If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used. **ERA Implications: Probably none--Currently the Stem Cell data items are completed by IC staff. Doubtful we would change that business process.**
 - **Key Personnel Section:**
 - A field has been added for the NIH Commons User Name. This data item is currently optional. **ERA Implications: Primarily needed for electronic submission. Key Personnel Data not currently captured as separate data elements in the paper world.**
 - A field has been added for the inclusion of a DUNS number for each organization listed in “Key Personnel”. **ERA Implications: This request actually came from eRA. Not sure if this will be required in electronic submission. Should be no change for data capture from paper submission since we don’t currently capture Key Personnel as separate data elements.**
 - **Key Words**—Suggested new section using CRISP key words. **ERA Implications: Discussion/decision will be needed to determine if these are data elements we would want to capture upon application receipt. Ultimately this could greatly aid the CRISP folks and could also aid the Knowledge Management initiatives.**
- **Biosketch:** A field has been added for the NIH Commons User Name. This data item is currently optional. **ERA Implications: None. Biosketch data not captured as separate data elements.**
- **Checklist Form Page:** A field has been added for “Change in Grantee Institution”. **ERA Implications: Discussion/decision will be needed to determine if this is a data element we would want to capture upon application receipt. Not sure to what extent R&R uses those boxes on the Checklist.**

Policy Changes

- **Definitions** have been harmonized with those used in the revised NIH Grants Policy Statement
 - Most of the wording remains essentially the same as before.
 - One important definition change proposed—Key Personnel. Now reads (changes highlighted):
“In addition to the PI, key personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. **Consultants should also be included if they meet the definition of “key personnel.”**

Key personnel must devote measurable effort to the project whether or not salaries are requested--"zero percent" effort or 'as needed' are not acceptable involvements for someone designated as key personnel.”

- Incorporates **policy changes since 5/01 version:**
 - Duns Number (*Existing Face Page data element—was previously “optional”, now required*)
 - Policy Reminder re: Direct Charges for IRB Costs (*Section VII—Policy, Assurances, Definitions, and Other Information*)
 - Eliminating the 2-yr time limit for amended applications (*Section VII—Policy, Assurances, Definitions, and Other Information*)
 - Clarifying Submission Address Zip-codes (*Section II—Submission & Review of Your Application*)
 - New Legislative Mandate re: Ban on Abortion (*Part of “Prohibited Research” Assurance in Section VII—Policy, Assurances, Definitions, and Other Information*)
 - Data Sharing (*Incorporated in Instructions for new section j in Research Plan & detailed in Section VII—Policy, Assurances, Definitions, and Other Information*)
 - Changes in policy re: “New” vs. “Amended” applications (*Section VII—Policy, Assurances, Definitions, and Other Information*)
 - Just-In-Time for Animal IACUC Approval Date (*Face Page Instructions & “Just-In-Time Policy” section of Section VII—Policy, Assurances, Definitions, and Other Information*)
 - Graduate Student Compensation—(*Incorporated as a budget instruction & Section VII—Policy, Assurances, Definitions, and Other Information*)
 - \$500,000 policy—prior acceptance 6 wks in advance (*Already incorporated in mid-cycle revisions, but now also part of Section VII—Policy, Assurances, Definitions, and Other Information*)
 - Amended Gender/Minority Inclusion policies (*Already incorporated in mid-cycle revisions*)
 - Human Subjects Education Requirement (*Incorporated in the “Just-In-Time Policy” section & Human Subjects Assurance section of Section VII—Policy, Assurances, Definitions, and Other Information*)
 - Stem Cells (*Already incorporated in mid-cycle revisions. Is now in both Instructions & Section VII—Policy, Assurances, Definitions, and Other Information*)