AURA-IRB Smart Form

Branching Document

This document provides an overview of how branching occurs in the AURA-IRB Initial Submission Smartform. Use the following to view how to access various branch views. Views labeled "Optional" are views your study will branch to based on how you answer required questions in the Smart Form.

	Views		Notes
Required	1.1 Study Identification		Required view for all initial submissions
Required	1.2 Study Personnel		Required view for all initial submissions
Required	1.3 Research Team Summary		Required view for all initial submissions
Required	1.4 Funding Sources		Required view for all initial submissions
Optional		1.4.1 External Funding Information	Only Branch here from view 1.4 question 1
Required	1.5 Study Locations		Required view for all initial submissions
Optional		1.5.1 Multi-site Study	Only Branch here from view 1.5 question 3
Optional		1.5.2 Other US Sites	Only Branch here from view 1.5 question 4
Optional		1.5.3 International Sites	Only Branch here from view 1.5 question 5
Required	2.1 Research Categories		
Optional		2.1.1 Non-Human Subjects Research Request	Only Branch here from view 2.1 question 1. Once this view is completed, no additonal views are necessary. Researchers should be allowed to submit.
Optional		2.1.2 Exempt Request	Only Branch here from view 2.1 question 1. Once this view is completed, no additonal views are necessary. Researchers should be allowed to submit.
Required	2.2 Purpose		Only required if not an Exempt or Non-Human Subjects request.
Optional		2.2.1 Additional Activities (Methods & Procedures I)	Only Branch here from view 2.2 question 1
Optional		2.2.2 Additional Activities (Methods & Procedures II)	Only Branch here from view 2.2 question 1
Optional		2.2.3 Additional Activities (Methods and Procedures III)	Only Branch here from view2.2 question 1

Optional	**3.1 Outside IRB of Record**		*Only Branch here from view 2.2 question 8. Once this view is completed,* ***skip all other views and go directly to view 17.1***
Optional	**4.1 Drugs**		Only Branch here from view 2.2.1 question 1
Optional		**4.1.1 Experimental Drugs**	Only branch here from view 4.1 question 1
Optional		**4.1.2 FDA Approved Drugs**	Only branch here from view 4.1 question 1
Optional		**4.1.3 Washout Period**	Only branch here from view 4.1 question 2
Optional		**4.1.4 Placebo/No Treatment Arm**	Only branch here from view 4.1 question 3
Optional		**4.1.5 Drug Receipt, Dispensing, and Monitoring**	Branch here from view 4.1 question 5, Branch here from view 4.1.2 question 2
Optional	**4.2 Biologics**		Only Branch here from view 2.2.1 question 1
Optional	**4.3 Vitamin/Herbal Supplements**		Only Branch here from view 2.2.1 question 1
Optional	**4.4 Medical Devices**		Only Branch here from view 2.2.1 question 1
Optional		**4.4.1 Approved/Cleared Medical Devices**	Only branch here from view 4.4 question 1
Optional		**4.4.2 Experimental/Investigational Medical Devices**	Only branch here from view 4.4 question 1
Optional	**4.5 Novel Surgical/Clinical Intervention**		Only Branch here from view 2.2.1 question 1
Optional	**5.1 Surveys & Questionnaires**		Branch here from view 2.2.1 question 1, Branch here from view 2.2.2 question 1, Branch here from view 2.2.3 question 1
Optional	**5.2 Interviews/Oral History**		Branch here from view 2.2.1 question 1, Branch here from view 2.2.2 question 1, Branch here from view 2.2.3 question 1
Optional	**5.3 Focus Groups**		Branch here from view 2.2.1 question 1, Branch here from view 2.2.2 question 1, Branch here from view 2.2.3 question 1
Optional	**5.4 Observational/Ethnographic Research**		
Optional	**5.5 Participant Observation**		Branch here from view 2.2.2 question 1

