HUMAN SUBJECT RESEARCH REPOSITORY POLICY - FAQS

I. Do I Have a Repository that Requires Compliance?

1. **My study has been determined by the IRB to be "Not Human Subjects Research" (NHS) but I'm keeping the data and/or samples and might use them for future research. Do I need to do anything to comply with the new policy?**

   No. No additional submission is needed for data generated by studies determined by the IRB to be NHS.

2. **My study has been determined by the IRB to be "Exempt" from IRB oversight but I'm keeping the data or samples and might use them for future research. Do I need to do anything to comply with the new policy?**

   Yes, but only if you are maintaining identifiable data/samples. You will need to start a "Repository Only" submission, because repositories with identifiers cannot be considered exempt, even if their source studies were exempt.

3. **My study includes a plan to "batch" samples so that assays may be run more efficiently. Does holding samples for this purpose constitute a repository?**

   No. Only the storage of samples for future unspecified research uses constitutes a repository. If you are storing samples for a purpose specific to the protocol in which they were collected, you are not creating a repository.

4. **After my study is done and my paper is published, I don't plan to do any future research, but I want to keep my identifiable data in case someone questions my findings. Is this a repository?**

   No, but if you decide at any time that you want to re-visit your data to answer a new research question, you will need to set up a repository and also have separate IRB approval for the new research activity. To save yourself work later, we highly recommend setting up a repository if there's any chance you think you'll want to re-use your data for something new in the future.

5. **Our department has a "shadow database" we've used for quality improvement/quality assurance (QI/QA) purposes. Should we submit this for IRB approval?**

   You are not required to get IRB approval for the database if you never intend to use it for research purposes. However, the IRB recommends that such databases be reviewed and approved by the IRB and used as a research resource when practicable.

6. **I have a registry of contact information from people who have asked/consented to be contacted about future research opportunities. Is this a repository?**

   Yes.

7. **I have a collection of samples and/or data that has not been submitted to the IRB for approval. Do I need to do anything to comply with the new policy?**

   If you have data and/or samples stored here at OHSU that are not stored as part of a current IRB-approved study, you must submit a new request for approval any time before August 31, 2011. Utilize the "Repository Only" path in the eIRB.

   If you are storing data or samples that were collected through an IRB approved study, but the study protocol and/or consent form does not state that data or samples will be stored, you do not have IRB approval to store the data or samples and you must obtain approval for the repository in the next continuing review for that study (or in a modification). You will be required to answer new questions in the eIRB at continuing review, which will help you come into compliance with the policy. You may also need to submit a repository protocol and/or modify your consent/authorization process.

II. Developing a Compliant Repository

8. **I have a study that includes the storage of data and/or specimens for future research, and this storage is already approved by the IRB. Do I need to do anything different at the next continuing review?**

   If you already have current IRB approval for the storage of samples and/or data in a repository and the repository is located at OHSU, you must complete a series of new questions in the eIRB at your next continuing review. You will also need to ensure that you have submitted a repository protocol. This is almost always a separate document from your study protocol, but may be incorporated into your existing protocol. The required elements for a repository protocol can be found in the IRB Help Sheet – Repository Protocol Checklist, available on the [repository website](#). If you don't want to wait until your next continuing review to come into compliance with the policy, or you have already had a continuing review since August 20, 2010 but have not yet come into compliance, you can do it via modification. All repositories must be compliant with the policy by August 31, 2011.

9. **What are the requirements for repositories maintained by study sponsors, cooperative groups, or other institutions outside OHSU?**

   If the data and/or samples you collect in a study will be stored in a repository outside OHSU, you need IRB approval to store the data and/or samples as part of your protocol, but you do not need IRB approval for the management of the repository itself. You will have the opportunity to select the non-OHSU repository option in the eIRB when you submit your study for initial review, and you will be directed to answer a few questions about the non-OHSU repository.

   If you already have approval for a study that includes the storage of data and/or samples in a non-OHSU repository, an IRB analyst will be contacting you at your next continuing

review or sometime before August 31, 2011 to ensure that the IRB has all of the needed information concerning the repository.

