



Title:	Research Involving Coded Private Information or Biological Specimens		
SOP Number:	3801	Effective Date:	June 2, 2017
Previous Version Dates:			

1 Research Involving Coded Private Information or Biological Specimens

1.1 Biological Specimens

All activities involving the collection of human biological specimens for research purposes, as well as the research use of specimens collected for clinical care, must be conducted under the terms of an IRB approved research protocol. The collection and use of human biological specimens (either identifiable or de-identified) must comply with all applicable laws and regulations for research involving human biological specimens or superseding requirements.

1.2 Regulatory Oversight

Under HHS regulations, a human subject is a living individual about whom an investigator conducting research obtains

- data through intervention or interaction with the individual, or
- identifiable private information

Whether research involving biological specimens meets the definition of human subjects research is based on a) how the specimens were obtained and b) whether the specimens include identifiable private information. If the specimens are obtained specifically for research purposes, then they have been collected through intervention or interaction with the individual and, thus, the research meets the definition of human subjects research. If the specimens were not collected for research purposes but as part of routine clinical care or other non-research purpose, then the research only meets the definition of human subjects research if the specimens include identifiable private information (See below for policies on coded specimens).

An exception to this is federally-funded research involving Newborn Blood Spots. Per the Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240), federally-funded research funded using newborn dried spots is considered human subjects research regardless of whether the specimens are identifiable. Further, the law eliminates the ability of the IRB to approve alterations or waivers of informed consent under 45 CFR 46.116(c) and 116(d) for research involving newborn dried blood spots.

1.3 Research use of cord blood from births at UNC Hospitals

According to UNC Hospitals policy (February 15, 2000), any collection for research use of placental tissue, umbilical cord tissue or cord blood from births at UNC Hospitals will require written consent of the mother. Investigators seeking to acquire such specimens for research use should prepare an IRB application including a consent form. They must also notify the Department of OB/GYN, since protocols involving obstetrical patients also require review by the OB/GYN Department Research Committee and requests for cord blood may need to be prioritized. Investigators will be responsible for making arrangements for obtaining consent and collecting the specimens.

This policy is based on the following considerations:

1. Cord blood and placental tissue are a unique source of stem cells and other biologic materials, with great therapeutic potential. Consequently there is increasing demand.
2. Certain research uses of these tissues already require informed consent. In particular, the recent designation of UNC Hospitals as a collection site for an NHLBI-sponsored Cord Blood Bank for stem cell research will result in approaching most if not all mothers for permission to collect cord blood for this purpose.
3. Certain ethnic groups do not view the placenta and placental blood as waste, but as sacred objects. Using tissues from such persons without their consent would constitute a serious violation of their rights.

FDA regulations do not apply to biological specimens unless they are gathered as part of a clinical investigation involving human subjects or being used to test a medical device. HIPAA does not cover biological specimens but does cover protected health information (PHI) linked to the specimens.

Registries are sometimes created by a public authority (e.g., the North Carolina Central Cancer Registry was created by the North Carolina Legislature, see [North Carolina General Statute Chapter 130A - Article 7](#)) If the research meets the definition of human subjects research, then all of the requirements of this document apply.

1.4 IRB Review

Research involving only biological specimens may be exempt under Exemption Category #4: “Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.” However, in order to qualify under this category, all of the specimens must exist prior to the research being submitted to the IRB. Additionally, this exemption cannot be applied to federally-funded research involving Newborn Blood Spots.

Non-exempt research only involving biological specimens may be eligible for expedited review if it is minimal risk and falls within one of the following categories:

- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture [with restrictions]
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.
- (5) Research involving materials... that have been collected, or will be collected solely for non-research purposes

All non-exempt research involving biological specimens that are not eligible for expedited review must be reviewed at a convened IRB meeting.

For all non-exempt research involving biological specimens, informed consent and documentation of consent is required unless waived by the IRB. Informed consent is required for all federally-funded research using Newborn Blood Spots.

1.5 Coded Human Data or Biological Specimens

The UNC-Chapel Hill IRB policy is based on the OHRP guidance document entitled, "Guidance on Research Involving Coded Private Information or Biological Specimens" (October 16, 2008 <http://www.hhs.gov/ohrp/policy/cdebiol.html>). This document:

1. Provides guidance as to when research involving coded private information or specimens is or is not research involving human subjects, as defined under HHS regulations for the protection of human research subjects (45 CFR part 46).
2. Reaffirms OHRP policy that, under certain limited conditions, research involving only coded private information or specimens is not human subjects research.
3. Clarifies the distinction between (a) research involving coded private information or specimens that does not involve human subjects and (b) human subjects research that is exempt from the requirements of the HHS regulations.
4. References pertinent requirements of the HIPAA Privacy Rule that may be applicable to research involving coded private information or specimens.

Note: The FDA definition of human subjects differs from the Common Rule definition. Use of coded specimens for FDA-regulated research such as research on In Vitro Diagnostic Devices requires assessment according to the FDA regulations and guidelines. Investigators should contact the IRB office for guidance.

For purposes of this policy, coded means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Guidance:

Obtaining identifiable private information or identifiable specimens for research purposes constitutes human subjects research. Obtaining identifiable private information or identifiable specimens includes, but is not limited to:

1. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to the investigator from any source; and
2. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that were already in the possession of the investigator.

In general, private information or specimens are considered to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Research involving only coded private information or specimens (other than federally-funded research using Newborn Blood Spots) do not involve human subjects per the Common Rule definition if both of the following conditions are met:

1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
 - There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
 - There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

In some cases an investigator who obtains coded private information or specimens about living individuals under one of the conditions cited in 2(a)-(c) above may (1) unexpectedly learn the identity of one or more living individuals, or (2) for previously unforeseen reasons now believe that it is important to identify the individual(s). If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private

information or specimens pertain, then the research activity now would involve human subjects. Unless this human subjects research is determined to be exempt, IRB review of the research would be required. Informed consent of the subjects also would be required unless the IRB approved a waiver of informed consent.

1.6 Who Should Determine Whether Coded Private Information or Specimens Constitutes Human Subjects Research

The investigator in consultation with the IRB Chair or Director of the IRB Office will determine if the research involving coded information or specimens requires IRB review following the procedures for Human Subjects Research Determinations.