COLUMBIA UNIVERSITY
IRVING MEDICAL CENTER

Mandatory Pre-IRB Review for Pediatric Clinical Studies

The Division Chief (or designate) MUST pre-review and approve protocols prior to Rascal submission.

Goals:

1) To provide scientific review by the divisional chair or his/her designee
2) To facilitate IRB submission and review for research involving children

Principal Investigator:	
IRB Protocol #	
Pediatric Faculty role (if not PI):	
Protocol Title:	
Divisional Chair or Designee:	
Prior review of protocol (please check all that apply):	☐ NIH ☐ COG ☐ PECARN ☐ Single IRB (sIRB) Other:

****Please attach the Rascal *Protocol, Data Sheet* and all *Consent Forms* for review.****

Scientific Review:

- The division chair or his/her designee should review the proposal to the extent necessary to ensure that the science is sound, and that the research does not overlap unnecessarily with other divisional research.
- The Divisional Chair or Designee has to be added as one of the "Departmental Approvers" within RASCAL
- This approval is required for Ms Sanders to proceed with Departmental Review at initial submission.

If research is being conducted at one of the following locations, please add:

Location	**Departmental Approver (Other)**
Neonatal Intensive Care Unit (NICU)	Dr. Marianne Garland **(mg71)**
Ambulatory Care Network (ACN) sites (Audubon, Washington Heights, Rangel, Broadway), and Newborn clinic	Dr. Melissa Stockwell (**mss2112**)
Inpatient and Well Baby Nursery	Dr. Teresa McCann (**tm501**)
School Based Clinics	Dr. Melanie Gold (**mag2295**)

IRB submission and Review:

The attached checklist must be completed prior to submission to the IRB.

ALL OF THE FOLLOWING MUST BE ATTACHED TO THE RASCAL PROTOCOL IF THEY EXIST:	
Funding proposal/grant and/or Notice of Award	Attached ☐ N/A ☐
All questionnaires/surveys in PDF format	Attached ☐ N/A ☐
Full sponsor's protocol	Attached ☐ N/A ☐
Investigator's brochure	Attached ☐ N/A ☐
All proposed recruitment media in PDF format	Attached ☐ N/A ☐
Certificate of confidentiality (if indicated)	Attached ☐ N/A ☐
Assent form (if the study will involve cognitively normal children 7 years old or older.)	Attached ☐ N/A ☐

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Complete prior to submitting to division chief/designee for review

PLEASE ENSURE THAT ALL OF THE FOLLOWING ARE COMPLETE:		
1.	All study personnel have completed Rascal HIPAA, HSP (Human Subjects Protection), and Research with Minors training. FDA-Regulated Research as applicable. (Look at the datasheet to confirm HIPAA and confirm that HSP was completed in the last 3 years). CRC training by all Coordinators and Data Managers. GCP training on NIH funded trials. Genetics consent as applicable.	Done ☐
2.	The appropriate HIPAA form has been attached or language added to the informed consent. (*S*tudies collecting PHI identifiers from the EMR need HIPAA forms; self-disclosed RHI don't).	PHI ☐ RHI ☐ N/A ☐
3.	In Personnel, add as "Non-Engaged Personnel" with view only access, and the role of "Research Administration": Kimberley Telesford (**KAT2165**) and Dimitra Koutsantoni (**DK2617)**..	Done ☐
4.	Fiona Sanders (FS2107) has been listed as "Department Administrator." (Click on Approvals in Rascal) on initial (and all renewals).	Done ☐
5.	Indicate if internal (Gerstner, Driscoll, CTSA, Irving Scholar award, Provost's grant) or external funding has been applied for or awarded. If **external funding**, please add RASCAL PT number, and all necessary information. If unsure of RASCAL PT number, please contact Dimitra Koutsantoni (dk2617). If **unfunded**, please send justification to Fiona Sanders (fs2107).	Done ☐
6.	Clarify in Rascal whether wards/foster children will be involved. (If there is a reason to involve wards, please clarify why).	Done ☐
7.	IND/IDE applications submitted, if required. (See p. 33 of 'A User's Guide to the RASCAL IRB module', website below).	Done ☐ N/A ☐
8.	Human Subjects – JRSC Application has been submitted in Rascal's Haz Mats module to the Joint Radiation Safety Committee. (If study involves any radiation beyond that which is clinically indicated).	Done ☐ N/A ☐
9.	Clarify plans for enrollment of non-English speaking subjects in Rascal. (For non-therapeutic studies *only*, it is acceptable to limit enrollment to English speakers. Translation should happen after consent is approved.).	Done ☐ N/A ☐
10.	Add final statement to the parent consent form: "I am the [ ] mother / [ ] father / [ ] legally authorized guardian of the child named below." Or on PDFs consents, add line for "Relationship to Participant". _____	Done ☐ N/A ☐
11.	In Rascal Consent builder, General tab, remember under "Number of Signature Lines to Display" to include "Child (PRINT NAME)" = 1. Or on PDF consents, include "Child (PRINT NAME): _____".	Done ☐ N/A ☐
12.	If participants is an **inpatient** at the time of enrollment, in Rascal, check ☐**Print signature lines with "Date and Time"** on parental permission/adult consent. On PDFs consents associate "Person Obtaining Consent" with "Date/**Time**".	Done ☐ N/A ☐
13.	Ensure that all document(s) which require an IRB stamp of approval (that will be given to, used with, or read to a participant as recruitment material, a consent form, or a data collection measure) are **attached in Rascal in a PDF format** and have 1" high by 4" wide blank space in the lower right-hand corner**.**	Done ☐ N/A ☐
14.	If research will be conducted at one or more non-CU site(s) including ACN, authorization and/or IRB approval at each site, explanation of funding and organizational relationships, description of procedures at each site, and plans for data and safety monitoring should be attached.	Done ☐ N/A ☐
15.	Have you listed CUMC RecruitMe as a method of recruitment?	Done ☐ N/A ☐
16.	*CLINICAL TRIALS:* Has the trial been registered or are there plans to register the trial with ClinicalTrials.gov?	Registered ☐ Plans to register ☐ N/A ☐

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A User's Guide to the RASCAL IRB Module:

https://research.columbia.edu/maintaining-irb-approval

Pearls to improve your chances with the IRB

- For complex studies, consider an attachment with a flow diagram or other diagrammatic means to clarify study procedures.

- Signature lines on the consent form:
  - 1 parent: Minimal risk or greater than minimal risk with the prospect of direct benefit
  - 2 parents: More than minimal risk without the prospect of direct benefit.

- Ask a non-study person to read your consent form for clarity. Better still, ask a lay person to read it.

- Call or email the IRB team manager if you have questions or problems.

- Be certain that the protocol and the consent clearly indicate what procedures are standard of care and which are specific to the research.

***BONUS:* Pearls to consider regarding future publication**

- Review Author's requirements for the journals where you would like to publish.

- A few journals are now requiring that all new manuscripts for clinical trials must be registered ***prior*** to the enrollment of the first participant.

- According to the World Health Organization:

  "For the purposes of registration, ***a clinical trial*** *is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.* Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc."

- According to the NIH:

  "A research study[1] in which one or more human subjects[2] are prospectively assigned[3] to one or more interventions[4] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[5]"