Optional	**5.6 Deception**		Branch here from view 2.2.1 question 1, Branch here from view 2.2.2 question 1, Branch here
Optional	**5.7 Psychological Testing**		Branch here from view 2.2.2 question 1
Optional	**6.1 Specimen Collection and/or Analysis**		Branch here from view 2.2.1 question 1, Branch here from view 2.2.2 question 1, Branch here from view 2.2.3 question 1
Optional		**6.1.1 Existing Specimens**	Only branch here from view 6.1 question 1
Optional		**6.1.2 Prospective Collection of Specimens**	Only branch here from view 6.1 question 1
Optional		**6.1.3 Genetic Analysis**	Only branch here from view 6.1 question 3
Optional		**6.1.4 Specimen Banking**	Only branch here from view 6.1 question 4
Optional	**6.2 Data Collection/Record Review**		Branch here from view 2.2.1 question 1, Branch here from view 2.2.2 question 1, Branch here from view 2.2.3 question 1
Optional		**6.2.1 Retrospective Data/Secondary Analysis**	Only branch here from view 6.2 question 1
Optional		**6.2.2 Prospective Data**	Only branch here from view 6.2 question 1
Optional		**6.2.3 Data Registry or Database**	Only branch here from view 6.2 question 2
Required	**7.1 Study Population**		Branch here from all submissions that have completed any questions from section 4, 5, and/or 6.
Optional		**7.1.1 Healthy Children (Minors)**	Only branch here from view 7.1 question 1
Optional		**7.1.2 Children with Diagnosed Disease, Disorder or Condition**	Only branch here from view 7.1 question 1
Optional		**7.1.3 Wards of the State**	Only branch here from view 7.1 question 1
Optional	**7.2 Decisionally Impaired**		Only branch here from view 7.1 question 2

Optional	**7.3 Subordinates of the Research Team or Employees of the UChicago or the UChicago Hospitals**			Only branch here from view 7.1 question 2
Optional	**7.4 Undergraduate Students**			Only branch here from view 7.1 question 2
Optional	**7.5 Prisoners**			Only branch here from view 7.1 question 1
Optional	**7.6 Pregnant Women, Fetuses**			Only branch here from view 7.1 question 1
Optional	**7.7 Placenta, Dead Fetus or Fetal Material**			Only branch here from view 7.1 question 1
Optional	**7.8 Non-Viable Neonates**			Only branch here from view 7.1 question 1
Optional	**7.9 Non-English Speakers**			Only branch here from view 7.1 question 2
Required	**8.1 Recruitment and Screening**			Branch here from all submissions that have completed any questions from section 7.
Optional		**8.1.1 Recruitment**		Only branch here from view 8.1 question 1
Optional		**8.1.2 Screening using Medical Records**		Only branch here from view 8.1.1 question 1
Optional		**8.1.3 Waiver of Authorization for Recruitment**		Only branch here from view 8.1.2 question 5
Required	**9.1 Compensation**			Branch here from all submissions that have completed any questions from section 8.
Optional		**9.1.1 Compensation Details**		Only branch here from view 9.1 question 1
Required	**10.1 Risk Assessment**			Branch here from all submissions that have completed any questions from section 9.
Required	**10.2 Data Confidentiality**			Branch here from all submissions that have completed any questions from section 9.
Optional		**10.2.1 Data Confidentiality (Coded or Identified Data)**		Only branch here from view 10.2 question 1

