

# 18880 Revised

## Sending or Receiving Specimens/Data/Images Guidance

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This guidance describes additional steps study teams may need to take if they wish to send specimens/data/images to or receive them from any site or personnel external to the UW-Madison/UWHC/Madison VA for a study that is currently approved by the HS-IRBs.

[Decision Guide for UW-Madison Study Teams that Plan to Share Data, Samples, or Images with a Non-UW Site for Research Purposes](#)

### Sending Specimens/Data/Images to Other Sites

*How can I send specimens/data/images collected for a currently approved study to another site/researcher at another institution?*

If the currently approved IRB application does not specifically state that specimens/data/images will be shared with a site and/or personnel external to the UW-Madison/UWHC/Madison VA, a change of protocol must be submitted to the HS-IRBs before specimens/data/images are sent to that site/researcher.

If the currently approved IRB application specifies that specimens/data/images collected for the study will be shared with another site or researchers at another institution, no change or notification to the IRB is required if the scope of what the samples will be used for falls within those described within the UW IRB application.

*If a change of protocol to share specimens/data/images with others site is needed, what information about the proposed sharing of specimens/data/images should be included in the change of protocol?*

The change of protocol should address the following:

- Describe the reason for sharing the specimens/data/images externally;
- Describe whether the individuals who receive the specimens/data/images are collaborating with the UW-Madison/UWHC/Madison VA researchers, using them for their own research, or providing a professional, non-collaborative function for the study;
- Identify where the specimens/data/images will be sent;
- Describe what information (particularly identifying information) is associated with the specimens/data/images;
- Explain how the specimens/data/images will be transmitted securely (i.e., what confidentiality protections will be in place); and

- Address whether the data, specimens, or images will be returned to the UW-Madison/UWHC/Madison VA and if not, why not (e.g., samples will be exhausted). NOTE: Research that falls under VA purview has specific requirements related to the transmittal of specimens/data/images.

*Does the researcher receiving the specimens/data/images from the UW-Madison/UWHC/Madison VA need to have IRB approval from his/her institution before receiving the specimens/data/images?*

Whether the researcher receiving specimens/data/images must obtain IRB approval depends on several factors:

1. **Will the specimens/data/images be analyzed solely as a professional service?** Personnel who a) receive the specimens/data/images to analyze them solely as a professional service for a research study and b) who do not perform truly collaborative activities would not be considered engaged in human subjects research. In these situations, IRB approval would not typically be required. Institutional policies about this may differ, however, and personnel receiving specimens/data/images are strongly encouraged to consult with their own IRBs regarding whether IRB approval is needed.
2. **Will the specimens/data/images being sent be completely anonymized (i.e., no one can trace them back to the individual from whom they were derived) to external personnel who is not a collaborator?** Personnel who receive a) specimens/data/images that have been completely anonymized and b) are not collaborating with UW-Madison/UWHC/Madison VA researchers would not be considered engaged in human subjects research. In these situations, IRB approval would not typically be required. Institutional policies about this may differ, however, and personnel receiving specimens/data/images are strongly encouraged to consult with their own IRBs regarding whether IRB approval is needed.
3. **Will the specimens/data/images being sent be coded and the code will not be released to the external researcher who is not a collaborator?** Personnel who receive a) specimens/data/images that have been coded and the code will not be released to the external researcher; and b) are not collaborating with UW-Madison/UWHC/Madison VA researchers would not be considered engaged in human subjects research. In these situations, IRB approval would not typically be required. Institutional policies about this may differ, however, and personnel receiving specimens/data/images are strongly encouraged to consult with their own IRBs regarding whether IRB approval is needed.
4. **Will the specimens/data/images be identifiable to any personnel at any site?** Personnel who receive specimens/data/images that are identifiable to members of the research team at any site and who are collaborating with UW-Madison/UWHC/Madison VA researchers may be considered engaged in human subjects research. This may be the case even if the specimens/data/images are not identifiable to those receiving the specimens/data/images. The HS-IRBs will request either documentation of IRB approval from the collaborators' site or

documentation that the collaborators' IRB does not require oversight of their personnel's research activities related to the study. If the collaborators do not have an IRB of record or an IRB that has an FWA, the HS-IRBs may be requested to serve as their IRB of record.

### **Receiving Specimens/Data/Images from Other Sites**

*How can I receive specimens/data/images for a currently approved study from another site/researcher at another institution?*

If the currently approved IRB application does not specifically state that specimens/data/images will be received from a specific site/researchers, a change of protocol must be submitted to the HS-IRBs before specimens/data/images are sent by that site/researcher.

*What information about the proposed specimens/data/images to be received should be included in the change of protocol?*

The change of protocol should address the following:

- Identify the sites from which the data, specimens, or images will be received;
- Describe what information (particularly identifying information) is associated with the specimens/data/images;
- Explain how are they transmitted securely (i.e., what confidentiality protections will be in place);
- Address whether the data, specimens, or images will be returned to the other site/research or stored at UW-Madison, UW Health, or the Madison VA; and
- If the study does not have a coordinating center, provide a copy of the IRB approval and consent form under which the data, specimens, or images were collected.