IRB Staff Reviewer Form – Biomedical Research

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 shaded require further "action".

GENERAL		**YES**	**NO**	**NA**	**NEI**
1	Research?	☐	☐*		☐
2	Human subjects research in accordance with 45 CFR 46?	☐	☐*		☐
3	Does the research fall under an IRB Authorization Agreement (i.e., Cornell, NYSPI, NCI-CIRB, BRANY, WIRB, Harlem)?	☐	☐	☐	☐
	a. If yes, are the required documents per the Agreement attached?	☐	☐		☐
	b. If yes to 3, is CUMC the IRB of record?	☐	☐		☐
4	Does PI have appropriate expertise and is PI qualified per CU policy?	☐	☐		☐
5	Human subjects/HSP training requirements met?	☐	☐		☐
6	HIPAA training requirements met?	☐	☐	☐	☐
7	Study Sponsor: ☐ Internal ☐ Federal ☐ External-commercial ☐ External-other ☐ None				☐
	a. If external funding, is Columbia the applicant organization?	☐	☐	☐	☐
	b. If external funding, and the study is a clinical trial, has RASCAL Proposal Tracking # been entered?	☐	☐	☐	☐
8	Is funding proposal (i.e., grant, subcontract) attached in RASCAL documents section?	☐	☐	☐	☐
	a. If yes to 8, is the proposal complete?	☐	☐	☐	☐
9	Are all other required documents attached (e.g., IDB, protocol, consent documents, study instruments)?	☐	☐	☐	☐
10	Does the research qualify as exempt per the 6 federal regulatory categories?	☐*	☐	☐	☐
	*Skip to question 70.				
RECRUITMENT		**YES**	**NO**	**NA**	**NEI**
11	Subject demographic information in RASCAL subjects section complete?	☐	☐	☐	☐
12	Subject demographic information in RASCAL consistent among subjects section, protocol and consent form?	☐	☐	☐	☐
13	Vulnerable population(s) *If yes, please check appropriate box(es) below. a. ☐ Pregnant women /fetuses /neonates (Subpart B) b. ☐ Prisoners (Subpart C) (requires review by prisoner advocate) c. ☐ Children (Subpart D) i. CITI course completed by all key personnel? ii. Wards d. ☐ Diminished autonomy (due to illness, mental impairment, economical or educational status) e. ☐ Non-English speaking (if expected, translations required) f. ☐ Students, subordinate employees, or others potentially subject to undue influence or coercion g. ☐ Other, please describe:	*☐ ☐ ☐	☐ ☐ ☐		☐ ☐ ☐
14	Is selection of subjects equitable?	☐	☐	☐	☐
15	Recruitment procedures described/included?	☐	☐	☐	☐
	a. Recruitment procedures appropriate?	☐	☐	☐	☐
16	Recruitment materials attached?	☐	☐	☐	☐
	a. Recruitment materials appropriate?	☐	☐	☐	☐
17	If identification of prospective subjects by review of medical records or other restricted data, are procedures for accessing the data appropriate?	☐	☐	☐	☐

REVIEW OF STUDY PROTOCOL

Study Design		YES	NO	NA	NEI
18	Are there any concerns with the design of the study?	☐	☐		☐
19	Are there any concerns with the number of subjects to be studied?	☐	☐		☐
20	Are research procedures adequately described?	☐	☐		☐
21	Is there a plan for statistical analysis of data?	☐	☐	☐	☐
22	If appropriate, does the protocol explain how the research differs from standard practice?	☐	☐	☐	☐
23	If appropriate, does the protocol explain which procedures are in excess of standard practice (e.g., survey, biopsy, radiation, etc.)?	☐	☐	☐	☐
24	Does the research study involve deception of the subjects?	☐	☐		☐
	a. If deception is involved, is a debriefing form included and/or a debriefing plan described?	☐	☐		☐
	b. If yes to 24a, is the debriefing form/plan acceptable?	☐	☐		☐
25	Will the research be conducted at non-Columbia performance sites under the direction of the CU investigator(s)?	☐	☐	☐	☐
	a. If yes to 25, are the sites identified in Rascal?	☐	☐		☐
	b. If yes to 25, and local IRB approval is required, is approval documentation attached?	☐	☐	☐	☐
	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?	☐	☐	☐	☐
	d. If yes to 25 and federally-supported, is an FWA needed for any site?	☐	☐	☐	☐
26	If the study presents more than minimal risk, is a data and safety monitoring plan included?	☐	☐	☐	☐
27	If a multi-site, Phase III clinical trial, is there a DSMB?	☐	☐	☐	☐
	a. If no, is a DSMB necessary?	☐	☐	☐	☐
28	Are there adequate plans to protect confidentiality of the subjects and the data?	☐	☐	☐	☐
29	Are there any concerns with the content in the questionnaires or survey instruments?	☐	☐	☐	☐

