

## Essential Documents

### List of Essential Documents

Below are the list of documents required during new study submission. If any of these documents are password protected please provide such information within the comments field of the document at time of upload

- Word Version of CTA or Work Order
- Word Version of Confidentiality Agreement (for CDA Submission)
- Protocol
- Investigator Brochure
- Lab Manual
- Pharmacy Manual
- Sponsor Budget
- Sponsor Proposed ICF
- CTU Services Order Form (Required, if applicable)
- Ancillary Services Agreements (if applicable)
- IND Application/CMS Letter (if applicable)
- CIC Checklist (if applicable)
- Device
  - IDE Documentation/Number
  - CMS Documentation
  - Investigation Brochure
  - VAC Form