

**IRB Staff Reviewer Form**

Protocol #	PI:	Staff Reviewer:	
Date Submitted:	Date Assigned:	Date Reviewed:	Date Logged In/Returned:

Note: "NEI" means "Not Enough Information" provided to answer the question. Items marked in red and shaded require further "action".

GENERAL		YES	NO	NA	NEI
1	Research?	<input type="checkbox"/>	<input checked="" type="checkbox"/> *		<input type="checkbox"/>
2	Human subjects research in accordance with 45 CFR 46?	<input type="checkbox"/>	<input checked="" type="checkbox"/> *		<input type="checkbox"/>
3	Does the research fall under an IRB Authorization Agreement (i.e., Cornell, NYSPI, NCI-CIRB, BRANY, WIRB)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, are the required documents per the Agreement attached?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	b. If yes to 3, is CUMC the IRB of record?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
4	Does PI have appropriate expertise and is PI qualified per CU policy?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
5	Human subjects training/GCP requirements met?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
6	HIPAA training requirements met?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Study Sponsor: <input type="checkbox"/> Internal <input type="checkbox"/> Federal <input type="checkbox"/> External-commercial <input type="checkbox"/> External-other <input type="checkbox"/> None				<input type="checkbox"/>
	a. If external funding, is Columbia the applicant organization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. If external funding, and the study is a clinical trial, has RASCAL Proposal Tracking # been entered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Is funding proposal (i.e., grant, subcontract) attached in RASCAL documents section?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes to 8, is the proposal complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Are all other required documents attached (e.g., IDB, protocol, consent documents, study instruments)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Does the research qualify as exempt under one of the six federal regulatory categories?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	*Skip to question 56.				
RECRUITMENT		YES	NO	NA	NEI
11	Subject demographic information in RASCAL subjects section complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Subject demographic information in RASCAL consistent among subjects section, protocol and consent form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Vulnerable population(s) *If yes, please check appropriate box(es) below.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	a. <input type="checkbox"/> Pregnant women /fetuses /neonates (Subpart B)				
	b. <input type="checkbox"/> Prisoners (Subpart C) (requires review by prisoner advocate)				
	c. <input type="checkbox"/> Children (Subpart D)				
	i. CITI course completed by all key personnel?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	ii. Wards	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	d. <input type="checkbox"/> Diminished autonomy (due to illness, mental impairment, economical or educational status)				
	e. <input type="checkbox"/> Non-English speaking (if expected, translations required)				
	f. <input type="checkbox"/> Students, subordinate employees, or others potentially subject to undue influence or coercion				
	g. <input type="checkbox"/> Other, please describe:				
14	Is selection of subjects equitable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Recruitment procedures described/included?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. Recruitment procedures appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Recruitment materials attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. Recruitment materials appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	If identification of prospective subjects by review of medical records or other restricted data, are procedures for accessing the data appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