Risks/Benefits		YES	NO	NA	NEI
30	Risks adequately described?	☐	☐		☐
31	Determination of risk level: Minimal risk ☐ Greater than minimal risk ☐				☐
32	Are risks minimized?	☐	☐		☐
33	Risks appropriate to study design?	☐	☐		☐
34	Benefits accurately described?	☐	☐		☐
35	Is the Risks/Benefits ratio acceptable?	☐	☐		☐

Costs/Compensation		YES	NO	NA	NEI
36	Payment/reimbursement to subjects?	☐	☐	☐	☐
	a. If yes, is it reasonable?	☐	☐		☐
	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)	☐	☐	☐	☐
37	Does the subject have to pay for research related costs?	☐	☐	☐	☐
	a. If yes, is it acceptable?	☐	☐		☐

INFORMED CONSENT

Informed Consent Process		YES	NO	NA	NEI
38	Consent documents attached?	☐	☐	☐	☐

39	Waiver of some/all elements of informed consent requested?	☐	☐		☐
	a. If yes to 39, is justification attached?	☐	☐		☐
	b. If yes to 39a, is justification satisfactory?	☐	☐		☐
40	Will informed consent be obtained at a reasonable time with respect to enrollment in the study?	☐	☐	☐	☐
41	If greater than minimal risk, is special consideration needed for who will be authorized to obtain consent?	☐	☐	☐	☐

Informed Consent Process		YES	NO	NA	NEI
42	Does the research involve enrolling subjects who may lack the capacity to provide informed consent? ***If NO, skip to Q44.***	☐	☐		☐
	a. If yes, is there a plan to assess capacity?	☐	☐	☐	☐
	b. If yes to 42a, is the plan acceptable?	☐	☐	☐	☐
43	If subjects will lack capacity for consent, is surrogate consent proposed?	☐	☐	☐	☐
	a. If yes, are proposed surrogate consent procedures consistent with state and federal laws/regulations and institutional policy?	☐	☐		☐
44	The circumstances of the consent process minimize the possibility of coercion or undue influence.	☐	☐	☐	☐
45	Is assent for minors required?	☐	☐	☐	☐
	a. Have local laws for age of majority and requirements for parental or surrogate consent been considered?	☐	☐	☐	

Documentation of Informed Consent		YES	NO	NA	NEI
46	Waiver of written documentation of informed consent requested	☐	☐		
	a. If yes, is justification attached?	☐	☐		
	b. If yes, is justification satisfactory?	☐	☐		

Elements of Informed Consent **NA** ☐

			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):					
For questions 47 and 48, 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.			**1**	**2**	**3**	**4**	**5**	**6**
47	Required elements							
	a.	Statement that involves research	☐	☐	☐	☐	☐	☐
	b.	Research purpose	☐	☐	☐	☐	☐	☐
	c.	Description of procedures	☐	☐	☐	☐	☐	☐
	d.	Expected duration of participation	☐	☐	☐	☐	☐	☐
	e.	Identification of experimental procedures	☐	☐	☐	☐	☐	☐
	f.	Risks and discomforts	☐	☐	☐	☐	☐	☐
	g.	Potential benefits	☐	☐	☐	☐	☐	☐
	h.	Alternative procedures or treatment(s), if appropriate	☐	☐	☐	☐	☐	☐
	i.	Provisions for confidentiality	☐	☐	☐	☐	☐	☐
		CU IRB and OHRP may review research records	☐	☐	☐	☐	☐	☐
		FDA and/or sponsor (as applicable) may review research records	☐	☐	☐	☐	☐	☐
	j.	Compensation for research-related injury, if greater than minimal risk	☐	☐	☐	☐	☐	☐
	k.	Contact Information						
		Research Qs	☐	☐	☐	☐	☐	☐
		Rights Qs	☐	☐	☐	☐	☐	☐

