

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

## JIT Request

| Item List | click on section name to expand        |
|-----------|--|
| ✓         | JIT/118                                |
| ✓         | <a href="#">JIT/118</a>                |
| ✓         | General Information                    |
| ✓         | <a href="#">1. General Information</a> |
| ✓         | <a href="#">2. Project Personnel</a>   |
| ✓         | <a href="#">3. Funding Sources</a>     |
| ✓         | Attachments                            |
| ✓         | <a href="#">Attachments</a>            |
| ✓         | Approving Depts                        |
| ✓         | Cover Memo                             |

## NHSR Request

| Item List | click on section name to expand                     |
|-----------|---|
| ✓         | General Information                                 |
| ✓         | <a href="#">1. General Information</a>              |
| ✓         | <a href="#">2. Project Personnel</a>                |
| ✓         | <a href="#">3. Funding Sources</a>                  |
| ✓         | <a href="#">4. Screening Questions</a>              |
| ✓         | <a href="#">Location</a>                            |
| ✓         | Part A. Questions Common to All Studies             |
| ✓         | <a href="#">A.9. Identifiers</a>                    |
| ✓         | Part C. Existing Data, Records, Specimens           |
| ✓         | <a href="#">C.1. Data Sources</a>                   |
| ✓         | <a href="#">C.2. Coding and Data Use Agreements</a> |
| ✓         | Data Security Requirements                          |
| ✓         | NHSR  |
| ✓         | <a href="#">NHSR Activities</a>                     |
| ✓         | Attachments   |
| ✓         | Approving Depts                                     |
| ✓         | Cover Memo  |

## NHSR Request for HUD, Expanded Access or Emergency Use

| Item List | click on section name to expand                        |
|-----------|--|
| ✓         | General Information                                    |
| ✓         | <a href="#">1. General Information</a>                 |
| ✓         | <a href="#">2. Project Personnel</a>                   |
| ✓         | <a href="#">3. Funding Sources</a>                     |
| ✓         | <a href="#">4. Screening Questions</a>                 |
| ✓         | <a href="#">Location</a>                               |
| ✓         | Data Security Requirements                             |
| ⚠         | NHSR   |
| ⚠         | <a href="#">HUD, Expanded Access, or Emergency Use</a> |
| ✓         | Attachments  |
| ✓         | Approving Depts  |
| ✓         | Cover Memo   |

## Exempt Request

- Consent forms are neither required nor presented

| Item List | click on section name to expand                           |
|-----------|---|
| ✓         | Exemptions  |
| ✓         | <a href="#">Request Exemption</a>                         |
| ✓         | <a href="#">Consent Process for Exemptions</a>            |
| ✓         | General Information                                       |
| ✓         | <a href="#">1. General Information</a>                    |
| ✓         | <a href="#">2. Project Personnel</a>                      |
| ✓         | <a href="#">3. Funding Sources</a>                        |
| ✓         | <a href="#">4. Screening Questions</a>                    |
| ✓         | <a href="#">Location</a>                                  |
| ✓         | Part A. Questions Common to All Studies                   |
| ✓         | <a href="#">A.1. Background and Rationale</a>             |
| ✓         | <a href="#">A.2. Subjects</a>                             |
| ✓         | <a href="#">A.4. Study design, methods and procedures</a> |
| ✓         | <a href="#">A.6. Risks and measures to minimize risks</a> |
| ✓         | <a href="#">A.9. Identifiers</a>                          |
| ✓         | <a href="#">A.10. Confidentiality of the data</a>         |
| ✓         | Part B. Direct Interaction                                |
| ✓         | <a href="#">B.1. Methods of recruiting</a>                |
| ✓         | Part C. Existing Data, Records, Specimens                 |
| ✓         | <a href="#">C.1. Data Sources</a>                         |
| ✓         | <a href="#">C.2. Coding and Data Use Agreements</a>       |
| ✓         | Data Security Requirements                                |
| ✓         | Attachments   |
| ✓         | <a href="#">Attachments</a>                               |

No consent form section

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

## The full IRB Application:

- Consent Form templates are tailored specifically to each application but are not presented until all preceding sections are complete.
- An application is considered “full” even if Part B is suppressed (i.e., response to Screening Q #2 is *No*).

