Change Request Justification for Select Instructions in 0925-0001

0925-0001 received clearance in August 2012. Since then several Federal-wide and agency-specific initiatives have begun that require modification to instructions used for completing applications cleared in this package. There is no new data collection being proposed on any of the existing forms. The burden increase associated with the addition of graduate and under graduate students is captured under 0925-0002 where the data collection instrument is located. 0925-0001 only captures the instruction changes. Changes are described below with corresponding information explaining the background and nature of the change.

I. Supplemental Grant Application Instructions

Form Section Being Modified	Background and Description of Change
Background	This section of Supplemental Instructions is used in conjunction with every completing application used by applicants to the NIH and other PHS agencies; e.g., the PHS398, SF424(R&R), PHS416-1. It is also used in conjunction with non-completing progress report used by grantees which are separately cleared as part of -0925-0002; e.g., PHS2590, PHS416-9 and the RPPR. Part II includes Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan. **There are no changes being proposed for this section.** Part III includes details on Policies, Assurances, Definitions and Other Information. The changes outlined below modify existing text within Part III.
Part III.1.7 & Part III.2.18, 2.19, 2.20	**Just-In-Time Instructions & SBIR, STTR Certifications** The SBIR program has always had a requirement that applicants meet certain eligibility conditions at the time of award and throughout the life-cycle of the award (see Part 5.2 below for life-cycle certification). The pre-award requirement is provided in these sections. The SBIR Reauthorization (13 C.F.R. §§121.701-121.705) includes new language for this pre-award certification. NIH collects this certification as a Just-in-Time requirement so that it is only requested for those applications likely to be funded and so that this certification is received just prior to the award. The changes to these sections replace previously used language

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	with the new language provided by the Small Business Association (SBA). New to this program is a similar Certification for Venture Capital Operating Companies, Hedge Fund, or Private Equity Firms (section 2.20). This is a new cohort of eligible institutions for the SBIR program. The language included here was also provided by the SBA to implement the final regulation. See attachment A for text for revised sections 1.7, 2.18, 2.19 and new section 2.20.
Part III.1.18	**Requirement for Individual Development Plans for Graduate Students and Postdoctoral Scientist** Based on advice received from a working group under the auspices of the Advisory Committee to the Director, NIH (ACD), the NIH is undertaking a variety of initiatives to develop a model for a sustainable and diverse U.S. biomedical research workforce that will inform decisions about training the optimal number of people for the appropriate types of positions that will advance science and promote health. These initiatives are referred to as The Biomedical Workforce Development (BMW) effort. This new requirement directs the applicant institution to have a process in place that assures that an Individual Development Plan (IDP) is developed for all individuals working on a NIH-funded research grant as a graduate student or postdoctoral scientist role. The actual IDPs will not be collected by the NIH. Instead this will be an institution-level requirement to develop a policy that supports this requirement and provide information on this policy in annual progress reports. See Attachment A for new text section 1.18.
Part III.5.2	**SBIR/STTR Award Guidelines, Reporting Requirements, and Other Considerations** This section is unique to the SBIR & STTR programs and provides program-specific information. Section 5.2 covers program-specific Terms and Conditions of Award. One of the other provisions of the SBIR Reauthorization (noted

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	above) is that grantees now certify program eligibility throughout the life-cycle of an award. This Life Cycle Certification provision has been added to 5.2 so that it is clear to all applicants this requirement will be part of all awards, those based on competing applications and non-competing progress reports. See Attachment A for new text for section 5.2.

II. Instructions for Competing Applications; e.g., PHS 398 Instructions

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Background	The Application Instructions for all Competing Applications include general sections that cover instructions applicable to all NIH applications and progress reports. The following sections of these General instructions will be modified in all applicable documents.
Section 2.2.4.2 - Commons Registration for PD/PI and Individuals with a Undergraduate, Graduate Student, or Postdoctoral Role	Registration in the eRA Commons has previously been required for individuals holding the PD/PI role and/or Postdoctoral role on all NIH-funded projects. This registration gives NIH the data necessary to satisfy a number of reporting requirements including those in section 489 of the PHS Act that require NIH to perform a continuing assessment of research personnel needs. In addition, section 402 of the 2007 NIH Reform Act requires NIH to report to Congress specifically on the outcomes and effectiveness of various types of training programs, including training supported through research grants. While this training report initially focused on individuals at a postdoctoral level, under the auspices of the Biomedical Workforce Development initiative, these reporting needs are now expanded to include data on students at the undergraduate and graduate student levels. Therefore the Commons Registration for individuals supported on NIH-funded grants will be extended to cover these student categories. This is not new data collection; merely an expansion of existing data to cover additional categories of individuals already working on NIH-funded grants. The eRA Commons registration requirement is managed through the creation of a Personal Profile for an individual. It is a one-

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	time registration process that collects specific data about the individual and is updatable by the individual as their relationship with NIH changes throughout their career. At the time an individual initially creates their Person Profile, answers to certain demographic data are required. The requirement for certain data items is also expanding to accommodate NIH reporting requirements to Congress. Note, in some cases an acceptable response is "Do Not Wish to Provide". See also separate sections below on Collection of Personal Demographic Data and Commons Personal Profile. See Attachment B for revised text for section 2.2.4.2.
1.7.1 Collection of Personal Demographic Data (in all Application Guides and Instructions)	This section of the general instructions is also being modified to reflect the expanded data collection for students at the Undergraduate and Graduate Student levels. Like the Commons ID noted above, this section previously focused only on individuals with the roles of PD/PI and Postdoctoral. This expansion of existing data collection for this cohort of individuals is necessary to satisfy the NIH reporting requirements to Congress. See Attachment B for revised text for section 1.7.1.

III. Biosketch Format and Instructions

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C. Publications	The Application Instructions for all Competing Applications include a format page for the biographical sketch completed by each senior/key person working on an NIH application. The biosketch includes section *C. Selected Peer-reviewed Publications and Patent Citations*. This section will be broadened to also give the individual the option to include for publications identified as important to the field, a short narrative description of the findings and how those findings have advanced scientific understanding. Further, the individual may describe the impact of those findings on our understanding of disease, standards of medical care, public policy, inventions, the development of commercial products and

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	any other related advancements. This will provide information on the impact of research findings that occur well after the initial publication; i.e., long term outcomes of biomedical research and the Federal investment. See Attachment C for revised text.

IV. Commons Personal Profile Data Set

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	This data set includes all the data currently collected in the eRA Commons Person Profile. No new data is being collected. However, as described in item II above, NIH will begin to require responses to certain data elements in this data set for individuals holding the following eRA Roles: PD/PI; Postdoctoral, Graduate Student, or Undergraduate. Data where a response is now required include: Citizenship Status Demographics (Gender, Ethnicity and Race, Disability) Note, these data items are not new; however, previously the individual could leave an item blank. As a result, there was no way to determine if the individual intentionally left it blank or just overlooked the item. Now a response will be required. However, for many of these data items, "Do Not Wish To Provide" is an acceptable response. Further, this Personal Profile will now include the ability to display the ORCID ID for the individual when available. ORCID is an open, non-profit, community-based effort to provide a registry of unique researcher identifiers and a transparent method of linking research activities and outputs to these identifiers. It provides a persistent digital identifier that distinguishes an individual from all other researchers. This will not be new data collection; rather it will accommodate a system-to-system data feed. Proposed Screen shots as well as an Excel Spreadsheet of the entire data set are provided. Screen changes are noted on pages 2, 3, and 16. See Attachment D for proposed screenshot. See Attachment E for spreadsheet of the entire data set.