



Guidance: Letters of support from external sites

In the absence of documentation from an ethics committee at the site of recruitment or research, a letter of support or other documentation of permission may be needed. The IRB may request that researchers provide this documentation to ensure that appropriate safeguards are in place, that the study is feasible, or the research plan is culturally appropriate.

What is the purpose of a letter of support?

The purpose of a letter of support 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.

Who writes and signs the letter of support?

Documentation of support should come from an individual in a position to provide permission for that site. The letter of support cannot come from a member of the study team.

What is the format of a letter of support?

Documentation of support or permission can come in a variety of forms. The specific format is not dictated by the Human Subject Research Protection office and should be left to the discretion of the organization or person providing permission.

What should be in a letter of support?

The letter should contain enough information to enable the IRB to assess whether the site understands and supports the study plan. *As applicable*, common elements include:

- Name, title or role, and contact information of the person providing permission.
- Name of the PI and brief description of the activities to be conducted at the site.
- Confirmation that the approach to recruitment, the method and timing for obtaining consent, and data collection activities are appropriate for the setting and the study participants.
- Confirmation that the research plan does not expose study participants to unnecessary risk
- Depending on the site and the study population, additional information may be required.

Research in public schools

All research conducted in, or in cooperation with, schools or school districts requires approval from the building principal or district prior to the initiation of the study. District approval comes in the form of a site letter (on institutional letterhead) signed by the administrator in charge of making such decisions at the school site, or via an email approval from an institutional email address. A copy of this letter or email should be included with the IRB application. Initially, protocols may be approved without these letters. If the letter is obtained after IRB approval, please submit it with a completed amendment form. No research, including subject recruitment, may take place until an amendment letter is issued.