		Injury Qs, if applicable	☐	☐	☐	☐	☐	☐
	l.	Voluntary participation and the right to discontinue participation without penalty	☐	☐	☐	☐	☐	☐
48	Additional elements, if appropriate							
	a.	Unforeseeable risks statement	☐	☐	☐	☐	☐	☐
	b.	Termination of participation by PI	☐	☐	☐	☐	☐	☐
	c.	Additional costs	☐	☐	☐	☐	☐	☐
	d.	Consequences of discontinuing participation	☐	☐	☐	☐	☐	☐
	e.	Notification of significant new findings	☐	☐	☐	☐	☐	☐
	f.	Approximate number of subjects	☐	☐	☐	☐	☐	☐
	g.	If subject is or becomes pregnant, study procedures may involve risks to the embryo or fetus which are currently unforeseeable (for intervention trials)	☐	☐	☐	☐	☐	☐
49	Subject will receive a copy of consent form		☐	☐	☐	☐	☐	☐
50	Subjects are not waiving any of their legal rights by signing the consent form		☐	☐	☐	☐	☐	☐
51	Have you considered all of the above elements?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
52	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)		☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI
53	Is there exculpatory language?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
54	Appropriate reading/comprehension level?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
55	Are the signature lines appropriate?		☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI
57	Translation needed?					☐ Yes	☐ No	☐ NEI

ADDITIONAL CONSIDERATIONS FOR BIOMEDICAL RESEARCH		**NA** ☐			
Investigational Drugs, Devices, Biologics		**YES**	**NO**	**NA**	**NEI**
58	Does the research involve an approved drug used in accordance with its approved indication?	☐	☐		☐
59	Is an approved drug used outside of the approved indication?	☐	☐		☐
a.	If yes, is the investigation intended to be reported to the FDA as a well controlled study in support of a new indication for use, or intended to be used to support any other significant change in the labeling or advertising of the drug?	☐	☐		☐
b.	If yes, does the investigation involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product?	☐	☐		☐
	If YES to 59 AND NO to 59a and 59b, the IND requirements can be waived by the committee				
c.	If yes to 59a and/or 59b, is an IND # provided?	☐	☐		☐
60	Is a lawfully marketed in vitro diagnostic biological product proposed for use?	☐	☐		☐
a.	If yes, is the in vitro diagnostic biological product one of the following: a blood grouping serum, reagent red blood cells or an anti-human globulin?	☐	☐		☐
b.	If yes to 60a, is it a) intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and (b) shipped in compliance with 312.160?	☐	☐	☐	
	If YES to 60a and 60b, the IND requirements can be waived by the committee				

61	Is use of a placebo ONLY proposed?	☐	☐		☐
	If YES to 61, the IND requirements can be waived by the committee				
62	Does the research involve an unapproved drug?	☐	☐		☐
	a. If yes, is an IND# provided?	☐	☐		☐
	b. Is documentation from the FDA of IND status included in submission?	☐	☐	☐	
63	Does the research involve an approved device?	☐	☐		☐
	a. If yes, is the device being modified or used for a new indication?	☐*	☐		☐
64	Does the research involve an unapproved device?	☐*	☐		☐
65	If yes to either 63 or 64, is the device a significant risk device?	☐	☐	☐	☐
	a. If yes to 65, is an IDE # provided?	☐	☐		☐
If device has an IDE that begins with "G" or is a carotid stent, pre-reviewer must contact the PI/study team, OFBC and CTO and deactivate consent documents if not deactivated automatically by RASCAL. Notes should include the requirement for the investigator to follow up with CTO and/or OBC in order to ensure Medicare certification is obtained, if necessary. RASCAL consents must be deactivated (hand stamped consents must be held) until CMS certification is received or the IRB has been informed by CTO or OFBC that CMS certification is not necessary.					
66	Is documentation from the FDA of device approval, IDE or 510k approval included in RASCAL submission?	☐	☐	☐	☐
67	Has the investigational Product section of RASCAL been completed for <u>each</u> drug or device?	☐	☐	☐	☐
68	Are there costs to subjects associated with use of the investigational product?	☐	☐	☐	☐

	NA ☐

Genetic Research		**YES**	**NO**	**NA**	**NEI**
69	Does the research involve genetic testing?	☐	☐		☐
	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?	☐	☐	☐	☐
70	Does the research involve the use of recombinant DNA/gene transfer?	☐	☐		☐
	a. If yes to 70, is appendix A attached for IBC review?	☐	☐		
	b. If yes to 70, is Recombinant DNA Advisory Committee (RAC) review required?	☐	☐	☐	☐
	c. If yes to 70b, has RAC approval or waiver been obtained?	☐	☐		☐
	d. If yes to 70, has appendix M been appropriately considered?	☐	☐	☐	☐