10. **What do I need to do if the data or specimens that I collect in a study are being stored in an OHSU repository, but the repository is managed by someone else (for instance, a department-wide database)?**

    You will have the opportunity, either at initial submission or at your next continuing review, to select the "Stored in an existing OHSU repository not maintained and operated as part of this project" option in the eIRB and enter the IRB number for the approved repository in which you intend to store data/samples. You do not need to submit any additional information about the repository.

    If the study is active, revisions to the consent and authorization forms and protocol may be necessary if they do not already describe the storage of data/specimens in a repository.

11. **If I have a number of currently IRB approved studies that include repositories, could I combine all of them into a single repository submission?**

    Yes. If you are maintaining IRB approval for studies that are virtually complete, but you want to retain the option of using the data/specimens for future research, publishing, etc., it may be beneficial to consolidate them into a single repository submission, with only one annual review. If the studies are very different, however, or the type of consent obtained in these studies varies widely, it may be difficult to manage this type of information in a single repository. You must be able to establish a management and tracking system which helps you to ensure that no data and/or specimens will be used for a purpose inconsistent with the original subject's consent.

12. **My approved research study includes banking of data and/or samples for future research. Once my study is complete, can I transition the banking portion of my study into a repository?**

    Yes, you can do this by submitting a "Repository Only" submission in the eIRB, then terminating your original study. Please see the Transitioning Study Decision Tree for further guidance on whether this option best fits your situation.

13. **Will OHSU's repository policy coincide with the policies of other institutions?**

    In most cases, yes. Defining and maintaining repositories is a national initiative in light of current legal and ethical considerations involving stored data and biological specimens. OHSU is working closely with its most frequent partners to standardize the process and facilitate research collaboration with other institutions. OHSU is committed to resolving any difficulties that may arise between institutions regarding repository maintenance and research.

14. **Is the PI of a repository always the "guardian?"**

No. The PI may be the guardian, or the PI may delegate someone else as the guardian, such as a co-investigator or study staff. The guardian should be someone who is willing and able to oversee and track all submissions, maintenance activities, and releases. However, the PI is ultimately responsible for keeping the repository in compliance with OHSU policy and regulatory requirements.

15. **Are there any special requirements for repositories that hold samples used for genetics research?**

Yes. Repositories that hold samples for genetics research must include a plan for compliance with the Oregon Genetic Privacy Law. This includes repositories that already contain genetic information as well as repositories where there is **any potential** of using stored specimens for genetic analysis in the future.

Individually identifiable genetic information and biological specimens **MAY NOT** be released from a repository for genetic research unless informed consent to genetic research is or has been obtained.   The IRB cannot grant a waiver for such research. For this reason, the IRB highly recommends getting informed consent for genetic research upfront if there is any chance that data/specimens will be stored and used later for genetic research.

If no such consent was obtained, the researchers desiring to use the data/specimens must request a waiver of consent from the IRB in order to use them for genetics research.   Only anonymous or coded (such that the investigator doing the research does not receive any identifiers) genetic research can be done pursuant to a waiver. For coded genetic research using stored specimens, genetic opt-out status must first be verified with the Information Privacy and Security office.

If genetic opt-out status cannot be verified because samples are not identifiable and/or there is no known history of opt-out, the samples cannot be used for genetic research.

Refer to the IRB's Genetic Research webpage for more information.

16. **Are the fees different for submissions involving a repository?**

No. The fee structure is the same and only applies to industry sponsored studies.

17. **Do I need to specify where the data or specimens in my repository are coming from? Can I list multiple sources? Do I need a modification every time I get a new source?**

The "Defining the OHSU Repository" page in the eIRB will ask for the sources of the data and/or samples. You will be required to list all sources.

If you anticipate collecting data/specimens from a variety of sources and this collection will be ongoing, describe in your repository protocol the general criteria that must be met in order to admit data/specimens into your repository. A modification is not required

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for each individual submission if the submission is consistent with the description of sources in your protocol. However, each submission should be tracked on a tracking spreadsheet for continuing review. You will also be able to update the list of sources in the CRQ (continuing review questionnaire) form in the eIRB.

