Registry-Repository Overview Table

Please see Data Repository, Recruitment Registry and Tissue Repository Guidance for additional information.

What the study team wants to do	What it's called by the UW HS IRBs	Type of IRB application required	Additional information
Create a file listing individuals who have similar characteristics, or who are just interested in participating in research, for the purpose of contacting them about specific research opportunities in the future.	Recruitment Registry*	Full Initial Review application	The expectations for recruitment registries are as follows: • People who are interested in participating in research will be recruited and consented specifically for the registry • The registry will be continually updated with new participants • The registry will be used as a recruitment tool for multiple studies. Please note that investigators sometimes keep a list of names and contact information of research subjects who consent to be contacted about other studies. If only name and contact information are kept, and the information will only be used by a specific Principal Investigator, then it does not constitute a recruitment registry (Note: The VA considers retaining a list, even if just name and contact information, to constitute a recruitment registry). Also, if the list is expanded to include other eligibility criteria and meets other expectations listed above, an initial review application to create a recruitment registry is required.

* The Health Sciences IRBs prefer the use of the word "registry" to be used to refer to lists of people along with limited personal and medical information. The primary use of these lists is to provide investigators with pools of potential study volunteers, as in recruitment registries. The terms "database" or "repository" are preferred if the intent is to create files of information or specimens to be used directly for research purposes.

Registry-Repository Overview Table

Please see Data Repository, Recruitment Registry and Tissue Repository Guidance for additional information.

What the study team wants to do	What it's called by the UW HS IRBs	Type of IRB application required	Additional information
Create a repository of patient information with the primary intent of improving patient care and/or clinical processes.	Quality Improvement (QI)/Quality Assurance (QA) Data Repository	None; IRB approval is not required for the creation of a QI/QA repository, although it must be registered with the HIPAA privacy officer.	QI/QA repositories may be used for research involving medical record reviews, but this use is secondary to QI/QA. An IRB application must be submitted for each research study that will use the QI/QA repository. These applications often qualify for exemption (Initial Review: Exemption) or expedited review (Initial Review: Non-Exempt Medical Record Review).
Submit CODED patient data for inclusion in a multi-institution repository dedicated to research on a specific disease or cluster of related conditions, which is NOT stored at UW-Madison.	Research Data Repository*	Initial Review application: Full Review	Informed consent and authorization is generally required for prospective multi-institution repositories. However, if the study team requests a waiver of informed consent and waiver of HIPAA authorization for this, direct identifiers generally are not permitted to be included in the data submitted. A waiver of HIPAA authorization must be requested in addition to the waiver of informed consent. Limited identifiers may be permitted to be included in the data submitted if a Data Use Agreement is executed with the institution that holds the data repository.
Submit ANONYMOUS patient data for inclusion in a multi-institution repository dedicated to research on a specific disease or cluster of related conditions, which is NOT stored at UW-Madison.	Research Data Repository*	Initial Review application: exemption	If the study team will access identifiable information and create a de-identified (anonymous) data set to share outside UW-Madison, a Category 4 exemption is appropriate as long as the data are in existence at the time of IRB submission and the data sharing will occur only once.

* The Health Sciences IRBs prefer the use of the word "registry" to be used to refer to lists of people along with limited personal and medical information. The primary use of these lists is to provide investigators with pools of potential study volunteers, as in recruitment registries. The terms "database" or "repository" are preferred if the intent is to create files of information or specimens to be used directly for research purposes.

Registry-Repository Overview Table

Please see Data Repository, Recruitment Registry and Tissue Repository Guidance for additional information.

What the study team wants to do	What it's called by the UW HS IRBs	Type of IRB application required	Additional information
Create a research repository stored at UW-Madison to be used only by the UW-Madison study team.	Research Data Repository	Initial Review application: Full Review	This type of application is appropriate if the purpose for creating the repository is predominantly to provide data for research intended to contribute to generalizable knowledge.
Create a research data repository stored at UW-Madison to be used by the UW-Madison study team, other researchers at the UW-Madison, and by other researchers outside the UW-Madison study team.	Research Data Repository	Initial Review application: Full Review	The study team must provide a stand-alone protocol or manual of operations within the IRB application that includes a description of how the study team will handle data requests, how data will be distributed for analysis outside the UW-Madison study team, how it will be ensured that the requests to use the data are consistent with the terms of the consent document, and how it will be ensured that the study team requesting the data has IRB approval or exemption for the use (or the study team's institution does not require IRB review of the data use).

* The Health Sciences IRBs prefer the use of the word "registry" to be used to refer to lists of people along with limited personal and medical information. The primary use of these lists is to provide investigators with pools of potential study volunteers, as in recruitment registries. The terms "database" or "repository" are preferred if the intent is to create files of information or specimens to be used directly for research purposes.

Registry-Repository Overview Table

Please see Data Repository, Recruitment Registry and Tissue Repository Guidance for additional information.