REVIEW OF STUDY PROTOCOL					
Study Design		YES	NO	NA	NEI
18	Are there any concerns with the design of the study?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
19	Are there any concerns with the number of subjects to be studied?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
20	Are research procedures adequately described?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
21	Is there a plan for statistical analysis of data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	If appropriate, does the protocol explain how the research differs from standard practice?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	If appropriate, does the protocol explain which procedures are in excess of standard practice (e.g., survey, biopsy, radiation, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24	Does the research study involve deception of the subjects?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	a. If deception is involved, is a debriefing form included and/or a debriefing plan described?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	b. If yes to 24a, is the debriefing form/plan acceptable?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
25	Will the research be conducted at non-Columbia performance sites under the direction of the CU investigator(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes to 25, are the sites identified in Rascal?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	b. If yes to 25, and local IRB approval is required, is approval documentation attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c. If yes to 25, and special authorization/approval is required from the other performance sites (e.g., schools, nursing homes), is authorization/approval documentation attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	d. If yes to 25 and federally-supported, is an FWA needed for any site?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	If the study presents more than minimal risk, is a data and safety monitoring plan included?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	If a multi-site, Phase III clinical trial, is there a DSMB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If no, is a DSMB necessary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	Are there adequate plans to protect confidentiality of the subjects and the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29	Are there any concerns with the content in the questionnaires or survey instruments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risks/Benefits		YES	NO	NA	NEI
30	Risks adequately described?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
31	Determination of risk level: Minimal risk <input type="checkbox"/> Greater than minimal risk <input type="checkbox"/>				<input type="checkbox"/>
32	Are risks minimized?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
33	Risks appropriate to study design?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
34	Benefits accurately described?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
35	Is the Risks/Benefits ratio acceptable?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
Costs/Compensation		YES	NO	NA	NEI
36	Payment/reimbursement to subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is it reasonable?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	b. If greater than \$600, is there an adequate description of how subject confidentiality will be maintained with the Office of the Treasurer? (Ensure this issue is addressed in consent form)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37	Does the subject have to pay for research related costs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is it acceptable?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
INFORMED CONSENT					
Informed Consent Process		YES	NO	NA	NEI
38	Consent documents attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39	Waiver of some/all elements of informed consent requested?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	a. If yes to 39, is justification attached?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	b. If yes to 39a, is justification satisfactory?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
40	Will informed consent be obtained at a reasonable time with respect to enrollment in the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41	If greater than minimal risk, is special consideration needed for who will be authorized to obtain consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Informed Consent Process		YES	NO	NA	NEI
42	Does the research involve enrolling subjects who may lack the capacity to provide informed consent? <b><i>If NO, skip to Q44.</i></b>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	a. If yes, is there a plan to assess capacity?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. If yes to 42a, is the plan acceptable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43	If subjects will lack capacity for consent, is surrogate consent proposed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, are proposed surrogate consent procedures consistent with state and federal laws/regulations and institutional policy?	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
Documentation of Informed Consent		YES	NO	NA	NEI
44	Waiver of written documentation of informed consent requested? <b><i>If NO, skip to Q45.</i></b>	<input type="checkbox"/>	<input type="checkbox"/>		
	a. If yes, is justification attached?	<input type="checkbox"/>	<input type="checkbox"/>		
	b. If yes, is justification satisfactory?	<input type="checkbox"/>	<input type="checkbox"/>		
Elements of Informed Consent				NA	<input type="checkbox"/>
1. Rascal Consent # or Short Title/Identifier (i.e. Assent):					
2. Rascal Consent # or Short Title/Identifier (i.e. Assent):					
3. Rascal Consent # or Short Title/Identifier (i.e. Assent):					
4. Rascal Consent # or Short Title/Identifier (i.e. Assent):					
5. Rascal Consent # or Short Title/Identifier (i.e. Assent):					
6. Rascal Consent # or Short Title/Identifier (i.e. Assent):					
<b><i>For questions 45 and 46, please check the box on the right if an element needs to be added or revised. Identify revisions or concerns in the Comment section at the end of the form.</i></b>					
		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
		<b>5</b>	<b>6</b>		
45	Required elements				
	a. Statement that involves research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Research purpose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c. Description of procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	d. Expected duration of participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	e. Identification of experimental procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	f. Risks and discomforts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	g. Potential benefits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	h. Alternative procedures or treatment(s), if appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	i. Provisions for confidentiality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	j. Compensation for research-related injury, if greater than minimal risk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	k. Contact Information				
	Research Qs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Rights Qs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Injury Qs, if applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	l. Voluntary participation and the right to discontinue participation without penalty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46	Additional elements, if appropriate				
	a. Unforeseeable risks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Termination of participation by PI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c. Additional costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	d. Consequences of discontinuing participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	e. Notification of significant new findings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	f. Approximate number of subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47	Have you considered all of the above	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes

	elements?	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No
48	If subjects will receive compensation, are the terms and amount stated? (If >\$600, the consent should reflect the potential for loss of confidentiality and delay in receipt of payment)	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
		<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No
		<input type="checkbox"/> NA	<input type="checkbox"/> NA	<input type="checkbox"/> NA	<input type="checkbox"/> NA	<input type="checkbox"/> NA	<input type="checkbox"/> NA
		<input type="checkbox"/> NEI	<input type="checkbox"/> NEI	<input type="checkbox"/> NEI	<input type="checkbox"/> NEI	<input type="checkbox"/> NEI	<input type="checkbox"/> NEI
49	Is there exculpatory language?	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
		<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No
50	Appropriate reading/comprehension level?	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
		<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No
51	Are the signature lines appropriate?	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
		<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No
		<input type="checkbox"/> NA	<input type="checkbox"/> NA	<input type="checkbox"/> NA	<input type="checkbox"/> NA	<input type="checkbox"/> NA	<input type="checkbox"/> NA
		<input type="checkbox"/> NEI	<input type="checkbox"/> NEI	<input type="checkbox"/> NEI	<input type="checkbox"/> NEI	<input type="checkbox"/> NEI	<input type="checkbox"/> NEI
					<b>YES</b>	<b>NO</b>	<b>NA</b>
52	Is assent for minors required? (7-17 years)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
53	Translation needed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
							<b>NA</b>
							<input type="checkbox"/>
	<b>Genetic Research</b>				<b>YES</b>	<b>NO</b>	<b>NA</b>
54	Does the research involve genetic testing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, and the testing meets the definition of genetic testing as per the New York State Genetics Privacy Law, and research will be conducted in New York, does the consent form contain all the information required by NY State law?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
55	Does the research involve the use of recombinant DNA/gene transfer?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes to 55, is appendix A attached for IBC review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. If yes to 55, is Recombinant DNA Advisory Committee (RAC) review required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c. If yes to 55b, has RAC approval or waiver been obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	d. If yes to 55, has appendix M been appropriately considered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>HIPAA - Questions 56-62 are presented to assist you in determining the appropriate general HIPAA form (if applicable). Once you have identified one correct form, you can skip to the supplemental forms section (Questions 64-65).</b>				<b>YES</b>	<b>NO</b>	<b>NA</b>
56	Does this research study involve the creation, use, disclosure or access of protected health information (PHI)? ! IF NO, HIPAA DOES NOT APPLY – PLEASE SKIP TO Q.82.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
57	Is this a research study involving interaction with subjects and the creation, use or disclosure of PHI?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is Form A attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
58	Does this research involve access to PHI (i.e., chart review, deidentification of electronic dataset) but use and/or disclosure of only deidentified data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is Form G attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
59	Is the PHI that will be used or disclosed limited to city, state, zip, dates (i.e., date of service/date of birth) and/or other numbers, characteristics or codes not specifically included in the list of 18 identifiers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is Form F attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
60	Does the entire study qualify for a full waiver of authorization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is form B attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
61	Does the study in part qualify for a full waiver of authorization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is form B attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
62	Is a form A attached?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>*Skip to question 63.</b>							
<b>IF YOU HAVEN'T REACHED AN ASTERISK (*), YOU HAVE NOT IDENTIFIED A HIPAA FORM – PLEASE RE-REVIEW THE QUESTIONS OR CONTACT THE PRIVACY OFFICER FOR ASSISTANCE.</b>							

HIPAA - SUPPLEMENTAL QUESTIONS		YES	NO	NA	NEI
63	Is it clear from the research proposal that decedent health information will be used or disclosed as a result of this research?	<input type="checkbox"/>	<input type="checkbox"/>		
	a. If yes, is form E attached?	<input type="checkbox"/>	<input type="checkbox"/>		
64	Will screening procedures include identification of subjects by review of medical records or other restricted data by an individual who does not have legitimate access (treatment, payment, operations)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is a form D attached?	<input type="checkbox"/>	<input type="checkbox"/>		
65	Will recruitment procedures include contacting potential subjects by an individual who does not have a treatment relationship (treatment, payment, operations) with the potential subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If yes, is a form C attached?	<input type="checkbox"/>	<input type="checkbox"/>		

