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| **SOP: RI 801****Effective Date: 3/6/2025** | **Investigator Submission Requirement Guidance****Corewell health Lakeland**  | **Replaces Document****Dated: 4/15/05** |

**Submitting a research study**

Corewell Health Lakeland (CHL) IRB covers all research studies within the jurisdiction of Corewell Health South. The IRB generally meets once a month. Submission materials should be received **2 weeks** preceding the meeting if a full board review is required. Submissions may be submitted via email to LakelandIRB@corewellhealth.org

All individuals engaged in research must complete personnel requirements including Citi training, conflict of interest training and an attestation, and submit a CV. Information on personnel requirements can be found on the [CHL IRB Sharepoint Site](https://spectrumhealth.sharepoint.com/sites/CHLIRB/).

# Basic Components of an IRB Submission

Forms & Templates can be found [here](https://spectrumhealth.sharepoint.com/sites/CHLIRB/SitePages/IRB-Forms-and-Templates.aspx).

**1. Study Summary Form (IRB Initial Application Form)**

The Study Summary Form must be completely filled out. If a section does not apply to you, indicate this with N/A.

 **2. The Informed Consent Form**

You must use the consent form templates with the Corewell Health logo. Include the process to obtain informed consent or if requesting Waiver or Alteration of Informed Consent the rationale for the request

 **3. The Research Protocol**

It is recommended to use the protocol templates provided on the IRB site. If sections are not applicable you may remove them. If your research is not biomedical in nature, completing Sections 10-16 on the Study Summary Form is acceptable in lieu of a detailed scientific protocol.

**4. Recruitment Material (Advertisements, Posters, Flyers, Press Releases, etc.)**

The IRB is required to review any advertisements, flyers, Internet postings (with the Internet address), etc., for subject recruitment, correspondence to subjects or other cooperating individuals such as referring physicians or facilities. In addition, the IRB reviews all press releases intended to facilitate recruitment of subjects. Contact documents are not approved or valid without an IRB signature and/or approval stamp and date.

**5. Surveys, Questionnaires, Etc.**

The IRB is required to review all research instruments such as surveys, questionnaires, etc.

**6. Investigator Brochure, Device Specifications, Package Inserts**

The IRB is required to examine the Investigator Brochure and/or device manual in order to adequately assess the risk/benefit ratio for subjects participating in the research. This document can be sent electronically to the IRB Analyst.