18. **According to the Transitioning Study Decision Tree, if I have an approved study that includes storing data and/or samples for future research, I have a choice of keeping it open as a full study or transitioning it to a repository and developing a repository protocol. Is there a point at which I am REQUIRED to turn it into a repository?**

Yes, you are required to transition the study to a repository when the data and/or specimens are going to be used for a defined research purpose beyond what was included in the original protocol. You may, however, transition the study to a repository at any time prior to that.

19. **Our department compiles data and/or specimens from several studies for future research. How many different repositories do we need? Can we set them all to the same continuing review schedule so they are easier to manage?**

How you organize different repositories is up to you, but keep in mind that you must be able to manage each repository that you create. This means developing a repository protocol for each repository that delineates all procedures and requirements for accepting, storing, and releasing data or specimens, and being able to follow that protocol without deviation. It is possible to set several repositories to the same continuing review schedule. Please work with an IRB analyst if you want to do this.

20. **Will I still have to do continuing reviews if I have a "Repository Only" submission?**

Yes, but the process is shorter and simpler.

21. **Do I have to use the templates for repository documents, such as the repository protocol, consent/authorization form, and repository sharing agreements?**

The templates are a starting point, but you do not have to follow them exactly (other than using specifically required language, such as liability language or HIPAA authorization language). Your documents must, however, contain all required elements.

22. **Who should be listed on a repository as study staff?**

Study staff should include anyone who is involved in the management of the data and/or specimens. For instance, if you have a repository with coded identifiers, anyone with access to the master code should be listed as study staff. Persons monitoring the acceptance or release of information should also be listed as study staff. Researchers or staff from other research teams who submit materials to the repository or take information from the repository for separate research projects should not be listed as repository staff.

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23. **If I want to create a new repository that collects data/samples from my current studies, do I need to submit a modification for each of my current studies? Is there anything else I need to do with the current studies?**

    You do not necessarily need to submit a modification for each of the studies that feed into your repository. When completing the IRQ for your new repository, you'll be asked to list the IRB numbers for the studies from which you are including data and/or specimens. At each continuing review for these current studies, you will be asked to indicate the status of your repository compliance. You should select the option that indicates the materials will be stored at OHSU in a repository that is not maintained or operated as part of that study. You will then list the IRB number for the repository in the CRQ where indicated.

    You may need a modification to the current studies if they are still active and not already set up to obtain consent/authorization for banking and future research. Work with the analyst assigned to your repository submission to determine which studies require modifications.

24. **Does my new "repository only" eIRB submission also require a regular protocol, or just the repository protocol?**

    A Repository Only submission only needs a repository protocol.

25. **Do I need a lay language summary with my Repository Only submission?**

    No. The purpose statement in the repository protocol should provide a sufficient summary of the repository.

26. **We're terminating a study that collected and banked samples. Is there a way to indicate in the termination report that those samples are going into our new repository?**

    Yes, there is an open-ended question in the eIRB termination questionnaire that asks for a summary of findings, reasons for termination, and any other relevant information. You should include this in your response to that question. You may also write a memo and upload it with your termination request.

27. **Is it beneficial to de-identify the data/samples in my repository?**

    Not necessarily. While there are fewer IRB review requirements for repositories with de-identified information, maintaining identifiers (including coded identifiers) can expand the potential research uses of the information. It is certainly possible to maintain a repository with identifiers, as long as the necessary confidentiality and security protections are in place.

28. **If I have two studies, and one is set up with a repository, can I submit data/samples from the other one into the one that's compliant with our policy?**

Yes, provided that you have consent/authorization (or a waiver) to store the data and/or samples in a repository and the submittal is consistent with the repository protocol for the compliant repository. You must submit a modification to your repository if the repository protocol does not provide for such a submittal. At the continuing reviews for the non-repository study, you will be asked to give the IRB number for the repository to which you are submitting the data and/or samples.

III. Managing Your Repository

29. **Someone wants to use my data and/or specimens! Do I need to submit a modification every time data and/or specimens are released from my repository?**

Not necessarily. Your repository protocol must delineate the requirements for release of data and/or specimens to other researchers. You must have a method for assuring that all future research uses have IRB approval from the institution conducting the research, including a waiver of consent and/or authorization or a plan to re-consent where appropriate. Provided that the release of data or specimens occurs within the scope of your repository protocol, a modification is not needed. You must, however, keep track of such releases on a spreadsheet and submit them to the OHSU IRB at continuing review.

