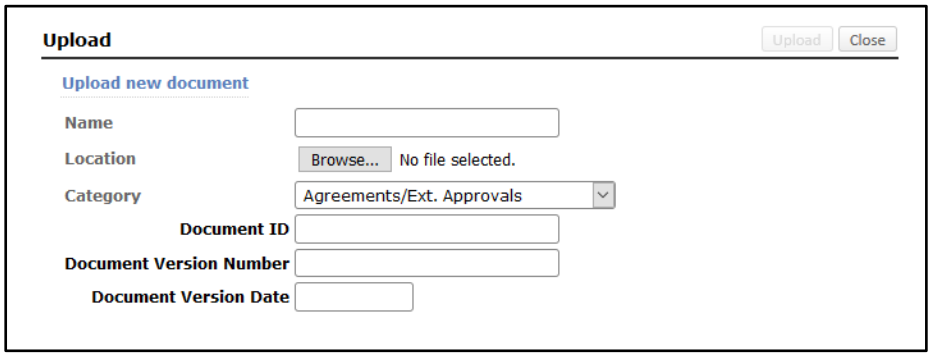
Naming and Categorizing Documents in InfoEd

COMIRB asks researchers to name and categorize their study documents according as described in the table on the following page. This helps with our review of your research and helps when locating documents in the future. Instructions for InfoEd are included below. If you need assistance, COMIRB staff are available to help; simply email us at COMIRB@ucdenver.edu.

When uploading a new document:

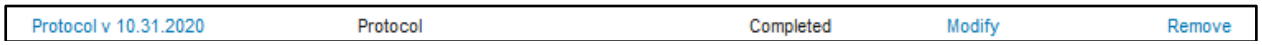
1. In the submission, start by hitting the blue 'Add' button at the top of the document list or, for the Application Form and PI Attestation, the blue 'Upload' button in the fourth column. A window will pop up that looks like this:



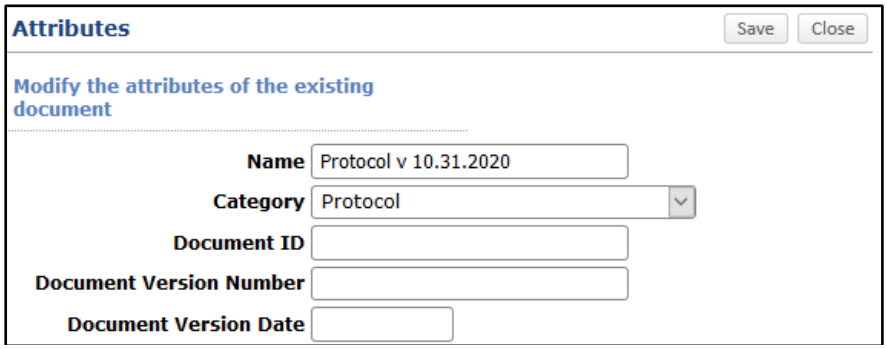
2. By clicking 'Browse' and selecting the document from your saved files, the name automatically populates as the document title. To change the name, click in the 'Name' box and rename it to match the Document v MM.DD.YY format.
    a. Please note: clicking in the 'Name' box will highlight all the text. Use the keyboard arrows if you need to navigate within the box.
3. After the name is resolved, select the appropriate category from the drop-down menu.
4. When complete, click 'Upload' in the top right corner.

Modifying documents already uploaded:

1. To edit the name of a document that has already been uploaded, select the 'Modify' button in the fourth column that will look like this:



2. From the pop-up window, select 'Modify the Attributes of this Document' and the following window will appear:



3. To change the name, click in the 'Name' box and rename it to match the Document v MM.DD.YY format.
    a. Please note: clicking in the 'Name' box will highlight all the text. Use the keyboard arrows if you need to navigate within the box.
4. To change the category, select the appropriate category from the drop-down menu.
5. When complete, click 'Save' in the top right corner.

