



IRB Guidance on Obtaining Letters of Support/Cooperation

When investigators seek to invite individuals into their study or use site resources (e.g., data sources, email lists, etc.), the IRB application may ask for documentation that permission to do so has been obtained from that site. Permission is when the investigator(s) is granted access to a specific population or data set for their study from someone who is authorized to act on this behalf, also known as an authorized official. IRB approval does not authorize permission for sites; therefore, it must come from the authorized official.

The following guidance in the form of questions and answers can aid researchers in understanding when and why a Letter of Support, also known as a Letter of Cooperation, is needed.

What is a Letter of Support/Cooperation?

A Letter of Support/Cooperation is a letter of support or statement from the authorized official to act on behalf of that site which outlines their support of the research activities proposed in the IRB application. Letters of Support/Cooperation are most typically required for sites where access would be considered “private” and not open for public use. Letters of Support/Cooperation must be obtained from the site’s authorized official prior to IRB approval.

What is the purpose of a Letter of Support/Cooperation?

The purpose of the Letter of Support/Cooperation is to provide the IRB with documentation that the site is aware of the study activities and has agreed to the plan for carrying out those activities.

When is a Letter of Support needed?

In the absence of documentation from another IRB or ethics committee at the site of recruitment or for data use, a Letter of Support/Cooperation and/or other supplemental documentation may be needed from the site. Radford University IRB may request that investigators provide this documentation within their research application prior to approval to ensure that appropriate safeguards are in place, that the study is feasible, or the research plan is culturally appropriate.

Examples of external sites without IRBs where permission may be needed include, but are not limited to:

- Schools/educational departments
- Medical offices or clinics
- Private companies, Non-Profits, or Non-Government Organizations
- Religious institutions
- Federal, state, or local governance institutions or offices
- Closed/private social media groups
- Other universities

Is a Letter of Support/Cooperation needed if my project is occurring at Radford University and not an external site?

Depending on the study recruitment or procedure methods, it is possible that permission from the specific department, college, or administration is needed.

Who writes and signs Letters of Support/Cooperation?

Letters of Support/Cooperation should come from an individual in a position of authority to provide permission for using that site, or data, at the requested level of access. The Letter of Support/Cooperation cannot come from a member of the study team, or from anyone who may have a conflict of interest relative to the study.



What is the format for a Letter of Support/Cooperation?

A Letter of Support/Cooperation can be documented in a hard copy letter and must contain the address site, professional title and contact information of the person providing permission.

What should be in a Letter of Support/Cooperation?

The letter should contain enough information to enable the Radford University IRB to assess whether the site understands and supports the study plan.

See the Letter of Support/Site Agreement template for your use.

Letters of Support/Cooperation must be traceable to the authority who gave the permission.

- Sent from an authorized official (i.e., school principal, site manager, director, owner)
- Acceptable signatures include a hand-signed, printed form, which is then scanned and uploaded to the IRB application
- Written on institutional/departmental letterhead or sent from the institutional email account
- Title and contact information (phone, address, and email) of person providing permission.
- Alternatively, email documentation with the letter of support is acceptable as long as full contact information is provided (e.g., a full signature) and the senior officer's official institutional email address is used (which can then be scanned and uploaded to the IRB application)

What is the responsibility of the Principal Investigator(s)?

1. Inform the site of the need for a Letter of Support/Cooperation for their IRB application
2. Inform the site of the proposed study features so that the site's authorized official can make an informed decision regarding site involvement
3. Obtain the letter of support/cooperation prior to beginning any research activities at the site
4. Upload the letter into the study application and maintain the Letter of Support/Cooperation with study documentation
5. The IRB reserves the right to require a copy of the letter before IRB approval, at the time of continuing review, or as part of a routine quality improvement review

Once I obtain the Letter of Support/Cooperation, can I conduct my research?

No, not until IRB approval is obtained. Site permission for a research project under IRB review does not grant the researcher permission to conduct their project at that site; rather, site permission grants support/permission to conduct the proposed activities once IRB approval has been obtained. Projects subject to IRB review must obtain IRB approval before research can occur.