REVIEW BY OTHER CUMC COMMITTEES		**YES**	**NO**	**NA**	**NEI**
71	Does the research involve the use of radiation beyond standard practice or solely for research purposes? (i.e., strong radio frequency, x-ray, fluoroscopy)	☐	☐		☐
	a. If yes, has Joint Radiation Safety Committee (JRSC) approval been obtained?	☐	☐		
72	Does the research involve the use of a class 3 or 4 laser?	☐	☐		☐
	a. If yes, is appendix D attached for IBC review?	☐	☐		
73	Does the research involve the use of a Radioactive Drug?	☐	☐		☐
	a. If yes, has approval from the Radioactive Drug Research Committee (RDRC) been obtained?	☐	☐		
74	Does the research involve analysis and/or storage of surgical specimens collected during routine medical procedures (i.e., bone marrow, tumor tissue)?	☐	☐		☐
If yes to 69, pre-reviewer should provide the investigator with a Pathology review form and include in the notes section that Pathology review and approval is required prior to approval by the IRB.					
75	Does the research involve the use of an infectious agent (i.e., human/animal virus, viral vectors)?	☐	☐		☐
	a. If yes, is appendix B attached for IBC review?	☐	☐		
76	Will human specimens be collected and/or stored?	☐	☐		☐

	a. If yes, has the Human Specimen section in RASCAL been completed for each sample?	☐	☐		
	b. If yes to 76, has appendix C been attached for IBC review?	☐	☐		
76	Is review by Cancer Committee (PRMC) required?	☐	☐		☐
	a. If yes, is Cancer Center listed in the "research facilities" section?	☐	☐		

HIPAA - General Decision Tree	**Questions 78-83 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 85-87).**	**YES**	**NO**	**NA**	**NEI**

78	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.88.**	☐	☐!		☐
79	Is this a research study involving interaction with subjects and the creation, use or disclosure of PHI?	☐	☐		☐
	a. If yes, is Form A attached?	☐*	☐*		
80	Does this research involve access to PHI (i.e., chart review, deidentification of electronic dataset) but use and/or disclosure of only deidentified data?	☐	☐		☐
	a. If yes, is Form G attached?	☐*	☐*		
81	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?	☐	☐		☐
	a. If yes, is Form F attached?	☐*	☐*		☐
82	Does the entire study qualify for a full waiver of authorization?	☐	☐		☐
	a. If yes, is form B attached?	☐*	☐*		
83	Does the study in part qualify for a full waiver of authorization?	☐	☐		☐
	a. If yes, is form B attached?	☐	☐		
84	Is a form A attached?	☐*	☐*		☐

***Skip to question 85.**
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.

HIPAA - SUPPLEMENTAL QUESTIONS	**YES**	**NO**	**NA**	**NEI**

85	Is it clear from the research proposal that decedent health information will be used or disclosed as a result of this research?	☐	☐		
	a. If yes, is form E attached?	☐	☐		
86	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)?	☐	☐	☐	☐
	a. If yes, is a form D attached?	☐	☐		
87	Will recruitment procedures include contacting potential subjects by an individual who does not have a treatment relationship (treatment, payment, operations) with the potential subject?	☐	☐	☐	☐
	a. If yes, is a form C attached?	☐	☐		

SUMMARY: COMMENTS & RECOMMENDATIONS

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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/CITI HSP, HIPAA, or if applicable Minors 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 Parental Permission requested:

Reminder: NOT APPLICABLE TO FDA-REGULATED RESEARCH. The criteria below, in addition to the criteria for waiver of consent (above, as applicable), must be satisfied.

Waiver of Parental Permission acceptable *(box must be checked, to indicate that criteria are satisfied, for waiver to be approved):*

- The research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects; and
- An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

_____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.

_____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 Pathology Approval Recruitment materials are described but not included Appendix C (human specimens) JRSC (radiation) Translation of IRB approved study materials will be required RDRC (radioactive drugs) Appendix B (infectious agents) Appendix D (research with lasers) Reimbursement letter to Medicare RAC review required Appendix A (Recombinant DNA) Appropriate HIPAA form(s)	**Training Requirements:** GCP or CITI HS Protection missing for: HIPAA missing for: CITI Minors missing for: **Items checked by PI in Research Procedures section (if applicable):** Device study Human Embryo Human Embryonic Stem Cells Radiation **Items checked by PI in Research Facilities section (if applicable):** Cancer Center Harlem Hospital

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

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

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

Informed Consent Process		YES	NO	NA	NEI
42	Does the research involve enrolling subjects who may lack the capacity to provide informed consent? ***If NO, skip to Q44.***	☐	☐		☐
	a. If yes, is there a plan to assess capacity?	☐	☐	☐	☐
	b. If yes to 42a, is the plan acceptable?	☐	☐	☐	☐
43	If subjects will lack capacity for consent, is surrogate consent proposed?	☐	☐	☐	☐
	a. If yes, are proposed surrogate consent procedures consistent with state and federal laws/regulations and institutional policy?	☐	☐		☐

