|  |  |  |
| --- | --- | --- |
| **Cayuse** | **IRBIS** | **Added** |
| Section: Submission Information | Section 4: Screening Questions  Section 5: Multi-site studies (if applicable) |  |
| Section: Study Information – **Status** | Section 2 Project Personnel: Question 1 |  |
| Section: Study Information – **Personnel** | Section 2 Project Personnel – Question 2 |  |
| Section: Study Information – **Funding** | Section 3 Funding – Question 1 |  |
| Section: Study Information – **Study Site** | Section B.1.7, B.3.4 |  |
| Section: Study Information – **Study Dates** | Section A.4.4 |  |
| Section: Study Selection – **Enrollment** | Sections A.2.1, A.2.2 |  |
| Section: Study Selection – **Ages** | Section A.2.6 |  |
| Section: Study Selection – **Children** | Section A.2.A (if applicable) |  |
| Section: Study Selection – **Vulnerable Populations**  **(if applicable)** | Sections A.2.A-F (whichever section is triggered)  \*If non-English speaking is selected look at the attachments section for the language (translated version of document) |  |
| **Section: Study Selection - children, mentally incompetent, or other legally restricted groups (if applicable)** | Sections A.2.A-F (whichever section is triggered) |  |
| **Section: Study Selection – special arrangements (if applicable)** | Section A.2.3, A.2.4 |  |
| Section: Study Design – **clinical trial** | Section A.4.A.2. |  |
| Section: Study Design – **study background** | Section A.1.1 |  |
| Section: Study Design – **hypothesis** | Section A.1.2 |  |
| Section: Study Design – **Objectives/Research Questions** | Section A.1.2 |  |
| Section: Study Design – **Objectives** | No IRBIS equivalent, please add manually |  |
| Section: Study Design – **Inclusion Criteria** | Section A.3.1 |  |
| Section: Study Design – **Exclusion Criteria** | Section A.3.1 |  |
| Section: Study Design- **Exclusion Criteria Justification** | Section A.3.2 |  |
| Section: Study Procedures – **Describe Study Procedures** | Section A.4.2, A.4.3 (or A.4.5 – depending if expedited or exempt) |  |
| Section: Study Procedures – **Recruitment** | Sections B.1.1 – B.1.11 |  |
| Section: Study Procedures – **Site Approval** | Section B.1.6 |  |
| Section: Study Procedures – **Study Documents** | Transfer all documents from IRBIS labeled as a recruitment script |  |
| Section: Study Procedures – **Payment/Incentives** | Section B.4.1 A-E |  |
| Section: Study Procedures – **Duration** | Sections A.4.3, B.3.1, B.3.2 B.3.3 |  |
| Section: Study Procedures – **Information to be gathered** | Section A.4.2 |  |
| Section: Study Procedures – **Study Instruments** | Upload any surveys, questionnaires, interview questions, focus group questions, etc |  |
| Section: Study Procedures – **Survey, Questionnaire, Interview** | Section A.4.2, A.4.3 |  |
| Section: Study Procedures – **Will survey, etc record identifiable data?** | Section: A.10.1 |  |
| **Section: Study Procedures - justify why the survey, questionnaire, or interview needs to record identifiable information.** | No IRBIS equivalent, please add manually |  |
| **Section: Study Procedures – Genetic Testing** | Sections: A.4.1 , A.4.A (if triggered) |  |
| **Section: Study Procedures – Drugs, Devices, Biologics** | Sections: A.4.A.1 - A.4.A.3 (if triggered) |  |
| **Section: Study Procedures – Data, Specimens, and Records** | Sections: C.1.1 – C.1.3 (if triggered)  Section: C.2.1 (if triggered) |  |
| **Section: Study Procedures – blood draw** | Sections: A.4.1, A.4.6 |  |
| **Section: Study Procedures – has Blood Borne Pathogen Registration Form been submitted** | Only respond “yes” if the study design states that a blood draw is involved as this document will have been submitted  If the study design section does NOT indicate blood will be drawn, respond “no” |  |
| **Section: Study Procedures - Will** [Protected Health Information (PHI](https://www.hhs.gov/answers/hipaa/what-is-phi/index.html)**) obtained directly from a** [covered entity (CE](https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html)**) be used?** | Sections: A.9.1, B.2.1, B.2.2 |  |
| **Section: Participant Protection – Do you anticipate risk** | Respond “yes” if any section in A.6 is checked  If no sections in A.6 are checked, respond “no” |  |
| **Section: Participant Protection – Potential Risks** | Sections: A.6.1 – A.6.11 – as applicable |  |
| **Section: Participant Protection - Describe any potential legal, financial, social, or personal affects on subjects of accidental data disclosure** | Section A.6.1 – A.6.9 – as applicable |  |
| **Section: Participant Protection - If relevant, describe procedures for providing a referral for any participants who are found, during the course of this study, to be in need of psychological counseling or medical follow-up. This would generally occur in studies where there are questions about depression or suicide or studies where there is potential for injury.** | Section A.6.11 |  |
| **Section: Participant Protection – Expected Benefits** | Sections: A.5.1 – A.5.3 |  |
| **Section: Participant Protection – Deception** | Section: D.3.3 |  |
| **Section: Participant Protection – Safeguarding Participants Identity – what uses will be made of the information obtained from participants** | No IRBIS equivalent, please add manually |  |
| **Section: Participant Protection – Safeguarding Participants Identity – Describe Privacy** | Section: A.10.1 |  |
| **Section: Participant Protection – Safeguarding Participants Identity – Describe Confidentiality** | Sections: A.10.1, A.10.2, A.10.8 (If this study is exempt, the question numbers may differ slightly, but will still be under A.10) |  |
| **Section: Participant Protection – Informed Consent** | Sections D.1.1 – D.1.7 (as applicable) |  |
| **Section: Participant Protection – Parental Consent/Assent** | Section D.1.1 (as applicable) |  |
| **Section: Participant Protection – Waiver of Documentation/Signed Consent** | Section: D.1 |  |
| **Section: Participant Protection – Full/partial waiver of consent** | Sections: D.3.1 – D.3.3 |  |
| **Section: Participant Protection – Limited Waiver HIPAA Authorization** | Sections: B.2.1 – B.2.2 |  |
| **Section: Participant Protection – Waiver of HIPAA** | Section: D.3.1 |  |
| **Section: Participant Protection – Upload Consent/Assent Forms** | Upload all Adult Consent, Parental Consent, and Assent Forms |  |
| **Section: Conflict of Interest** | Section: Personnel – question 5 (question number may vary depending on whether the study is expedited or exempt) |  |