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 PI *not* in Pediatrics):	
Protocol Title:	
Divisional Chair or Designee:	
Prior review of protocol (please check all that apply):	☐ NIH ☐ COG ☐ Single IRB (sIRB) ☐ Other Specify:_____

****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 with other divisional research

When Dept. of Pediatrics Approvers should be added	**Departmental Approver (Other)**
All protocols originating in the Dept. of Pediatrics	Divisional Chair or Designee
All protocols originating in the Dept. of Pediatrics or involving minors	

If research is be conducted at any of the following locations, please add	
Neonatal Intensive Care Unit (NICU)	Dr. Marianne Garland (mg71)
Ambulatory Care Network (ACN) sites (name of clinics, etc), and Newborn clinic	Dr. Melissa Stockwell (ms2112)
Inpatient	Dr. Divya Lakhaney (dl2182)
Well Baby Nursery	Dr. Wanda Abreu (wa2249)
School Based Clinics	Dr. Dina Romo (dlr96)
Pediatric Intensive Care Unit (PICU)	Dr. Hulya Bayir (hb2753)

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.	Attachments, HIPAA FORMS: 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.	Dept Approvers: For protocol originating in the Dept. of Pediatrics, in Personnel, Jon Evans (je2537) as "Non-Engaged Personnel" w/view only & the role of "Research Admin.-no patient contact"	Done ☐ N/A ☐
4.	Dept Approvers: Fiona Sanders (fs2107) has been listed as "Department Administrator" both initial submission & renewals.	Done ☐
5.	Funding: Indicate if internal or external funding has been applied for or awarded. If External is yes, please **add RASCAL PT number** and **ARC project number** and all necessary information. If unsure of RASCAL PT number and ARC project number, please contact departmental approver If unfunded, please send justification to Fiona Sanders (fs2107).	Done ☐ N/A ☐
6.	Attributes: Indicate if you need CTSA-Irving Institute Clinical Research Resource (CRR) support (e.g. room for visits, blood draws, Pks, or EKGs). CRR offers child life support for research protocols now.	Done ☐ N/A ☐
7.	Attachments, Documents: IND/IDE applications submitted, if required.	Done ☐ N/A ☐
8.	Attachments: Are Hazardous Materials/Radiation involved in this study and application sent to Haz Mat Committee? (If study involves any radiation beyond that which is clinically indicated).	Done ☐ N/A ☐
9.	Informed Consent & Subjects: 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.	On PDFs consents, add line for "Relationship to Participant"_____. Or on Rascal Consent, add final statement to the parent consent form: "I am the [ ] mother / [ ] father / [ ] legally authorized guardian of the child named below."	Done ☐ N/A ☐
11.	On PDF consents, include "Child (PRINT NAME):_____". Or in Rascal Consent builder, General tab, remember under "Number of Signature Lines to Display" to include "Child (PRINT NAME)" = 1.	Done ☐ N/A ☐
12.	On consents: 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.	Attachments, Documents: 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-<<Name of Institution>>.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.	Recruitment: Have you listed Columbia/NYP Recruitment Site as a method of recruitment?	Done ☐ N/A ☐
16.	Procedures: *CLINICAL TRIALS:* Has the trial been registered or are there plans to register the trial with ClinicalTrials.gov?	(Will) registered ☐ N/A ☐
17.	Attachments, Documents: If any Columbia/NYP Employees/Residents/Fellows/Interns/Students will be participants or be surveyed, please attach a letter of support from the Department Chair, Division Chief or Program Director (see page 4)	Done ☐ N/A ☐
18.	Will data or materials be shared outside of Columbia/NYP? Please complete SPA's DUA request form https://cumc.co1.qualtrics.com/jfe/form/SV_29rqFAm9Dh4xX6Z Once submitted you will receive a submission confirmation email (The sender would have been From: SPA - Do Not Reply <noreply@qemailserver.com> & the Subject: [EXTERNAL] MTA/DUA Request Form: PI's Name). Please save that submission confirmation email as a PDF and attach as "Data Usage and Business Associate Agreement"	Done ☐ N/A ☐

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.
- Turn on Word, Options, Proofing, by checking "Show Readability Statistics" to display Passive sentences, Flesch Reading Ease Flesch-Kincaid Grade Level whenever Spelling & Grammar is run.
- 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.
- According to ICMJE, many journals are now requiring that all new manuscripts for clinical trials must be registered ***at or before*** the time of first patient enrollment
- 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. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials."
- 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]"

Columbia Affiliates as Participants in Human Subject Research

Department of Pediatrics

Policy reference:

"Review by an institutional official is now required for studies that that propose to target Columbia University/NYP affiliates. Please attach a letter of support from the Chair (or other authorized representative) of each department in which affiliates are targeted, if applicable). The Columbia University IRB will initiate this review process upon receipt of this letter.

“Columbia/NYP Affiliate” refers to any employee or student of Columbia University and NewYork-Presbyterian Hospital

Dr. Orange’s approval is required for any study based in the Department of Pediatrics. To obtain approval prepare a letter (you may use the preamble below) with:

1. Please provide the following information:

   - ✓ Brief description of the protocol’s goals
   - ✓ Group(s) being surveyed:
   - ✓ Frequency the survey will be administered (per group if different):
   - ✓ Anticipated time to complete each survey type:
   - ✓ Total number of surveys per person:
   - ✓ Whether or not a CUIMC listserve will be used

2. Obtain Divisional and or Educational approval

   - ✓ Approval from the Chief(s) of division(s) of the affiliates involved
   - ✓ If learners are involved, please obtain permission from
     - Fellows: Sarah Lusman, MD
     - Residents: Patrisha Woolard, MD, PhD

Once you obtain Divisional approval, please send the request to Jon Evans (JE2537) who will review and, if complete, request Dr. Orange’s approval.

~~~~~~ To Institution Review Board Members
I have discussed the study IRB Approval AAAV#### with Dr.<< PI Name>> regarding the,<<Study title>> being submitted that would be administered to the target population within<<Name of Institution>>.

[Information from item 1]

I approve our affiliates’ participation in this study.

Sincerely,
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