



## IRB Guidance: Letters of Support from External Sites

When projects are conducted in whole or in part at sites external to Campbell University, project teams may be asked to provide letters (or emails) of support from those sites. The purpose of a letter of support is to provide documentation to the Campbell IRB that the site is aware of the project activities that will be conducted at that site and it supports participation in the project. This guidance describes when such letters may be needed, who should provide the letter, and suggestions for template language to include in the letter.

### What type of site(s) may require obtaining a Letter of Support?

Letters of support typically need to be submitted to the IRB for the following types of sites when project activities beyond recruitment and/or consenting of subjects will occur at that site:

- Sites that do not have an IRB or other committee or group (e.g., ethics committee, research review committee, etc.) reviewing the project; AND
- The Campbell IRB is not serving as IRB of record for those sites.<sup>1</sup>

### When is a Letter of Support needed for these types of sites?

Letters of support for sites that meet the above criteria are need for studies that are:

- Federally funded;
- FDA-regulated; and/or
- Involve the access or disclosure of protected health information (PHI) held by the external site.
- Any other reason as determined by the IRB

### Who should write the Letter of Support?

A letter or email of support should be signed by someone at the site who is in a position to provide permission for that site to be involved in the proposed project activities. (e.g., director or head of community center or organization, manager of a pharmacy). The letter of support should not be signed by a member of the project team conducting research at the site.

### Template Language:

- The letter should reference the name of the Principal Investigator and the title of research study.
- The letter should in some manner refer to the research activities that will be allowed at the site.
- The letter must be on the official organization or agency letterhead.
- Person or entity providing permission (including title, contact information, and confirmation of appropriate authority to provide permission)
- The letter should reference how the site will specifically assist with the project or what resources will be provided, if applicable. For example, a site may send a Research Information Sheet and survey via the organization's e-mail list; provide data that has been extracted from the organization's database for the research, send out recruitment notices, or hang flyers in their facilities and etc.
- When appropriate, the letter should indicate that the research is acceptable given the cultural norms and ethical beliefs of the site.
- For projects involving access to or disclosure of protected health information (PHI) held by that site, the following statement should be included: *I also understand that if the IRB has granted a waiver of HIPAA authorization, [name of entity] may rely on that waiver in using or disclosing PHI. If any PHI will be disclosed*

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<sup>1</sup> If the Campbell IRB is serving as IRB of record for an individual (not the site as a whole) then a letter of support may still be needed.



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*pursuant to the waiver, [name of entity] must account for such disclosures* or a copy of the sites HIPAA waiver which includes a statement that the patient's information may be used for research purposes.