**SUMMARY: COMMENTS & RECOMMENDATIONS**

66 **Pre-reviewer Recommendation and Comments:**  
Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_  
Protocol should be: \_\_\_\_\_ Returned

Reason for return:  
PI is not qualified, \_\_\_\_\_ no PI is listed, or \_\_\_\_\_ more than one individual is listed as PI.  
Cancer Center is not listed in Facilities section, and the research is cancer-related.  
Consent/parental permission and/or \_\_\_\_\_ Assent is not attached, and a waiver has not been requested.  
Recruitment procedures are not described.  
This is a greater than minimal risk study and there is no data monitoring plan  
Study instruments are described, but are not attached.  
Sponsor's protocol, \_\_\_\_\_ IB, or \_\_\_\_\_ Package Insert is not attached.  
Grant or \_\_\_\_\_ subcontract is not attached.  
There is not enough information included in the submission to conduct a thorough pre-review.

**Administrative staff should make an attempt to resolve issues or obtain missing materials prior to return.**

*If the protocol is being returned for one of the reasons noted above, and the following applies, it should be included in the correspondence:*  
Study personnel (identify by name in correspondence) have not completed required GCP, HIPAA, or if applicable CITI training (specify in correspondence which training requirement is not satisfied for each individual).  
HIPAA forms (identify the appropriate forms) must be attached for review.

Correspondence for return, if warranted:

Protocol should be: \_\_\_\_\_ Logged in

**To be considered by the Board Reviewer:**

Protocol  
1.

Consent Form:  
1.

HIPAA:  
1.

Exemption requested by the PI? \_\_\_\_\_ Yes \_\_\_\_\_ No

Recommended level of review:

- Full Board
- Expedited review; category #
- Exempt; exemption #
- Not human research (definition of research not met)
- Not human subjects research per 45 CFR § 46 (definition of human subject not met)
- Facilitated review per IRB cooperative agreement
- Human subjects involvement not yet defined (45 CFR § 46.118)
- Administrative review (infrastructure grant)

Basis for recommended level of review:

**Consent Requirements**

Waiver of Consent requested based on the following criteria (*one of the next two boxes must apply for waiver to be approved*)

Waiver of consent acceptable (all of the following elements apply)

- The research involves no more than minimal risk to the subjects;
- The waiver will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver; and
- Whenever appropriate, the subjects will be provided with additional information after participation

**OR**

Waiver of consent acceptable (all of the following elements apply)

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.

Waiver of Documentation of Consent requested based on the following criteria (*one of the next two boxes must apply for waiver to be approved*)

Waiver of written documentation of consent acceptable (all of the following elements apply)

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

**OR**

Waiver of written documentation of consent acceptable (all of the following elements apply)

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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 Information sheet provided (*optional summary of consent information*)

Written consent documents provided:

- Adult consent form(s); how many?
- Parental permission form(s); how many?
- Assent form(s); how many?
- Spanish translation? (*must have certified translation of final IRB approved English version*)
- Other: ; how many?

**Recruitment Material**

- Advertisement(s); how many?
- Recruitment letter; how many?

Other: ; how many?

**Study Instruments**

Survey(s)/questionnaire(s); how many?

Focus group/interview guide(s) how many?

Other: ; how many?

**Other requirements for approval prior to enrollment of human subjects unless otherwise indicated:**

Certificate of Confidentiality

Other institution's approvals:

Other:

**Institutional Requirements needed before IRB approval:**

Rascal Proposal Tracking number  
Recruitment materials are described but not included  
Appendix C (human specimens)  
Translation of IRB approved study materials will be required  
Appropriate HIPAA form(s)

**Training Requirements:**

GCP missing for:

HIPAA missing for:

CITI missing for:

**Regulatory items to be addressed at the time of IRB review:**

Subpart B Applies  
Subpart C Applies  
Subpart D Applies  
Consideration of waiver of IND  
requirement

Significant/non-significant risk determination  
Waiver of informed consent/documentation of informed Consent  
Waiver of parental permission and/or assent  
Other: Please describe