

SPECIMEN PROCUREMENT SERVICE
CENTER CARLE FOUNDATION HOSPITAL
TERMS
PHONE: 217-326-0421 FAX: 217-383-3466

IMPORTANT INFORMATION REGARDING TERMS OF SPECIMEN PROCUREMENT SERVICE CENTER (SPSC) SERVICES

1) Biosamples will be provided in one of three formats with regard to subject identity:

Anonymous: The biosample is stripped of all identifying information. Only basic demographic data available at the time of collection is provided. **No other clinical or pathologic data can be provided.** The Carle Foundation Hospital Institutional Review Board has determined that samples provided in this manner are exempt from Institutional Review Board (IRB) oversight.

Coded-linked: The biosample is stripped of all identifying information, and is given a code number that is linked to subject identity in the SPSC files. **You will not be given the subject's identity for any reason**, but de-identified clinicopathologic data and clinical follow-up may be provided by the SPSC. While such studies may qualify for IRB exemption, the IRB will make this determination. **A copy of IRB exemption or approval must accompany this application.**

Identified: The biosample is given to you with subject identifying information or you are provided the linking information to a code number. **This requires IRB review, and a copy of the approval must accompany this application.** You are responsible for complying with the subject informed consent procedures stipulated by the IRB approved protocol.

De-identified: Removal of health identifiers that can be tied to an individual. Under the Health Insurance Portability and Accountability Act (HIPAA) this includes the following 18 identifiers:

1. Names (Full or last name and initial)
2. All geographical identifiers smaller than a state, except for the initial three digits of a zip code if, according to the current publicly available data from the U.S. Bureau of the Census: the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
3. Dates (other than year) directly related to an individual. This includes date of service/collection.
4. Phone Numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health insurance beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers (including serial numbers and license plate numbers)
13. Device identifiers and serial numbers;
14. Web Uniform Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger, retinal and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code except the unique code assigned by the investigator to code the data

The investigator must agree not to seek to obtain subject identity for biospecimens received as anonymous or coded-linked, and to follow all Carle Foundation Hospital Research policies and procedures regarding human subject research by signing the Investigator agreement at the end of this section.

2) Infectious biohazards

The SPSC does not screen samples or subjects for any type of infections, and therefore the researchers and all laboratory personnel should observe universal precautions. **You must understand that in receiving anonymous or coded-linked samples, subject identity cannot or will not be disclosed even in the event of exposure of research personnel to potentially infectious material.** It is assumed the investigator adheres to all Carle Foundation Hospital Research policies, procedures, and regulations regarding biohazardous materials, including the appropriate training of, and notification of risk to, all personnel exposed to these materials.

3) Material transfer

All Carle Foundation Hospital Research policies and procedures regarding transfer of material to a third party apply to these biospecimens. **The transfer of coded-linked and/or identified human materials to individuals or entities not authorized by the IRB is a violation of Federal Law.**

4) Biorepository Fees

The current fee structure may be obtained on the Biospecimen Request Form.

5) Publications

To justify the investment by Carle Foundation Hospital in this facility, you must agree to acknowledge the contribution of the SPSC and Carle Foundation Hospital Research in any publications arising from the use of these biosamples. We also request that a copy of the manuscript(s) be sent to us upon publication.

6) Review of Specimen Use Requests

The Feasibility Review Committee (FRC) reviews all research proposals that will be conducted in part or in whole at Carle Foundation Hospital. Each FRC will meet on a regular basis in order to consider the feasibility and scientific merit of proposed studies prior to submission of any proposal to an IRB.

The level of review and administrative actions required by the SPSC may depend on the type of requests, such as.

- Requests for rare specimens and potential competition for their use
- Request for large amounts of data
- Request that require additional processing, pre-analysis, or special handling by the SPSC staff.

Specimen distribution is also based on a defined priority order of usage for investigators involved in a particular research field.

- Carle Physician Investigator Projects
 - Externally funded, peer-reviewed research projects (NIH, etc.)
 - Internally funded projects
 - Externally funded contracts with vendors
- NON-Carle Investigator Projects
 - Externally funded, peer-reviewed research projects (NIH, etc.)
 - Institutionally funded research projects
 - Externally funded contracts with vendors

The items listed above are primary considerations for the SPSC to determine the proper utilization of biospecimens. However, the SPSC may decide that additional considerations need to be made on a case-by-case determination.