File Storage Protocol

* Naming syntax for documents:
  + [Title of Document]\_Year-Month-Day\_[Initials]\_[Tracked/Clean]
* Major folders should include: Study Forms, MOPs, IRB, Study Meeting Agenda and Minutes, GCO, etc.
* Within each active folder there should be an “older” folder
  + Designate a point person to handle “older” file documents
* Final and current documents should live in the appropriate folder
  + E.g. current questionnaires should live in a folder entitled, “Questionnaires”
* Always have an IRB Folder that will chronologically capture the all the submissions of the study
  + Subfolders should be named according to the type of submission and the date that initialized the submission
    - E.g. Initial Submission 2018-04-30, Modification #1\_2018-05-21, Renewal #1\_2019-03-21, etc.
  + Each subfolder should contain the documents that were submitted, IRB’s communications, the responses, clean and tracked versions of the documents that were changed, and approvals
* Updating documents:
  + Since modifications to documents needs IRB approval, any change to a document should be made to the last version of the document from the most recently approved IRB submission
    - For example, a study was initially approved on 4/2/2018. A modification to the protocol needs to be made on 5/21/2018. To make the modification, use the approved clean version, make a copy of the document and move to a new folder within the main IRB folder (Modification #1\_2018-05-21). Then use that document to track the changes and rename with the correct syntax.
  + Updating documents in other folders should occur after IRB approval
    - Continuing with the same example from above, the IRB approved the protocol change on 5/25/2018. Rename and save the newly approved protocol with the date of approval (HRP-503a\_[Study Name]\_year-month-date\_APPROVED). Keep a copy in the IRB subfolder and make another copy to put in the appropriate folder outside the IRB folder. Since in this example it was a protocol that was modified and approved, the copy would move to a folder that would be named “Protocols.” This is redundant, however, if you needed a quick glance at the most recent protocol, having a document live in a main folder is helpful.