# Research Repository Standard Operating Procedure

## Who should use this Research Repository Standard Operating Procedure

* Any investigator who is establishing a research repository containing data and/or human biospecimens
* Any investigator who is converting an existing study into a research repository containing data and/or human biospecimens

Please carefully review the following information.

## What is a research activity?

Each study using identifiable data/human biospecimens is a research activity that is separate from the repository itself.

## What is a Guardian?

Guardians are responsible for:

1. ensuring that data/human biospecimens are received and released according to USC policy and the IRB approved protocol

2. executing a usage agreement each time data/human biospecimens are released for research purposes

3. ensuring the security and confidentiality of stored data/human biospecimens

4. distributing data/human biospecimens

5. tracking acquisitions and release of data/human biospecimens

A guardian must be appointed for each research repository.

The guardian must be listed in iStar section 2 as part of the study personnel. If there is a change in guardian status, please submit a simple amendment and an updated SOP with the new guardian.

## What will I need prior to submitting to the IRB?

All prior informed consent forms and/or information sheets. This will be uploaded to iStar section 40.1

## Data that is acceptable for the repository

Research repository data **must have had** informed consent and/or information sheets that permitted the future use of data/human biospecimens by the participant. Please upload all prior informed consent forms and/or information sheets to iStar section 40.1. If prior studies were approved by the USC IRB, please include all study numbers iStar section 40.2.

# Please fill out the following sections

## General Information

Research Repository Title:

PI Name:

## Purpose of Research Repository

What is the purpose of the repository? Please describe in paragraph format.

## Description of Repository

What kind of data/human biospecimens will be included in the repository? Please fill out the following table for each kind of data [e.g., medical records/tissue samples/survey data]. Be as specific as possible. Insert rows as needed.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Data/human biospecimens to be collected?** | **How will you collect the data/human biospecimens?** | **Where will you collect the data/human biospecimens?** | **How long will you store the data/human biospecimens?** | **Who is the data/human biospecimens guardian?**  | **Who will be responsible for maintenance of data/human biospecimens?** | **Who will have access to the data/human biospecimens?** | **Will data/human biospecimens be identifiable?** |
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## Description for other investigators who want access to this repository.

How will other investigators request data/human biospecimens from the repository, please describe the entire process in paragraph format?

## Information and Sharing

Please copy and the paste the exact list of the kinds of data/human biospecimens that will be placed in the repository from above in the first column of this table. Next, address each question.

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| --- | --- | --- | --- | --- | --- |
| **Data/human biospecimens be collected? (Please copy and paste from the list above. For each type of data please address each question).** | **Will the investigator need IRB review from their institution?**  | **Will a** [**Certificate of Confidentiality**](https://grants.nih.gov/policy/humansubjects/coc.htm) **be obtained to protect the confidentiality of the repository data/human biospecimens?** | **Will a data use agreement be required?** | **Was HIPAA Authorization given in order to access medical records data?** | **Will the investigator be required to sign documents? If ‘Yes’, specify which documents.** |
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## Security and confidentiality measures

Describe the plan to protect identifiers, as applicable, from improper use or disclosure in paragraph format.

How will data/human biospecimens be transferred securely?

**Please confirm:** Separate IRB approval/determination will be required for each specific human participant research activity that uses identifiable data/human biospecimens from the repository. Each study using identifiable data/human biospecimens is a research activity that is separate from the repository itself.

[ ] I confirm that Separate IRB approval/determination will be required for each specific human participant research activity that uses identifiable data/human biospecimens from the repository.