GUIDANCE: PPHS File Naming Convention

Beginning February 1, 2021, the Program for the Protection of Human Subjects (PPHS) will require the use of a new document naming convention (see below) to be used with the RUTH application submission system. Changes to document names for migrated projects is not required unless a change to the document is submitted for review. The effective start date is 2/1/2021, however study teams can begin immediately.

Format for the Structured File Name should be: File Type then Study Number then Study teams can add any wording (title, etc.) next, but should be somewhat descriptive including versions/dates, etc.

For dates use format: mm.dd.yyyy

	Structured File Name	**Examples**
Protocol	Protocol 20-00000	
HRP 503 (Full or R or E)	HRP503 20-00000	HRP 503E 20-00000 01.21.2021
Grant/Funding Application	Grant 20-00000	
IB (drug or device)	IB (drug/device) 20-00000	
Main ICF (structured file name include language if other than English)	Main ICF 20-00000	Main ICF 20-00000 Spanish 01.25.2021
Substudy ICF (structured file name include language if other than English)	Substudy ICF 20-00000	
Parental ICF (structured file name include language if other than English)	Parental ICF 20-00000	
LAR ICF (structured file name include language if other than English)	LAR ICF 20-00000	
Assent (structured file name include language if other than English)	Assent 20-00000	
Advertisement (structured file name include type of ad and language if other than English)	Advertisement 20-00000	Advertisement 20-00000 Facebook Spanish 02.14.2021 Advertisement 20-00000 Newspaper French 02.14.2021
Flyer (structured file name include type of flyer and language if other than English)	Flyer 20-00000	Flyer 20-00000 Warrior Watch Spanish 01.21.2021
Brochure (structured file name include type of brochure and language if other than English)	Brochure 20-00000	Brochure 20-00000 Mandarin 01.21.2021
Ancillary Review Form	Ancillary Review Form 20-00000	
Correspondence (Agency/Sponsor/Other) (i.e. letters)	Correspondence 20-00000	Correspondence 20-00000 FDA 12.01.2020
Documentation (Drug/Device/Other) (i.e pkg insert)	Documentation 20-00000	Documentation 20-00000 Device Manufacturer Brochure
HIPAA Wizard	HIPAA Wizard 20-00000	

External IRB Approval Letter	Approval Ext Initial 20-0000 Approval Ext Cont 20-00000 Approval Ext Mod 20-00000	
Worksheets/Checklists	HRP XXX 20-00000	HRP 232 20-00000 01.21.2021
Reliance Documents	Reliance 20-00000	
R2S Site Specific Documents (title to include document type)	R2S Site 20-000000	R2S Einstein ICF 20-00000 01.25.2021