Category to Select in InfoEd	Examples and Naming Convention	Description
Agreements/Ext. Approvals	Email - Subject v MM.DD.YY	*Email correspondence relevant to review of the study (e.g., communications from other committees, sponsors, researchers at other sites, etc.) regarding agreements or approvals that COMIRB needs to move forward.*
	HSR Portal Clearance v MM.DD.YY	*All CTRC and CHCO protocols are required to be submitted through the HSR portal. Full board and expedited (with patient interaction) UCD, DHHA, and UCHealth studies are also required to be submitted to the HSR portal. After submitting through the portal, you will receive a clearance email--please upload this email into the submission.*
	PRMS Letter v MM.DD.YY	*This letter documents review by the Cancer Center's Protocol Review and Monitoring System (PRMS)*
	SPARO Letter v MM.DD.YY	*This authorization letter is issued by Denver Health's Sponsored Programs and Research Office (SPARO) and is required for studies involving DHHA.*
	VA Purple Clearance Letter v MM.DD.YY	*This authorization letter is issued by the VA Eastern Colorado Health Care System (ECHCS), and is required for any research in which ECHCS is engaged. This should be obtained prior to submission to COMIRB and must be included with any submission requesting approval of ECHCS as a performance site.*
	VA Yellow Clearance Letter v MM.DD.YY	*This letter documents that any VA-affiliated investigators are not working on VA time and/or utilizing VA resources*
	IRB Reliance-relying institution-MM.DD.YY	*IRB Authorization Agreements (IAAs) or a Smart IRB Agreement. These are formal agreements documenting when a non-affiliated institution agrees to cede IRB oversight to COMIRB.*
	SARC Chair Memo v MM.DD.YY	*These documents should be submitted if your study required review by the Scientific Advisory and Review Committee (SARC) prior to COMIRB approval.*
	SARC Letter v MM.DD.YY	
Application/Protocol Summary	Application Form v MM.DD.YY	*Application form required for all other research. This may be the normal Application for Protocol Review or Secondary Research Application Please note: for the Initial Submission you will not be able to edit the name of the Application Form*
Change Form	Change Form	*This document is required for all Amendment submissions and should list any documents being changed with an Amendment as well as detailed descriptions of those revisions. Please note: the name of the Change Form cannot be modified*
Consent/Assent/Information Sheet	Assent Form *[language, if translated for non-English speakers]* v MM.DD.YY	*This form is to be used to document a child's affirmative agreement to participate in a research study.*
	Consent and Authorization Form *[language, if translated for non-English speakers]* v MM.DD.YY	*This form is to be used to document a research subject's informed consent to participate in a study.*
	Information Sheet v MM.DD.YY	*This document is used when subjects' consent is obtained without documentation via the subject's signature.*
	Previously Stamped Consent v MM.DD.YY	*If a study is enrolling subjects at the time of Continuing Review, study teams must upload the stamped copy of the most-recently approved consent form in their CRV submission.*
	VA Consent Form v MM.DD.YY	*If the study will enroll subjects from the VA Eastern Colorado Health Care System (ECHCS), a VA-specific consent fomr should be utilized.*
CRV Form/Misc CRV docs	PDF CR Form	*This mandatory form, submitted on an annual basis for studies that require Continuing Review, is used to provide general data regarding the progress of the study (e.g., subject numbers, demographic data, enrollment status, etc.). Please note: the name of the CR Form cannot be modified*
	Publication-Ref-MM.DD.YY	*For studies that require Continuing Review, if any data and/or findings related to the study have been published or submitted for publication in an academic journal since the previous CRV, these should be included in the CRV submission.*
Drug/Device Info	Investigator's Brochure v MM.DD.YY	*This document is a compilation of clinical and nonclinical data regarding an investigational product that is the subject of a drug study.*
	IND/IDE Letter v MM.DD.YY	*This letter from FDA documents receipt of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application, and should be submitted with Initial Applications for studies conducted under an IND or IDE, unless the IND/IDE number is provided in the sponsor protocol (for industry-funded studies).*
Emails/Letters	Cover letter v MM.DD.YY	*Please include the study title and list of uploaded documents*
	Email from study team - Subject v MM.DD.YY	*Email correspondence between the study team/PI and the IRB may sometimes need to be included in a submission.*
Grant/Contract	Grant v MM.DD.YY	*If the study is federally funded, submit the grant or grant application.*
HIPAA Forms	HIPAA A v MM.DD.YY	*HIPAA A forms are used to authorize the release of health information to the study team for research recruitment purposes when a clinical/research relationship does not currently exist.*
	HIPAA B v MM.DD.YY	*HIPAA B Forms are used to authorize the use of health information for research purposes.*
	Standalone HIPAA Authorization v MM.DD.YY	*If you plan to use a Short Form to enroll non-English speakers, an English-language version of the standalone HIPAA authorization should be included in your submission.*
HL/Unapproved Documents	Document title v MM.DD.YY HL (date of new version)	*When submitting a revised version of a previously approved document (typically in an Amendment, Response to Minor Modifications, or Response to Deferral), a "tracked changes" version of the revised document should be included in the submission along with the "clean" version.*
Internal Document	Conflict of Interest (COI) Management Plan v MM.DD.YY	*This document is required when the COI office determines that an investigator on a protocol has a conflict of interest necessitating a management plan. Such plans are drafted by the COI office and provided to COMIRB, which issues the final approval of the plan.*
Protocol	Protocol v MM.DD.YY	*A narrative protocol using the COMIRB template or one provided by the study sponsor.*
	SARC Approved Protocol v MM.DD.YY	*SARC approved version of the narrative protocol.*
Safety/Compliance Reports	DSMB, AE Log, AE Report, Protocol Deviation Log/Report v MM.DD.YY	*At continuing review, please supply any necessary safety and compliance documents from the review year.*
	Corrective Action Plan v MM.DD.YY	*May be requested for UAP submissions.*
Subject Materials	Advertising Components Form v MM.DD.YY	*This form is used in lieu of submitting each individual advertisement/recruiting material as separate documents. It is used to provide the content of advertisements that may be displayed in a variety of media.*
	Email Script v MM.DD.YY	*Templates for any emails sent to subjects for recruitment, study procedures, reminders, etc. should be submitted for review.*
	Flyer v MM.DD.YY	*Copy of flyer(s) used for study recruitment.*
	Phone Script v MM.DD.YY	*Scripts for any phone calls to subjects for recruitment, prescreening, reminders, etc. should be submitted for review.*
	Survey - Title v MM.DD.YY	*Survey(s) to be used with participants.*
	Questionnaire - Title v MM.DD.YY	*Questionnaire(s) to be used with participants. Please note that validated questionnaires do not need to be submitted.*