Documents to attach to submission xForms

(1) For the Principal Investigator

If not already on file with BRANY, provide:

- CV - Curriculum Vitae (signed & dated within 1 year)
- Professional license (if applicable), current
- Training (per your organization's requirements)
- User access form

(2) For Each Key Study Personnel:

If not already on file with BRANY, provide

- Training (per your organization's requirements)
- BRANY financial disclosure forms
  a) FORM 01: Conflict Disclosure Statement
  b) FORM 02: Conflict Report Form (only if answered "YES" on Form 01)

  OR

  - Documentation indicating the organization (i.e. the Relying Institution, or site for which the application will be submitted) has performed its own analyses under its relevant policy(ies) with respect to disclosure and management of its Research Personnel's conflicts of interest in connection with the study. In such case, the organization's resulting determinations, prohibitions, management plans, and any updates should be provided to BRANY IRB **instead of** BRANY's Form 01 and/or Form 02.
- User access form (*optional* – only if access to IRBManager is needed)

(3) Study Documents (all submissions)

- Protocol (include sufficient detail describing background, rationales, procedures, and data to be collected)
- Copy of grant documentation, if applicable
- Consent form(s) and Assent form(s) (if applicable)
  a) Use templates available at www.brany.com
  b) Microsoft Word compatible format
- Recruitment or advertisement materials
- Data collection tools
- Other subject-facing materials

(4) Study of Drugs or Biologics

- Investigator's Brochure
- Drug inserts or other documents relating to the study agent(s)
- IND documentation, or if an IND has not been filed, an explanation as to why

(5) Study of Medical Devices or In Vitro Diagnostics

- Device brochure or Instructions for Use
- One of the following:
  a) FDA Letter granting the investigational device exemption (IDE); or
  b) Letter from Sponsor stating that the study is a non-significant risk device study; or
  c) Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c), or otherwise exempt