

# **LETTER OF COOPERATION GUIDANCE**

## **Research Conducted Off-Site or at Multiple Sites**

The CWRU IRB Administrative Office (IAO) Head will evaluate whether investigators are complying with policies and procedures and whether further communication or information from multiple sites are required for both expedited and full review protocols. The RI will inform all institutions/sites of all adverse events or unanticipated problems associated with the respective protocol.

Investigators, affiliated with CWRU, recruiting or conducting research at sites other than CWRU (i.e., schools, businesses, community centers, clinics) must submit copies of those sites' IRB approval before the CWRU IRB will finalize approval (unless the research is conducted at an affiliated medical center, see below). The CWRU IRB will usually accept a common, or shared, informed consent document (i.e., the CWRU template is not required); however, the investigator must include all required elements of informed consent outlined at 45 CFR 46.116 (unless waived by the IRB), as well as contact information for the Responsible Investigator and the CWRU IRB.

If the site does not have an IRB, investigators must submit a letter of cooperation from an institutional official to confirm that the institution in question approves the proposed research (see attached for Letter of Cooperation templates). The letter should be on the site's letterhead, and include a statement indicating that the official understands and approves of the proposed research at his/her institution. This letter should contain an original signature.

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When research to be reviewed at CWRU plans to include research activities at external sites that do not have an IRB, investigators must provide documentation (e.g.; appropriate letter of cooperation on letterhead from that site) that the external site has agreed to host the research activities and also provide contact information for relevant parties and officials related to the conduct of the external site.

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## LETTER OF COOPERATION TEMPLATES

### EXAMPLE 1 (SCHOOL)

*[Institutional Letterhead]*

*Dr. Jane Researcher has described his proposed research to me, titled, "Insert Title Here." As Superintendent of XYZ Schools, I approve of this research to occur at our schools.*

*[Signature]*

*Dr. John Superintendent [or appropriate institutional official]*

### EXAMPLE 2 (ORGANIZATION)

*[Institutional Letterhead]*

*Dr. John Researcher has described her proposed research to me, titled, "Insert Title Here." As President of XYZ Corporation, I approve of this research to occur with our employees and administrative records.*

*[Signature]*

*Dr. Jane President [or appropriate institutional official]*

*XYZ Corporation*