Optional	**10.3 Audio/Video Recording and Photographs**		Branch here from view 2.2.1 question 1, Branch here from view 2.2.2 question 1, Branch here from view 2.2.3 question 1
Required	**11.1 Data Safety & Monitoring Plan**		Branch here from all submissions that have completed any questions from section 10.
Optional	**12.1 Radiation Safety**		Views 12.1, 12.2, 12.3 are required ONLY if "RADRAC" is selected as an ancillary review from
Optional	**12.2 Radiation Safety Training & Experience**		Views 12.1, 12.2, 12.3 are required ONLY if "RADRAC" is selected as an ancillary review from View 2.1 question 2.
Optional	**12.3 Radiation Safety Isotope Usage**		Views 12.1, 12.2, 12.3 are required ONLY if "RADRAC" is selected as an ancillary review from View 2.1 question 2.
Optional	**12.4 Facilities and Disposal**		Only branch here from view 12.3 question 12
Optional	**12.5 Monitoring Devices**		Only branch here from view 12.3 question 12
Required	**13.1 Benefits**		Branch here from all submissions that have completed any questions from section 11 (or 12 if needed).
Required	**13.2 Alternatives / Options**		Branch here from all submissions that have completed any questions from section 13.1.
Required	**14.1 HIPAA**		Branch here from all submissions that have completed any questions from section 13.
Optional		**14.1.1 Protected Health Information (PHI)**	Only branch here from view 14.1 question 1
Optional		**14.1.2 Waiver of Authorization**	Only branch here from view 14.1 question 5
Required	**15.1 Costs**		Branch here from all submissions that have completed any questions from section 14.
Optional		**15.1.1 Cost Details**	Only branch here from view 15.1 question 1
Required	**16.1 Informed Consent Determination**		Branch here from all submissions that have completed any questions from section 15.
Optional	**16.2 Process of Consent**		Only branch here from view 16.1 question 1
Optional	**16.3 Verbal (Oral) Consent**		Only branch here from view 16.1 question 1

Optional	**16.4 Waiver of Consent**		Only branch here from view 16.1 question 1
Optional	**16.5 Alteration of Consent**		Only branch here from view 16.1 question 1
Optional	**16.6 Children (Assent)**		Branch here from view 7.1.1 question 4, branch here from view 7.1.2 question 4
Optional		**16.6.1 Children (Waiver of Assent)**	Branch here from view 7.1.1 question 4, branch here from view 7.1.2 question 4
Optional	**16.7 Non-English Speaking Participants**		Only branch here from view 7.1 question 2
Required	**16.8 Consent/Assent Documents**		Branch here from all submissions that have completed any questions from section 16.1.
Required	**17.1 Additional Supporting Documents**		Branch directly here from view 3.1 (Outside IRB of Record), Branch here from all submissions that have completed any questions from section 16. Once this view is completed, no additonal views are necessary. Researchers should be allowed to submit.

Branching Criteria/ Detail

View	Question		Response	Branch to View(s):
1.4	1	Funding Sources	Externally Funded/Supported	1.4.1
1.5	3	Is this a multi-site study?	Yes	1.5.1
1.5	4	Are the University of Chicago researchers conducting this study or any portion of the study at a non-University of Chicago site (in the United States)	Yes	1.5.2
1.5	5	Are the UChicago researchers conducting this study or any portion of the study at an international site (outside the United States)?	Yes	1.5.3
2.1	1	What type of IRB review are you requesting?	Non Human Subjects Research	2.1.1
2.1	1	What type of IRB review are you requesting?	Exempt	2.1.2
2.1	2	Required Additional Reviews	RADRAC – Radioactive Drug Research Advisory Committee – Reviews the use of radioactive drugs as well as the purchase and use of radioisotopes in humans (including research and routine).	12.1
2.2	1	What is the primary activity of the study?	Administration of drug, use of device, investigation of a medical intervention, or research involving UCMC patients	2.2.1
2.2	1	What is the primary activity of the study?	Administration of survey(s), interviewing, conducting focus groups, observational research, psychological testing, or similar activities	2.2.2
2.2	1	What is the primary activity of the study?	Specimen collection and/or analysis	2.2.3
2.2	1	What is the primary activity of the study?	Collection or study of existing records/data	2.2.3
2.2	1	What is the primary activity of the study?	Approval of a grant ONLY: Research to be conducted under the grant will be submitted later for separate review and approval	17.1
2.2	8	Are you requesting that an outside IRB (not University of Chicago) be the IRB of record for this study?	Yes	3.1
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Drugs	4.1
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Biologics	4.2
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Vitamin/Herbal Supplements	4.3
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Medical Devices	4.4
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Novel Surgery or Clinical Intervention	4.5
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Surveys/Questionnaires	5.1
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Interviews/Oral History	5.2
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Focus Groups	5.3
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Deception	5.6

