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

PHS 416-1 Grant Application Form Page 1 (Face Page) Item 4k. Citizenship data fields updated to modify for Permanent Resident Of U.S. Pending and add checkboxes for Permanent Resident of U.S. and Non-U.S. Citizen with Temporary U.S. Visa Item 10a. Delete IACUC approval date 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 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 General Changes Addition of section on Select Agent Research to the Research Training Plan Human subject and vertebrate animal research plan instructions modified to address indefinite plans in these areas. Added instructions in Responsible Conduct of Research (RCR) to include peer review, collaboration, and mentor/mentee relationship. 416-1, Part II, Instructions for Preparing the Protection of Human Subjects exemptions are provided in one scenario; corresponding instructions modified accordingly. • New scenario "Delayed Onset Human Provide instructions on addressing indefinite plans instructions modified accordingly. • New scenario "Delayed Onset Human Provide instructions on addressing indefinite plans instructions modified accordingly.	Change	Rationale
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416-1, Part III, Policies, Assurances	
Definitions	
Added information on NIH Public Access	New policy requirement for NIH awardees only
Policy requirements in the Publications section	
and in Part III	
Added Institutional Assurance for Fellow and	New business process necessitated to
Sponsor Approvals	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	Information no longer needed as structured data
Expedited Review	elements
Item 9. Training Site(s)- Section updated to	Required by FFATA
collect information for each Training	
(Project/Performance) Site; addition of DUNS	
and Congressional District fields for Training	
(Project/Performance) Site	
Eliminate Applicant and Sponsor Signatures;	Consistent business practice associated with
included as part of the institutional assurances;	transition to SF424 (R&R) and electronic
only the signature of Official Signing for	submission
Applicant Organization is required	
Form Page 2	
Item 16. Addition of item on Select Agents	Implementing specific requirements for Select
Research	Agent Research
General Changes	
Only the signed original progress report is	New business process for submission of the
required to be submitted to the centralized	progress report. Reduces burden to applicant.
mailing address. No additional copy is	
required.	
Addition of section on Select Agent Research	Implementing specific requirements for Select Agent Research
Include information on NIH Public Access	New policy requirement for NIH awardees only
Policy requirements in the Progress Report	
section	
PHS 416-7 Termination Notice	
Revised instructions to broaden use of form for	Enable broader use of form.
all Individual Fellowship Programs (NRSA and	
other Training Authorities), Institutional Career	
Award scholars, and Research Education	
appointees.	
PHS 416-5 Activation Notice	
No Change	

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