## A complete application:

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

## Multi-Site Application

- Same requirements as Full Form
- Additional section to list external sites

| Item List   | click on section name to expand  |
|---|--|
| <ul style="list-style-type: none"> <li>✓ General Information                             <ul style="list-style-type: none"> <li>✓ 1. General Information</li> <li>✓ 2. Project Personnel</li> <li>✓ 3. Funding Sources</li> <li>✓ 4. Screening Questions</li> <li>✓ Location</li> </ul> </li> <li>✓ Scientific Review                             <ul style="list-style-type: none"> <li>✓ Scientific Review</li> </ul> </li> <li>✓ Part A. Questions Common to All Studies                             <ul style="list-style-type: none"> <li>✓ A.1. Background and Rationale</li> <li>✓ A.2. Subjects</li> <li>✓ A.3. Inclusion/exclusion criteria</li> <li>✓ A.4. Study design, methods and procedures                                     <ul style="list-style-type: none"> <li>✓ A.4.A. Biomedical methods and procedures</li> </ul> </li> <li>✓ A.5. Benefits to subjects and/or society</li> <li>✓ A.6. Risks and measures to minimize risks</li> <li>✓ A.7. Data and safety monitoring</li> <li>✓ A.8. Data analysis</li> <li>✓ A.9. Identifiers</li> <li>✓ A.10. Confidentiality of the data</li> <li>✓ A.11. Data sharing and transmission</li> <li>✓ A.12. Post-study disposition of identifiable data or human biological materials</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>✓ Part B. Direct Interaction                             <ul style="list-style-type: none"> <li>✓ B.1. Methods of recruiting</li> <li>✓ B.2. Protected Health Information (PHI)</li> <li>✓ B.3. Subject Contact, Duration and Privacy</li> <li>✓ B.4. Incentives for participation</li> <li>✓ B.5. Costs to be borne by subjects</li> </ul> </li> <li>✓ Part C. Existing Data, Records, Specimens                             <ul style="list-style-type: none"> <li>✓ C.1. Data Sources</li> <li>✓ C.2. Coding and Data Use Agreements</li> </ul> </li> <li>✓ Part D. The Consent Process                             <ul style="list-style-type: none"> <li>✓ D.1. Obtaining informed consent from subjects</li> <li>✓ D.2. Waiver of written documentation of informed consent</li> <li>✓ D.3. Full or partial waiver of consent</li> </ul> </li> <li>✓ Data Security Requirements                             <ul style="list-style-type: none"> <li>✓ Consent Forms</li> </ul> </li> <li>✓ Attachments</li> <li>✓ Approving Depts</li> <li>✓ Cover Memo</li> </ul> |
| <ul style="list-style-type: none"> <li>✓ General Information                             <ul style="list-style-type: none"> <li>✓ 1. General Information</li> <li>✓ 2. Project Personnel</li> <li>✓ 3. Funding Sources</li> <li>✓ 4. Screening Questions</li> <li>✓ 5. Multi-site Study Information</li> <li>✓ Location</li> </ul> </li> <li>✓ Scientific Review                             <ul style="list-style-type: none"> <li>✓ Scientific Review</li> </ul> </li> <li>✓ Part A. Questions Common to All Studies                             <ul style="list-style-type: none"> <li>✓ A.1. Background and Rationale</li> <li>✓ A.2. Subjects</li> <li>✓ A.3. Inclusion/exclusion criteria</li> <li>✓ A.4. Study design, methods and procedures                                     <ul style="list-style-type: none"> <li>✓ A.5. Benefits to subjects and/or society</li> <li>✓ A.6. Risks and measures to minimize risks</li> <li>✓ A.7. Data and safety monitoring</li> <li>✓ A.8. Data analysis</li> <li>✓ A.9. Identifiers</li> <li>✓ A.10. Confidentiality of the data</li> <li>✓ A.11. Data sharing and transmission</li> <li>✓ A.12. Post-study disposition of identifiable data or human biological materials</li> </ul> </li> </ul> </li> </ul>          | <ul style="list-style-type: none"> <li>✓ Part B. Direct Interaction                             <ul style="list-style-type: none"> <li>✓ B.1. Methods of recruiting</li> <li>✓ B.2. Protected Health Information (PHI)</li> <li>✓ B.3. Subject Contact, Duration and Privacy</li> <li>✓ B.4. Incentives for participation</li> <li>✓ B.5. Costs to be borne by subjects</li> </ul> </li> <li>✓ Part C. Existing Data, Records, Specimens                             <ul style="list-style-type: none"> <li>✓ C.1. Data Sources</li> <li>✓ C.2. Coding and Data Use Agreements</li> </ul> </li> <li>✓ Part D. The Consent Process                             <ul style="list-style-type: none"> <li>✓ D.1. Obtaining informed consent from subjects</li> <li>✓ D.2. Waiver of written documentation of informed consent</li> <li>✓ D.3. Full or partial waiver of consent</li> </ul> </li> <li>✓ Data Security Requirements                             <ul style="list-style-type: none"> <li>✓ Consent Forms</li> </ul> </li> <li>✓ Attachments</li> <li>✓ Approving Depts</li> <li>✓ Cover Memo</li> </ul> |

