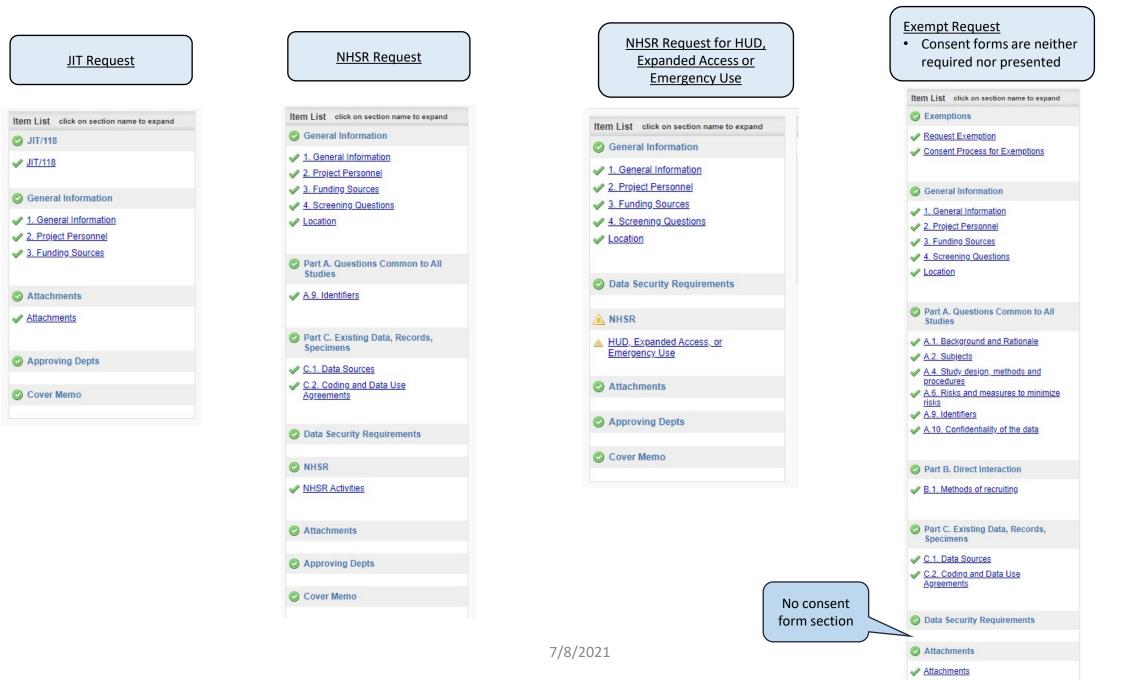
Initial Application Types - As Reflected in the ITEM LIST (1)



Initial Application Types - As Reflected in the ITEM LIST (2)