If any desired release exceeds the scope of your repository protocol, however, you must submit a modification to your repository. A modification is also needed if you are releasing identifiable data and/or specimens for a research project outside OHSU that does not have approval from any IRB. In addition, if your repository contains sensitive information or information from vulnerable populations, the IRB may require that your protocol provide for modification submissions before certain types of identifiable releases.

30. **What is the difference between a material transfer agreement and a repository sharing agreement?**

A material transfer agreement is a contract that addresses the physical transfer and ownership of specimens from one entity to another. A repository sharing agreement addresses the conditions of use of the data and/or specimens, and may pertain to data use, confidentiality protections, IRB approval between institutions, and other topics.

31. **How do we keep the IRB informed of the releases from our repository to other researchers?**

You should maintain a spreadsheet of all acquisitions and releases, and submit the spreadsheet at your continuing review. A template spreadsheet is available on our repository website for reference, but feel free to modify it to suit your needs. If an acquisition or release will occur in a different way than what is specified in your

repository protocol, you will first need to submit a modification to obtain IRB approval for that activity.

32. **How much information does the IRB want regarding any inquiries for feasibility and/or study development in my repository throughout the year? (For example, is it okay for our group to conduct data searches on the banked data to see if there is adequate data to conduct the trial?)**

These activities are generally considered Activities Preparatory to Research ("prep to research") under HIPAA. If there is no systematic investigation designed to contribute to generalizable knowledge, then they do not meet the definition of research. How to handle this depends on who is making the request:

- **If investigators want to query their own repository** (identifiable data) for prep to research purposes, no submission to the IRB is required, but the query should be documented in your tracking spreadsheet. The repository protocol should specify the procedures for handling these activities and include verification that all three criteria for prep to research activities are true:
   - Access to the PHI is limited to activities preparatory to research (such as preparing a research protocol or finding subjects to recruit)
   - Access to the PHI is necessary for the activities preparatory to research
   - The PHI will not be removed from OHSU in the course of review
- **If an OHSU investigator not listed as an investigator on the repository** wants to query identifiable data for prep to research purposes, the investigator should seek a request for determination from the IRB and submit a prep to research form. The investigator can query de-identified data with no IRB action (but this should be tracked on the repository spreadsheet).
- **If a non-OHSU investigator** wants to access identifiable data from the repository for prep to research purposes, a waiver of authorization is needed. First, verify that the investigator cannot conduct the inquiry with de-identified data, or an investigator on the repository cannot conduct the inquiry on behalf of the non-OHSU investigator. No IRB action is required if the inquiry can be done in either of these two ways. If identifiable data is truly required (this will be rare), submit a modification to the repository submission with a request for a waiver of authorization.

33. **Is a repository sharing agreement needed when I want to access data/specimens from my own repository?**

No. However, the specific research project for which you are using them needs separate IRB approval. Also, the use must be tracked on the repository tracking spreadsheet and reported at continuing review.

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34. **Can data/samples be considered "de-identified" if they are stored with coded identifiers and subsequently used for a research project by one of the investigators listed on the repository?**

> No. If the investigator using the data/samples has access to the code, they will not be considered de-identified. Likewise, investigators who submitted coded data or samples to the repository and later want to use them are not working with de-identified materials unless they were re-coded by repository staff and the investigator does not have access to the current code.

> Remember that all research with identifiable data/samples is human subjects research and requires separate IRB approval for the proposed research before the data/samples can be released from the repository.

35. **Do all faculty contributing to a department-wide repository need to sign individual submittal agreements? Can the department create one general submittal agreement? Does the one agreement need to list each individual faculty member? Do they need to be entered as Co-I's on the repository in eIRB?**

> Faculty members within a department contributing to a department-wide repository do not necessarily need to sign individual submittal agreements. Instead of using submittal agreements, you may write a procedure into your repository protocol to verify submittal criteria before these faculty members may submit data/specimens. For instance, you'll want to verify that they have a current appointment in the department, that they had IRB approval for the collection, and document any limitations on future use. If you want to use submittal agreements, you could have each investigator sign one that is modified from the template to cover repeat submissions, rather than having the same investigator sign multiple agreements.

