Guidance for Determining when Ancillary Review and Approval is Required for IRB Submissions

Ancillary Review and approval by safety committees and departments providing resources for the conduct of a study must be obtained before the protocol application will be reviewed by the IRB.

Investigators should select the appropriate committee(s) and/or department(s) in section 2.0 (Required Reviews) of the IRBear application form. The application will automatically be routed to the selected committee(s)/department(s) when the PI uses the “Submit Study” activity.

Refer to the following guidelines to determine whether pre-IRB Ancillary Review is required for your research:

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<th>ANCILLARY REVIEW TYPE</th>
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| Clinical Research Quality Assurance (QA) Program | Applicable to investigator-initiated clinical drug trials with an Investigational New Drug (IND).  
- Investigators who are initiating an IND trial are required to use the Children’s National Clinical Trial Protocol Template unless the external sponsor requires a different protocol format. The template is available under Protocol Templates on the IRBear website (Home > General Information > Forms and Templates).  
- Ancillary review is not required if the IND holder is not a Children’s National employee. | Angela Berry, RN, MSN, CCRA ABerry@childrensnational.org        |
| Compliance                                   | Select only when instructed to do so by an IRB Analyst. Reviews study-specific conflict of interest disclosure forms which indicate possible financial interests related to the research.                                                                                                                                                                                                 | Nolen Morton, JD, CHC nmorton2@childrensnational.org           |
| Coverage Analysis                            | Selection is based on the investigator’s responses to certain questions in the IRBear application. **DO NOT UNCHECK THE BOX IF THE SYSTEM SELECTS IT FOR YOU.**  
- Applicable to studies with procedures conducted in Radiology, Oncology, Cardiology, Laboratory Medicine, Pharmacy, Physical Therapy, Anesthesia, or any other clinical care department in the hospital.  
- Purpose of the Coverage Analysis ancillary review is to determine whether the research Sponsor/ Funder must pay for procedures or whether charges can be billed to subjects’ medical insurance. | Mehzabin Khan, MD MKHAN2@childrensnational.org                 |
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| Diagnostic Imaging and Radiology           | Applicable to research protocols proposing to 1) use radiology studies that are not part of standard of care, or 2) extend radiological studies that are being conducted as standard of care so that research data can be collected. | Dorothy Bulas, MD  
DBULAS@childrensnational.org |
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| Laboratory Medicine   | Applicable to studies involving the use of laboratory and diagnostic tests or procedures, including the use of hematology services and the Children’s National Blood Bank.  
- Ancillary review by Lab Medicine is particularly important if tests/procedures are to be performed in-house at unusual times (i.e., evenings or weekends) or if the required turn-around time is outside of those posted in the Children’s National Lab Information System.  
- Lab Medicine review is also required if the investigator assumes that specimens can be salvaged for use in the future by others outside of the Children’s National lab.  
- Lab Medicine review is not needed if all or most of the lab testing will be performed through a contract with an outside vendor or if testing/procedures are being performed as part of established clinical care. | Meghan Delaney, DO, MPH  
mdelaney2@childrensnational.org |
| Magnetic Resonance Imaging and/or Magnetic Resonance Spectroscopy (MR) | Applicable to research protocols that use Magnetic Resonance Imaging and/or Magnetic Resonance Spectroscopy as part of the proposed research protocol.  
- EXCEPTION: Ancillary review is not required if data collection is limited to retrospective studies that are taken from the PACS server or printed at Radiology’s film library. | Sunil Valaparla, PhD, DABR  
svalaparla@childrensnational.org |
| Medical Records       | Applicable to studies requiring access to and use of Children’s National patient medical records for research purposes. This includes retrospective medical chart reviews.  
- EXCEPTION: Ancillary review by the Medical Records Department is not required if study data is abstracted concomitant with patient treatment. | Fatoumata Traore, RHIA  
ftraore@childrensnational.org  
Dulcie Miller, RHIA, CPC-H  
DMahmud@childrensnational.org |
| Nursing Research Advisory Committee (NRAC) | Applicable to Nursing Research studies to be conducted by a PI who is in the Department of Nursing but not a faculty member. NRAC will assign a Masters- or doctorally-prepared nurse with research experience as a mentor to the PI.  
- Select NRAC ancillary review even if you have already received the advisory committee’s approval and upload the NRAC approval document in your IRBear application. | Peggy Surratt  
MSurratt@childrensnational.org  
Mia Waldron, PhD  
MWaldron@childrensnational.org |
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| **Pathology** | Applicable if a study requires:  
• Anatomic pathological specimens obtained from a surgical procedure (i.e., tumor tissue, bone marrow) to be used for the research; or  
• Access to the pathology database to obtain a list of patients with a particular diagnosis and their PHI | Meghan Delaney, DO, MPH  
mdelaney2@childrensnational.org |
| **Public Relations & Marketing** | Applicable if the research will use materials that are targeted broadly at the public for subject recruitment. PR & Marketing requires that Children’s National branding and the layout and graphics of the materials conform to institutional policies.  
• Review is required for recruitment tools that are used in public settings such as, but not limited to, flyers and brochures, audio- or video-recorded advertisements, print advertisements, and internet website and social media postings.  
• PR and Marketing review is not required for recruitment materials targeted at specific individuals/families pre-identified as meeting some or all of the eligibility criteria. This includes items such as introductory letters from health care providers to their patients and telephone scripts. (These materials still must be submitted for review and approval by the IRB.) | Michelle Tran  
MTran@childrensnational.org |
| **Radiation Oncology** | Applicable if a study asks a Radiation Oncology research question.  
• Ancillary review is not required if the radiation dose/field dictated by the study is considered standard therapy. | Matthew Ladra, MD, MPH  
mladra@jhmi.edu |
| **Radiation Safety Committee** | • Applicable for studies involving radiation exposure (from x-rays or radiopharmaceuticals) of human research subjects from routine diagnostic radiologic procedures or administration of drugs such as radioactive iodine that the subject otherwise would not receive as a part of their medical care.  
• Also applicable if standard of care procedures are being altered for research purposes (e.g., extending the length of a standard-of-care procedure so that research data can be collected). | Eglal Shalaby-Rana, MD  
ERANA@childrensnational.org |
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<td>Scientific Review Committee (SRC)</td>
<td>Selection is based on the investigator’s responses to certain questions in the IRBear application. <strong>DO NOT UNCHECK THE BOX if the system selects it for you.</strong>  • Applicable to research proposals that have not had prior rigorous peer-review by, for example, the NIH or well-established foundation awards (such as the American Heart Association awards). The SRC will focus on the scientific merit and feasibility of the proposed research.</td>
<td>Camilla Colvin, MPH  <a href="mailto:CColvin@childrensnational.org">CColvin@childrensnational.org</a></td>
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