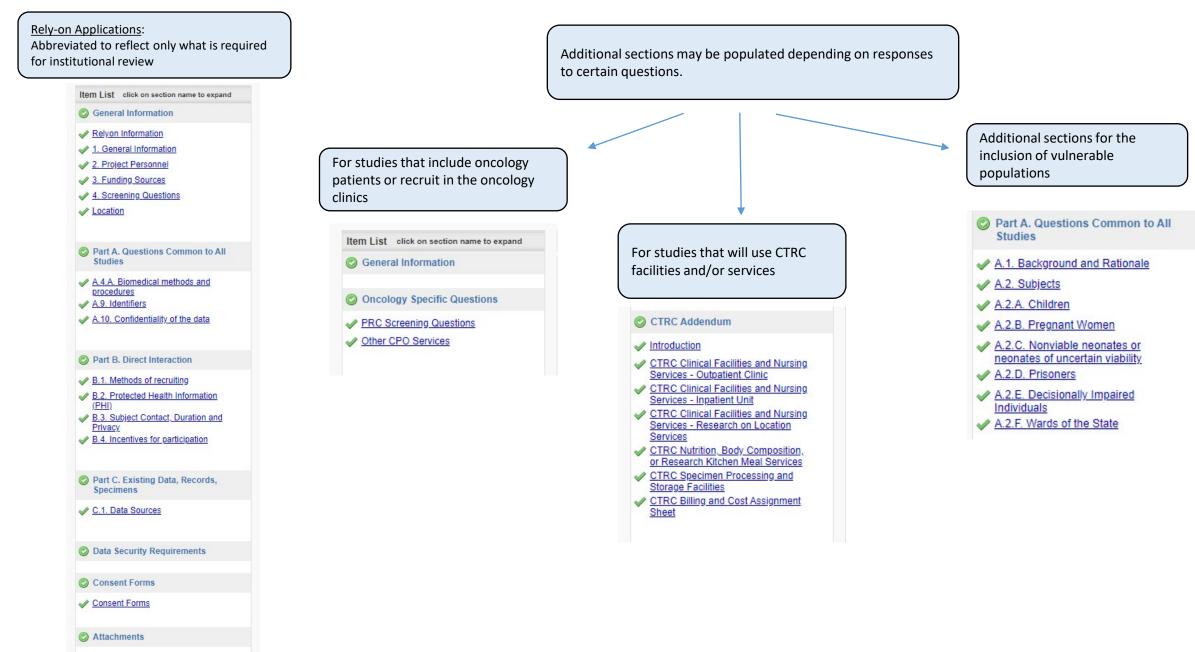
The full IRB Application: Multi-Site Application • Consent Form templates are tailored specifically to each • Same requirements as Full Form application but are not presented until all preceding sections Additional section to list external sites are complete. • An application is considered "full" even if Part B is suppressed (i.e., response to Screening Q #2 is No). Item List click on section name to expand Part B. Direct Interaction General Information Item List click on section name to expand Part B. Direct Interaction B.1. Methods of recruiting B.2. Protected Health Information C General Information <u>1. General Information</u> B.1. Methods of recruiting (PHI) B.2. Protected Health Information 2. Project Personnel <u>1. General Information</u> B.3. Subject Contact, Duration and (PHI) Privacy 3. Funding Sources 2. Project Personnel B.3. Subject Contact, Duration and B.4. Incentives for participation Privacy 4. Screening Questions 3. Funding Sources B.5. Costs to be borne by subjects B.4. Incentives for participation 5. Multi-site Study Information <u>4. Screening Questions</u> B.5. Costs to be borne by subjects Location Part C. Existing Data, Records. Specimens Part C. Existing Data, Records. Scientific Review Specimens Scientific Review C.1. Data Sources Scientific Review C.1. Data Sources C.2. Coding and Data Use Scientific Review Agreements C.2. Coding and Data Use Agreements Part A. Questions Common to All Part A. Questions Common to All Part D. The Consent Process Studies Studies Part D. The Consent Process D.1. Obtaining informed consent from subjects A.1. Background and Rationale D.1. Obtaining informed consent from D.2. Waiver of written documentation subjects A.2. Subjects of informed consent D.2. Waiver of written documentation D.3. Full or partial waiver of consent A.3. Inclusion/exclusion criteria of informed consent D.3. Full or partial waiver of consent A.4. Study design, methods and procedures procedures A.4.A. Biomedical methods and A.5. Benefits to subjects and/or O Data Security Requirements procedures society Data Security Requirements society A.6. Risks and measures to minimize Consent Forms A.6. Risks and measures to minimize risks Consent Forms risks A.7. Data and safety monitoring A.8. Data analysis Attachments Attachments A.9. Identifiers A.10. Confidentiality of the data Approving Depts Approving Depts ✓ A.11. Data sharing and transmission A.11. Data sharing and transmission Cover Memo A.12. Post-study disposition of Cover Memo identifiable data or human biological identifiable data or human biological materials

A complete application:

- The PI is prevented from submitting until all sections/parts of the IRB application are complete (as denoted by green checkmarks).
- Location

- A.1. Background and Rationale
- A.2. Subjects
- A.3. Inclusion/exclusion criteria
- A.4. Study design, methods and
- A.5. Benefits to subjects and/or
- A.7. Data and safety monitoring
- A.8. Data analysis
- A.9. Identifiers
- A.10. Confidentiality of the data
- A.12. Post-study disposition of materials

Initial Application Types - As Reflected in the ITEM LIST (3)



Ø Approving Depts