> This method may also be used for repository sharing agreements, as long as the repository protocol states that documentation of IRB approval will be required before releasing identifiable data/specimens to a department investigator.

> It is not advantageous to list all faculty in the department as co-investigators on the repository. This makes it less likely that they will be able to access de-identified data for research. However, all individuals actively involved with repository management, including those with access to individual identifiers (such as the key to coded data) should be listed.

36. **I have a study that includes a repository. All study activities are complete, but repository activities are ongoing. What should my study status be?**

> Your study status would be "closed to enrollment." If you terminate the study and create a "Repository Only" submission for the repository, your repository status would then be "active."

IV. Consent and Authorization Issues

37. **What do I need to submit to the OHSU IRB if I am adding data/specimens to my repository that were collected from a non-OHSU site? Does the IRB want to see the original consent form or do I just need to keep a copy on file?**

    If the submittal is consistent with the criteria in your repository protocol, you don't need a separate submission to the OHSU IRB (just track it on your spreadsheet). Make sure the submitting investigator has signed a submittal agreement, which should verify the consent/authorization status of the data/samples being submitted and should state any limits imposed by that prior consent/authorization. If the investigator has documentation of IRB approval and/or the original consent form, it is best practice to keep that on file with the submittal agreement.

38. **Can I create a new repository that collects data/samples from completed studies in which subjects did NOT consent to or authorize banking and it's not practicable to re-contact them?**

    Generally, yes, but you will need to request waivers of consent and authorization when you submit the repository. You must provide the IRB with justification as to why these data and samples should be included in the repository and why it is not practicable to go back and obtain consent and authorization from these subjects. There also may be restrictions on the future use of these data and specimens. For instance, you might be required to de-identify the data and specimens before releasing them to other investigators and/or using them in future research.

    You MAY NOT include identifiable data/samples from these studies if the original terms of the consent/authorization prohibits storage or future research. In addition, you must have procedures in place to ensure that any future research uses are not contrary to any limits imposed by the original consent/authorization.

    A request for a waiver of authorization for these studies should be submitted with your repository. You should generally describe the information from all such studies in the waiver form. It should roughly parallel the description of the same information in your repository protocol. You don't need to list specific study numbers. You only need to complete one waiver form for your entire repository. The description of information covered in the waiver may be written to cover future studies conducted under a waiver of authorization as well (such as "all data from retrospective chart review studies conducted by the department of neurology from 1990 forward").

    There is no form to request a waiver of consent. Instead, include this request in your repository protocol or in a separate memo. Address the following four elements in your request:
    - Storage in the repository and future research uses will not pose greater than minimal risks to subjects;
    - The waiver of consent will not adversely affect the rights and welfare of the subjects;

- It is not practicable to obtain consent from the subjects for storage in the repository and future research; and
- If appropriate, subjects will be provided with pertinent information after the research.

39. Does the "indefinitely" in the boilerplate HIPAA language cover the requirement that people give HIPAA authorization for banking?

No. The "indefinitely" means that subjects authorize the use of their information for the purposes indicated, however long it takes to carry out those purposes. Any use that goes beyond the listed purposes is not authorized. So, if the authorization does not specifically list banking as a permitted use of the protected health information, then you do not have authorization to store it in a repository and must obtain either an additional authorization or a waiver of authorization.

40. What happens to the consent forms signed by subjects when their data/specimens are released from a repository to another location?

The subject's consent at the time data/specimens were collected defines the scope of permissible future uses of the data or specimens. You should retain a copy of the original consent/authorization, if it's available, as part of managing your repository. The recipient of the repository information might also require a copy for its own IRB approval or other purposes. You must communicate any limits on use of the data and/or specimens when releasing them to another researcher/repository for use.

41. Does it matter whether you set up a repository using a waiver of consent and/or authorization as opposed to obtaining informed consent from all subjects up front?

Yes. The permissible future uses of data and specimens are limited by the scope of the subjects' consent at the time the data/specimens were collected. Collecting data/specimens under fully informed consent, including consent to future research using the stored data/specimens that may include genetic research, provides the most flexibility in how the information may be used in the future. Data and/or specimens collected under a waiver may not be used as broadly; for instance, you may be required to de-identify them for future research, which could limit the value/extent of that research.