File Naming Conventions: Documents for NCATS Clinical Studies Requesting Prior Approval of Delayed Onset Research involving Human Subjects

(For use in conjunction with the "Document Checklist for Prior Approval of Delayed Onset Research Involving Human Subjects")

Standard Naming Convention:

CTSA_InvestigatorLastNameFirstInitial_ProtocolShortTitle_Document_YYYYMMDD.pdf or **.doc**

example: UCollege_AndersonM_Ped Resp Infection Genomic Determinants_Biosketch_20160125.pdf

Element		Explanation
CTSA		Name of the funded CTSA hub; truncated names are acceptable (e.g., University of California, San Francisco would be 'USCF'; Yale would 'Yale')
InvestigatorLastNameFirstInitial		Name of the pilot project investigator or KL2 scholar performing the proposed clinical study (e.g., Mark Anderson would be 'AndersonM'; Jennifer Black-Egan would be 'Black-EganJ')
ProtocolShortTitle		Short identifier for proposed clinical study (e.g., Framingham Heart Study could be 'FHS'; Fecal Transplantation in recurrent C. difficile infection could be 'CDiff Fecal Transplant')
Document		Identifies the type of document being submitted:
	Biosketch	NIH Biosketch of the pilot project investigator or KL2 scholar performing the proposed clinical study
	Protocol	Complete clinical research protocol
	Consent	Informed consent document
	Assent	Assent document, if applicable
	NCATS Support ID	Identification of the specific amendment/portion of the protocol supported by NCATS funding (if entire parent protocol is included in the submission)
	NCATS Support Explain	Explanation of exactly what is being supported by NCATS pilot or KL2 scholar funding (if proposed clinical research protocol is considered an amendment to a parent protocol)
	Product Info	Product information, such as the clinical investigator brochure, package insert, or description of the device, if a clinical trial is proposed
	IND IDE	Documentation that an IND or IDE has been obtained, or letter from the FDA that the study is IND-exempt or the IDE has been waived, if a clinical trial is proposed
	HS Section	New or Revised human subjects section that clearly describes the risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities (as described in Part II of NIH competing application instructions)
	Inclusion	Inclusion plans for women, minorities, and children, if applicable
	Enrollment	Targeted Enrollment Table or Inclusion Data Record (IDR) (optional)
	Safety	Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
	HS Edu	Certification that the pilot project awardee or KL2 scholar and any Key Personnel directly involved in the study have taken appropriate education in protection of human subjects, if not provided previously
	IRB Approval	Most recent IRB approval of the proposed clinical study (including IRB approvals from each participating site, if proposing a multi-site trial)
YYYYMMDD		Identifies the date the document is sent to NCATS (e.g., January 25, 2016, would be 20160125)