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

**Rely-on Applications:**  
Abbreviated to reflect only what is required for institutional review

Additional sections may be populated depending on responses to certain questions.

For studies that include oncology patients or recruit in the oncology clinics

Additional sections for the inclusion of vulnerable populations

For studies that will use CTRC facilities and/or services

- Item List click on section name to expand
- ✓ General Information
  - ✓ [Relyon Information](#)
  - ✓ [1. General Information](#)
  - ✓ [2. Project Personnel](#)
  - ✓ [3. Funding Sources](#)
  - ✓ [4. Screening Questions](#)
  - ✓ [Location](#)
- 
- ✓ Part A. Questions Common to All Studies
  - ✓ [A.4.A. Biomedical methods and procedures](#)
  - ✓ [A.9. Identifiers](#)
  - ✓ [A.10. Confidentiality of the data](#)
- 
- ✓ Part B. Direct Interaction
  - ✓ [B.1. Methods of recruiting](#)
  - ✓ [B.2. Protected Health Information \(PHI\)](#)
  - ✓ [B.3. Subject Contact, Duration and Privacy](#)
  - ✓ [B.4. Incentives for participation](#)
- 
- ✓ Part C. Existing Data, Records, Specimens
  - ✓ [C.1. Data Sources](#)
- 
- ✓ Data Security Requirements
- 
- ✓ Consent Forms
  - ✓ [Consent Forms](#)
- 
- ✓ Attachments
- 
- ✓ Approving Depts

- Item List click on section name to expand
- ✓ General Information
  - ✓ Oncology Specific Questions
  - ✓ [PRC Screening Questions](#)
  - ✓ [Other CPO Services](#)

- ✓ CTRC Addendum
- ✓ [Introduction](#)
- ✓ [CTRC Clinical Facilities and Nursing Services - Outpatient Clinic](#)
- ✓ [CTRC Clinical Facilities and Nursing Services - Inpatient Unit](#)
- ✓ [CTRC Clinical Facilities and Nursing Services - Research on Location Services](#)
- ✓ [CTRC Nutrition, Body Composition, or Research Kitchen Meal Services](#)
- ✓ [CTRC Specimen Processing and Storage Facilities](#)
- ✓ [CTRC Billing and Cost Assignment Sheet](#)

- ✓ Part A. Questions Common to All Studies
- ✓ [A.1. Background and Rationale](#)
- ✓ [A.2. Subjects](#)
- ✓ [A.2.A. Children](#)
- ✓ [A.2.B. Pregnant Women](#)
- ✓ [A.2.C. Nonviable neonates or neonates of uncertain viability](#)
- ✓ [A.2.D. Prisoners](#)
- ✓ [A.2.E. Decisionally Impaired Individuals](#)
- ✓ [A.2.F. Wards of the State](#)