|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document** | **Initial Review** | **Continuing Review** | **UAP** | **Study Closure** |
| ***Cover Letter*** | All | Optional | Optional | All |
| ***COMIRB Application and relevant attachments*** | All | All | - | - |
| ***Protocol*** | Full and Expedited | Full and Expedited | - | - |
| ***“Clean” (unstamped) Consent/Assent Forms******(Includes Information Sheets or Verbal Consent Scripts)*** | Full and Expedited | Full and Expedited (if still enrolling) | - | - |
| ***“Stamped” copy of Consent/Assent Forms******(Includes Information Sheets or Verbal Consent Scripts)*** | - | Full and Expedited |  |  |
| ***HIPAA A*** | If applicable | - | - | - |
| ***HIPAA B*** | Full and Expedited | VA Research | - | - |
| ***Grant Application*** | If primary recipient | If new funding | - | - |
| ***Surveys/Questionnaires/Interview Guides/Focus Group Guides/ Diaries*** | If applicable | - | - | - |
| ***Institutional Approvals (Includes VA Clearance Letter, SPARO Letter, Portal Clearance, etc.)*** | If applicable | - | - | - |
| ***IRB Approvals from other sites (if UCD or affiliate is the lead site)*** | If applicable | If applicable | - | - |
| ***Data collection tools, sheets, or forms*** | If applicable | - | - | - |
| ***Recruitment Materials*** | If applicable | - | - | - |
| ***Documentation of IND or IDE number*** | If applicable | - | - | - |
| ***Investigator’s Brochure (for investigational drugs)*** | If applicable | - | If changed | - |
| ***Product labelling information (if studying an approved drug or device)*** | If applicable | - | - | - |
| ***Conflict of Interest Management Plan*** | If applicable | - | - | - |
| ***DSMB/DMC Charter*** | If applicable | - | - | - |
| ***DSMB/DMC Reports*** | If applicable | If applicable | If applicable | If applicable |
| ***Other safety reports or multicenter trial updates*** | If applicable | If applicable | If applicable | If applicable |
| ***Copies of abstracts or publications resulting from the research*** | - | If applicable | - | If applicable |
| ***Protocol deviations/violations and or adverse events since last review that were not previously reported*** | - | If applicable | - | If applicable |

Amendment submissions should include a Change Form, Cover Letter, and **two copies of each revised document**. One copy must have tracked changes, and the other copy must be “clean.”