Documentation of Informed Consent		YES	NO	NA	NEI
44	Waiver of written documentation of informed consent requested? ***If NO, skip to Q45.***	☐	☐		
	a. If yes, is justification attached?	☐	☐		
	b. If yes, is justification satisfactory?	☐	☐		

Elements of Informed Consent	NA ☐
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):	

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.			1	2	3	4	5	6
45	Required elements							
	a.	Statement that involves research	☐	☐	☐	☐	☐	☐
	b.	Research purpose	☐	☐	☐	☐	☐	☐
	c.	Description of procedures	☐	☐	☐	☐	☐	☐
	d.	Expected duration of participation	☐	☐	☐	☐	☐	☐
	e.	Identification of experimental procedures	☐	☐	☐	☐	☐	☐
	f.	Risks and discomforts	☐	☐	☐	☐	☐	☐
	g.	Potential benefits	☐	☐	☐	☐	☐	☐
	h.	Alternative procedures or treatment(s), if appropriate	☐	☐	☐	☐	☐	☐
	i.	Provisions for confidentiality	☐	☐	☐	☐	☐	☐
	j.	Compensation for research-related injury, if greater than minimal risk	☐	☐	☐	☐	☐	☐
	k.	Contact Information						
		Research Qs	☐	☐	☐	☐	☐	☐
		Rights Qs	☐	☐	☐	☐	☐	☐
		Injury Qs, if applicable	☐	☐	☐	☐	☐	☐
	l.	Voluntary participation and the right to discontinue participation without penalty	☐	☐	☐	☐	☐	☐
46	Additional elements, if appropriate							
	a.	Unforeseeable risks	☐	☐	☐	☐	☐	☐
	b.	Termination of participation by PI	☐	☐	☐	☐	☐	☐
	c.	Additional costs	☐	☐	☐	☐	☐	☐
	d.	Consequences of discontinuing participation	☐	☐	☐	☐	☐	☐
	e.	Notification of significant new findings	☐	☐	☐	☐	☐	☐
	f.	Approximate number of subjects	☐	☐	☐	☐	☐	☐
47	Have you considered all of the above elements?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ 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)	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI
49	Is there exculpatory language?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
50	Appropriate reading/comprehension level?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
51	Are the signature lines appropriate?	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI	☐ Yes ☐ No ☐ NA ☐ NEI

		YES	NO	NA	NEI
52	Is assent for minors required? (7-17 years)	☐	☐		☐
53	Translation needed?	☐	☐		☐

NA ☐

Genetic Research		**YES**	**NO**	**NA**	**NEI**
54	Does the research involve genetic testing?	☐	☐		☐
	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?	☐	☐	☐	☐
55	Does the research involve the use of recombinant DNA/gene transfer?	☐	☐		☐
	a. If yes to 55, is appendix A attached for IBC review?	☐	☐		
	b. If yes to 55, is Recombinant DNA Advisory Committee (RAC) review required?	☐	☐	☐	☐
	c. If yes to 55b, has RAC approval or waiver been obtained?	☐	☐		☐
	d. If yes to 55, has appendix M been appropriately considered?	☐	☐	☐	☐
HIPAA - General Decision Tree	**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).**	**YES**	**NO**	**NA**	**NEI**
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.	☐	☐!		☐
57	Is this a research study involving interaction with subjects and the creation, use or disclosure of PHI?	☐	☐		☐
	a. If yes, is Form A attached?	☐*	☐*		
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?	☐	☐		☐
	a. If yes, is Form G attached?	☐*	☐*		
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?	☐	☐		☐
	a. If yes, is Form F attached?	☐*	☐*		☐
60	Does the entire study qualify for a full waiver of authorization?	☐	☐		☐
	a. If yes, is form B attached?	☐*	☐*		
61	Does the study in part qualify for a full waiver of authorization?	☐	☐		☐
	a. If yes, is form B attached?	☐	☐		
62	Is a form A attached?	☐*	☐*		☐

***Skip to question 63.**

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.

HIPAA - SUPPLEMENTAL	**YES**	**NO**	**NA**	**NEI**

QUESTIONS					
63	Is it clear from the research proposal that decedent health information will be used or disclosed as a result of this research?	☐	☐		
	a. If yes, is form E attached?	☐	☐		
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)?	☐	☐	☐	☐
	a. If yes, is a form D attached?	☐	☐		
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?	☐	☐	☐	☐
	a. If yes, is a form C attached?	☐	☐		

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.

_____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