2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Use of Audio or Video Taping/Recording and/or Photographs	10.3
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Specimen Collection and/or Analysis	6.1
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Review of Additional Data (Chart Review)	6.2
2.2.1	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Data Registry	6.2
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Surveys/Questionnaires	5.1
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Interviews/Oral History	5.2
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Focus Groups	5.3
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Observational/Ethnographic Research	5.4
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Participant Observation	5.5
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Deception	5.6
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Psychological Testing	5.7
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Use of Audio or Video Taping/Recording and Photographs	10.3
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Specimen Collection and/or Analysis	6.1
2.2.2	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Data Collection Study and/or Secondary Analysis	6.2
2.2.3	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Specimen Collection/Analysis	6.1
2.2.3	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Data Collection and/or Secondary Analysis	6.2
2.2.3	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Genotyping/GWAS	6.1
2.2.3	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Surveys/Questionnaires	5.1
2.2.3	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Interviews/Oral History	5.2
2.2.3	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Focus Groups	5.3
2.2.3	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Deception	5.6

2.2.3	1	What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)	Use of Audio or Video Taping/Recording and Photographs	10.3
3.1		After questions 1-6 in section are completed	N/A - automatically routes after section is completed	17.1
4.1	1	Please select the types of drugs that will be administered in this study (check all that apply):	Experimental/Investigational Drugs	4.1.1
4.1	1	Please select the types of drugs that will be administered in this study (check all that apply):	FDA Approved Drugs	4.1.2
4.1	2	Does this study involve a washout period of previous medications, drugs, or devices?	Yes	4.1.3
4.1	3	Does this study involve the use of a placebo or No-treatment arm?	Yes	4.1.4
4.1.1	5	Will arrangements be made for the Pharmacy Department to receive or dispense the drugs involved in this study?	No	4.1.5
4.1.2	2	Will arrangements be made for the Pharmacy Department to receive or dispense the drugs involved in this study?	No	4.1.5
4.4	1	Please select the types of devices that will be used in this study (check all that apply):	Approved/Cleared Medical Devices **(used for approved use or unapproved use), including HUDs**	4.4.1
4.4	1	Please select the types of devices that will be used in this study (check all that apply):	Experimental/Investigational Devices	4.4.2
6.1	1	What type of specimens will be involved in this study? (check all that apply)	Existing (already sitting on the shelf at the time of initial IRB submission)	6.1.1
6.1	1	What type of specimens will be involved in this study? (check all that apply)	Prospective (will be collected)	6.1.2
6.1	3	Will genetic analysis/testing be done on any of the specimens?	Yes	6.1.3
6.1	4	Will this study involve banking of specimens (storing for future research use)?	Yes	6.1.4
6.2	1	What type of data will be collected/analyzed in this study?	Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)	6.2.1
6.2	1	What type of data will be collected/analyzed in this study?	Prospective (data is not yet in existence and/or collected)	6.2.2
6.2	2	Will this study involve adding data to a registry or database?	Yes	6.2.3
7.1	1	Select the population(s) that will be enrolled from the list of vulnerable populations below.	Healthy Children (under the age of 18)	7.1.1
7.1	1	Select the population(s) that will be enrolled from the list of vulnerable populations below.	Children with a Disease, Disorder, or condition (under the age of 18)	7.1.2
7.1	1	Select the population(s) that will be enrolled from the list of vulnerable populations below.	Wards of the State	7.1.3
7.1	1	Select the population(s) that will be enrolled from the list of vulnerable populations below.	Prisoners	7.5
7.1	1	Select the population(s) that will be enrolled from the list of vulnerable populations below.	Pregnant Women, Fetus	7.6
7.1	1	Select the population(s) that will be enrolled from the list of vulnerable populations below.	Placenta, Dead Fetus, or Fetal Material	7.7
7.1	1	Select the population(s) that will be enrolled from the list of vulnerable populations below.	Nonviable Neonates	7.8
7.1	2	Please select any additional populations that will be enrolled in this study. (Please check all that apply)	Decisionally Impaired Individuals	7.2
7.1	2	Please select any additional populations that will be enrolled in this study. (Please check all that apply)	Individuals with Mental Retardation	7.2
7.1	2	Please select any additional populations that will be enrolled in this study. (Please check all that apply)	Non-English Speakers	7.9 AND 16.7
7.1	2	Please select any additional populations that will be enrolled in this study. (Please check all that apply)	Subordinates of the Research Team or Employees of the University of Chicago or the University of Chicago Hospitals	7.3
7.1	2	Please select any additional populations that will be enrolled in this study. (Please check all that apply)	Undergraduate Students of the University of Chicago	7.4

