

Off-Campus Study Site Form

HR Number

Study Title:

Principal Investigator:

Off-Campus Study Site:

Address:

Name of non-MUSC investigator at off-campus site:

Degree(s):

Institutional title:

1. Is the off-campus site “engaged” in human subjects research pertaining to this study?

To make this determination you will need to consult the OHRP website.

See the following link for categories and guidance:

<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>

Check either A or B below:

(A) Activities at the off-campus site are consistent with examples under Category A; the site is engaged in human subjects research

If you checked this section, please identify the specific type of activity or activities to be done at this off site campus by providing the number of the example from the OHRP website. For example: A1, A2, A3, etc.

(B) Activities at the off-campus site are consistent with examples under Category B; the site is not engaged in human subjects research

If you checked this section, please identify the specific type of activity or activities to be done at this off site campus by providing the number of the example from the OHRP website. For example: B1, B2, B3, etc.

2. Does the off-campus site have a Federal Wide Assurance (FWA)?

Yes
 No

If yes, what is their FWA#:

3. Does the off-campus site have an Institutional Review Board for Human Research?

Yes No

If Yes, provide the name, address and phone number of the IRB:

If Yes, has the off-campus site's IRB approved this study?

Yes No

If the off-campus site's IRB has not approved this study, will review by that IRB be required?

Yes No