What the study team wants to do	What it's called by the UW HS IRBs	Type of IRB application required	Additional information
Create a multi-institution data repository dedicated to research on a specific disease or cluster of related conditions, which IS stored at UW-Madison.	Research Data Repository	Initial Review application: Full Review	The study team must provide a stand-alone protocol or manual of operations that includes a description of how data from outside investigators will be submitted for inclusion in the repository, how the study team will handle data requests, and how data will be distributed for analysis outside the UW-Madison study team, how it will be ensured that the requests to use the data are consistent with the terms of the consent document, and how it will be ensured that the study team requesting the data has IRB approval or exemption for the use (or the study team's institution does not require IRB review of the data use).

* The Health Sciences IRBs prefer the use of the word "registry" to be used to refer to lists of people along with limited personal and medical information. The primary use of these lists is to provide investigators with pools of potential study volunteers, as in recruitment registries. The terms "database" or "repository" are preferred if the intent is to create files of information or specimens to be used directly for research purposes.

Registry-Repository Overview Table

Please see Data Repository, Recruitment Registry and Tissue Repository Guidance for additional information.

What the study team wants to do	What it's called by the UW HS IRBs	Type of IRB application required	Additional information
Create a multi-institution data repository dedicated to research on a specific disease or cluster of related conditions, which IS stored at UW-Madison.	Variable	Initial Review application: Full Review	Informed consent and authorization is generally required for prospective multi-institution specimen banks. However, if the study team requests a waiver of informed consent for this, direct identifiers generally are not permitted to be included with the specimens submitted. A waiver of HIPAA authorization must be requested in addition to the waiver of informed consent. Limited identifiers may be permitted to be included with the specimens if a Data Use Agreement is executed with the institution that holds the specimen bank. If protected health information (PHI) will be maintained along with samples, the same information must be provided for the data. See also the information above regarding submitting data for inclusion in a research registry or database outside UW-Madison.
Submit ANONYMOUS patient specimens for inclusion in a multi-institution specimen bank dedicated to research on a specific disease or cluster of related conditions, which is NOT stored at UW-Madison.	Variable	Initial Review application: exemption	If the study team will access identifiable samples and strip all identifiers to share outside UW-Madison, a Category 4 exemption is appropriate. However, to qualify for exemption, samples must be in existence at the time the exemption application is submitted to the IRB. If the study team will access and share anonymous samples, see Sending or Receiving Specimens/Data/Images Guidance [link to 18880].

* The Health Sciences IRBs prefer the use of the word "registry" to be used to refer to lists of people along with limited personal and medical information. The primary use of these lists is to provide investigators with pools of potential study volunteers, as in recruitment registries. The terms "database" or "repository" are preferred if the intent is to create files of information or specimens to be used directly for research purposes.

Registry-Repository Overview Table

Please see Data Repository, Recruitment Registry and Tissue Repository Guidance for additional information.

What the study team wants to do	What it's called by the UW HS IRBs	Type of IRB application required	Additional information
Create a multi-institution specimen bank dedicated to research on a specific disease or cluster of related conditions, which IS stored at UW-Madison.	Tissue/Specimen Repository	Initial Review application: Full Review	The study team must provide a stand-alone protocol or manual of operations that includes a description of how samples from outside investigators will be submitted for inclusion in the repository, how the study team will handle sample requests, and how samples will be distributed for analysis outside the UW-Madison study team, how it will be ensured that the requests to use the data are consistent with the terms of the consent document, and how it will be ensured that the study team requesting the data has IRB approval or exemption for the use (or the study team's institution does not require IRB review of the data use). If protected health information (PHI) will be maintained along with samples, the same information must be provided for the data.
Create a bank of tissue specimens stored at UW-Madison to be used only by the UW-Madison study team. Note: VA regulations include additional requirements for maintaining a tissue/specimen repository.	Tissue/Specimen Repository	Initial Review application: Full Review	This applies only if the stored samples are intended to be used in multiple future studies. Storage of samples to be used for a single study does not constitute banking, even if the analyses for that study are expected to be carried out over several years.

* The Health Sciences IRBs prefer the use of the word "registry" to be used to refer to lists of people along with limited personal and medical information. The primary use of these lists is to provide investigators with pools of potential study volunteers, as in recruitment registries. The terms "database" or "repository" are preferred if the intent is to create files of information or specimens to be used directly for research purposes.

Registry-Repository Overview Table

Please see Data Repository, Recruitment Registry and Tissue Repository Guidance for additional information.

What the study team wants to do	What it's called by the UW HS IRBs	Type of IRB application required	Additional information
Create a bank of tissue specimens stored at UW-Madison to be used by the UW-Madison study team and by other researchers outside the study team, including those outside the UW-Madison.	Tissue/Specimen Repository	Initial Review application: Full Review	The study team must provide a stand-alone protocol or manual of operations that includes a description of how the study team will handle sample requests and how samples will be distributed for analysis outside the UW-Madison study team, how it will be ensured that the requests to use the data are consistent with the terms of the consent document, and how it will be ensured that the study team requesting the data has IRB approval or exemption for the use (or the study team's institution does not require IRB review of the data use). If protected health information (PHI) will be maintained along with samples, the same information must be provided for the data that will be banked.

* The Health Sciences IRBs prefer the use of the word "registry" to be used to refer to lists of people along with limited personal and medical information. The primary use of these lists is to provide investigators with pools of potential study volunteers, as in recruitment registries. The terms "database" or "repository" are preferred if the intent is to create files of information or specimens to be used directly for research purposes.