7.1.1	4	Will Assent from Children be obtained?	Obtaining assent	16.6
7.1.1	4	Will Assent from Children be obtained?	Request to waive assent	16.6.1
7.1.1	4	Will Assent from Children be obtained?	Both (assent will be obtained from some, but not all, child subjects)	16.6 AND 16.6.1
7.1.2	4	Will Assent from Children be obtained?	Obtaining assent	16.6
7.1.2	4	Will Assent from Children be obtained?	Request to waive assent	16.6.1
7.1.2	4	Will Assent from Children be obtained?	Both (assent will be obtained from some, but not all, child subjects)	16.6 AND 16.6.1
8.1	1	Will any member of the UChicago research team be approaching potential participants for involvement in this study and/or will the UChicago researchers be recruiting with advertisements?	Yes	8.1.1
8.1.1	1	How will you identify or screen potential subjects to recruit/include in this study? (Check all that apply)	Medical records review or clinic schedules	8.1.2
8.1.2	5	How will you obtain permission to allow the use/disclosure of the individual's protected health information (PHI) for screening?	Requesting waiver of authorization for recruitment purposes	8.1.3
9.1	1	Will subjects be paid or otherwise compensated for participation in the study?	Yes	9.1.1
10.2	1	How will data be recorded?	Identified (Data will be linked directly to individuals)	10.2.1
10.2	1	How will data be recorded?	Coded (Data will be linked to subjects via encrypted codes)	10.2.1
12.3	12	Will any use of radioactive material occur outside an approved clinical area?	Yes	12.4 AND 12.5
14.1	1	Will the study view, share, collect, use, or analyze health information that is individually identifiable?	Yes	14.1.1
14.1.1	5	How will you obtain permission to allow the use/disclosure of the individual's protected health information (PHI)?	Requesting waiver/alteration of authorization including oral consent	14.1.2
15.1	1	Are there any costs associated with the study (that the subject will be responsible for or will be billed to someone else)? This includes costs to subjects, costs to subject's insurance, or costs to the research account.	Yes	15.1.1
16.1	1	Please indicate the type(s) of consent that will be involved in this study (check all that apply).	Written Consent Form	16.2
16.1	1	Please indicate the type(s) of consent that will be involved in this study (check all that apply).	Request to Waive Signed Consent – Verbal/Oral Consent	16.2 AND 16.3
16.1	1	Please indicate the type(s) of consent that will be involved in this study (check all that apply).	Request to Waive Consent/Parental Permission – Consent is not being obtained	16.4
16.1	1	Please indicate the type(s) of consent that will be involved in this study (check all that apply).	Request to Alter Consent (Some Elements Waived)	16.2 AND 16.5