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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	

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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)	

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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) **obtained directly from a** covered entity (CE) **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	

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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)	