

**Summary Table of Significant Changes
PHS 416-1, 416-9, 416-7, 416-5, 6031 and 6031-1**

Change	Rationale
PHS 416-1 Grant Application	
Form Page 1 (Face Page)	
Item 4k. Citizenship data fields updated to modify for Permanent Resident Of U.S. <i>Pending</i> and add checkboxes for Permanent Resident of U.S. and Non-U.S. Citizen with Temporary U.S. Visa	Agency need to receive more specific responses as distinct data elements
Item 10a. Delete IACUC approval date	Information collected under Just-in-Time
Eliminate Applicant and Sponsor Signatures as signatures on the Face Page; included requirement now as part of the institutional assurances; only the signature of Official Signing for Applicant Organization is required	Change in business process necessitated with transition to electronic (Grants.gov) submission process
Form Page 3	
Item 22. Training Site(s) - Section updated to collect information for each Training (Project/Performance) Site; addition of DUNS and Congressional District fields for Training (Project/Performance) Site	Required by Federal Financial Accountability and Transparency Act (FFATA) Of 2006
General Changes	
Addition of section on Select Agent Research to the Research Training Plan	Implementing specific requirements for Select Agent Research
Provide suggested cover letter format	Greater consistency and facilitation of applicant requests for specific NIH Institute/Center and Scientific Review Group assignment.
Human subject and vertebrate animal research plan instructions modified to address indefinite plans in these areas.	Provide guidance to applicants with indefinite plans at the time of application
Added instructions in Responsible Conduct of Research (RCR) to include peer review, collaboration, and mentor/mentee relationship.	Reflects current NIH policy
416-1, Part II, Instructions for Preparing the Protection of Human Subjects Section of the Research Plan	
Changes to scenarios: <ul style="list-style-type: none"> • All six human subjects exemptions are provided in one scenario; corresponding instructions modified accordingly. • New scenario "Delayed Onset Human Subjects Research" incorporated. 	Less confusing to applicants. Provide instructions on addressing indefinite plans for including human subjects

416-1, Part III, Policies, Assurances Definitions	
Added information on NIH Public Access Policy requirements in the Publications section and in Part III	New policy requirement for NIH awardees only
Added Institutional Assurance for Fellow and Sponsor Approvals	New business process necessitated to accommodate electronic (Grants.gov) submission of these applications
PHS 416-9 Progress Report	
Form Page 1 (Face Page)	
Item 7. Delete checkboxes for Full IRB or Expedited Review	Information no longer needed as structured data elements
Item 9. Training Site(s)- Section updated to collect information for each Training (Project/Performance) Site; addition of DUNS and Congressional District fields for Training (Project/Performance) Site	Required by FFATA
Eliminate Applicant and Sponsor Signatures; included as part of the institutional assurances; only the signature of Official Signing for Applicant Organization is required	Consistent business practice associated with transition to SF424 (R&R) and electronic submission
Form Page 2	
Item 16. Addition of item on Select Agents Research	Implementing specific requirements for Select Agent Research
General Changes	
<u>Only the signed original progress report is required to be submitted to the centralized mailing address. No additional copy is required.</u>	New business process for submission of the progress report. Reduces burden to applicant.
Addition of section on Select Agent Research	Implementing specific requirements for Select Agent Research
Include information on NIH Public Access Policy requirements in the Progress Report section	New policy requirement for NIH awardees only
PHS 416-7 Termination Notice	
Revised instructions to broaden use of form for all Individual Fellowship Programs (NRSA and other Training Authorities), Institutional Career Award scholars, and Research Education appointees.	Enable broader use of form.
PHS 416-5 Activation Notice	
No Change	

PHS 6031 Payback Agreement	
No Change	
PHS 6031-1 Annual Payback Activities Certification	
No Change	