To Request CNMC to be the IRB of Record for an external site using the SmartIRB agreement

Requesting CNMC IRB to be the IRB of Record means that CNMC IRB will oversee the review of a study for an external site (relying site), and that site will cede review to us. Reliance agreements are only applicable to non-exempt human subject research.

In addition to the terms of the reliance agreement, the study team at CNMC is required to:

1. Submit a request (new study or amendment) in IRBear requesting a reliance agreement,
2. Review and understand the following documents:
   a. SmartIRB SOPs sections: Responsibilities: PIs and study teams; Responsibilities: Reviewing IRBs and Relying Institutions,
   b. Institutional x IRB responsibilities document,
3. Coordinate and communicate with the relying site IRB and study teams to obtain and distribute required documents and information,
4. In collaboration with the relying sites study teams, complete the blank questions in the communication plan for each site – do not make any changes to the questions pre-filled by the CNMC IRB,
5. Create and submit to CNMC IRB for review all the consent and assent forms for the relying sites. Site-specific boilerplate language must be merged with the CNMC or sponsor consent/assent templates,
6. Submit in IRBear (as applicable) the Initial Review, Amendments, Continuing Reviews, and Reportable Events for the relying sites. IRBear accounts will not be given to external staff,
7. Maintain enough staff and resources to oversee and manage (as applicable) the study at CNMC and relying sites.

In addition to the terms of the reliance agreement, the relying site is required to:

1. Be a signatory of the SmartIRB agreement (https://smartirb.org/join/),
2. Have access to SmartIRB Online Reliance System (https://smartirb.org/reliance/) to accept the reliance request electronically,
3. Conduct their local context review per their institutional policy and procedures,
4. The SmartIRB POC must complete the SmartIRB Local Considerations forms (Institutional Profile and Protocol-specific document) to provide information about the state laws and policies applicable to their site. The SmartIRB POC is the person listed in the SmartIRB website as the point of contact, not a study team member. If unsure who is the SmartIRB POC at your institution, please refer to https://smartirb.org/participating-institutions/.

Consultations with both IRBs are recommended before submitting a request for reliance.

The list of SmartIRB signatory institutions can be found here: https://smartirb.org/participating-institutions/

Requests are made via IRBear:

1. Start a new study in IRBear

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2. Initial steps are exactly like any study. Before submission, make sure that all staff has current and complete CITI training, and the COI forms are completed and signed for all staff.

3. Type of Submission: select ‘Human Subjects Research Study’ (even if your study is only data)

4. Regulatory Oversight - The key to request a reliance agreement in IRBear is Question 1.6.
   a. 1.0 - Which IRB are you requesting to serve as the IRB of Record and provide regulatory oversight?
      i. Select Option 2: Children's National is requested to serve as the IRB of record for one or more external sites. In other words, one or more external collaborating sites will rely on the Children's National IRB to review, approve and maintain oversight of the multi-site research on their behalf.

   b. Children's National as the IRB of Record for External Sites – select the proposed reliance authorization agreement. There are two options:
      i. OPTION 1: Select SMART IRB, click ‘Continue’
         1. Question 1: Search and add the name of all relying sites
         2. Question 2: Upload the following documents from the relying sites.
            Your application will not be reviewed unless all required documents are uploaded for each relying site. The templates are available in IRBear.
            a. SmartIRB Local Context Considerations: Institutional Profile
            b. SmartIRB Local Context Considerations: Protocol-specific Document
      ii. OPTION 2: If the institution relying on CNMC IRB is not found on the list in IRBear, please return to step b (above) and select ‘N/A: This study is not included under any existing multi-study reliance authorization (...)” and upload the SmartIRB documents on the follow up question. This is a workaround in case IRBear is not up to date with all the current SmartIRB signatory institutions (the list changes often)

5. Complete the remainder of the application. For the document section:
   a. 1.0 – Upload the research protocol (must match the sites listed as relying)
   b. 2.0 – Upload the consent forms
      i. The relying IRB should sign off on the consent and assent documents before being submitted to CNMC IRB to assure that the site-specific language is appropriate.
      ii. The consent and assent documents will be created by the study team (CNMC or external site, depending on the arrangements made between the investigators). The IRB does not provide editorial service.
      iii. Use the consent form template available in IRBear to assure it is the most recently approved version.
      iv. The CNMC templates may be edited in some sections (see below) to include the external site-specific language. The rest of the consent form must be the same for all sites unless a rationale is provided (for example, one of the sites is not enrolling pediatric population so assent does not apply to that site.)

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v. Customizations of consent and assent documents are generally not allowed except by the items listed below. Exceptions will be made when required by a state law or institutional policy, which must be provided with the Local Context Consideration forms. The following sections may be edited to reflect the external site template language:

1. Logos, label boxes, and bar codes
2. Certificate of Confidentiality (unusual)
3. ClinCard or equivalent compensation method (unusual)
4. IRS (unusual)
5. Research related injury
6. HIPAA
7. Privacy Notice
8. IRB contact information (must also list CNMC as the IRB of Record contact info)
9. Research advocate (if applicable for the relying site)
10. Signature lines, blocks and affidavits as applicable

c. CNMC IRB will stamp the consent and assent documents for studies for all the relying sites.

If your study is already approved at CNMC IRB, and you want to add a site, please start an amendment (Full Amendment) and follow the steps above. When preparing your submission, the critical steps are:

- Consult with both IRBs before you start your submission – entering a reliance agreement depends on several factors including risk level of the study, expertise and accreditation level of the institutions, staffing, funding, etc...
- CITI training is complete and current for all study team
- Ancillary reviews were selected correctly
- COI forms for the CNMC staff are complete, signed and dated
- The relying site is a signatory of SmartIRB and SmartIRB Online Reliance.
- The Local Context Consideration forms are complete and signed by the IRB staff from each relying site(s)