

### 3 The SHIRB Review Process

The Review of research at Sunrise Health is conducted in accordance with a Federal-wide Assurance (FWA) which is an agreement with the federal government, approved by the National Institutes of Health, Office for Protection from Research Risks (OPRR). The FWA (*Appendix 9*) stipulates that Sunrise Health will protect the rights and welfare of human research subjects through a review process detailed in [45 CFR 46.](#) Through the FWA, the Sunrise Health Institutional Review Board (SHIRB) retains the sole authority at Sunrise Health for the approval of research with human subjects. SHIRB review applies to research conducted by employees, staff or others, either on the Sunrise Health premises or utilizing the facilities or resources of Sunrise Health, as well as research conducted elsewhere by Sunrise Health personnel in connection with their institutional responsibilities. The review requirements apply to all research conducted under the auspices of Sunrise Health, regardless of funding source or institutional support.

#### The Sunrise Health Institutional Review Board (SHIRB)

In order to maintain a review process that is responsive to the concerns of all involved, the federal regulations require that SHIRB membership reflect experience, expertise and diversity in academic, research and professional background, racial and cultural heritage, and a sensitivity to community attitudes. When the SHIRB reviews research involving a vulnerable category of subjects, such as cognitively impaired individuals or prisoners, it is required to include one or more individuals qualified to represent that group, either through personal experience or experience working with that population.

The SHIRB is responsible for ensuring that all approved research complies with the letter and spirit of the human subject protections regulations as well as the three principles previously defined in [the Belmont Report](#), respect for persons, beneficence, and justice. The SHIRB examines recruitment procedures, proposed remuneration (in cash or in kind), the informed consent process, and evaluate the risks and potential benefits to participants outlined in each protocol. The review will help ensure that investigators recruit subjects in an equitable, non-coercive manner; ensure that subjects are fully informed about the risks and benefits entailed in participating, and that subjects are not exposed to disproportionate risks.

The review of applications to involve human subjects in research consists of a process of **negotiation** between the investigator and the SHIRB. The process of negotiation begins with the submission of the application to the SHIRB. The SHIRB creates a dialogue with investigators regarding the risks and benefits posed to potential subjects participating in the research, the nature of the consent process, and the document that represents the legal written part of the consent process, the informed consent form. The dialogue between the SHIRB and investigators will most often take the form of correspondence resulting from the Committee review of the study. Receiving correspondence from the SHIRB is typical and should not be viewed as a negative comment about the content of the research nor is it necessarily analogous to disapproval of the study.

The SHIRB has the authority to approve, to require modification in, and to disapprove proposed human subject research. The SHIRB also has the authority to suspend or revoke its approval of ongoing research [\[45 CFR 46.113\]](#). Failure to comply with SHIRB requirements is considered

serious misconduct and may be subject to sanctions including possible termination of approved research.

### **Issues Considered by the SHIRB**

The SHIRB will consider the following issues when reviewing requests to involve human subjects in research.

#### ***Study Design:***

The SHIRB will examine the study design insofar as it has an impact on the rights and welfare of the human subjects. The OHRP indicates in the, *Protecting Human Subjects, Institutional Review Board Guide Book*, that, "...if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even inconvenience them through participation in such a study." Many experts agree that an IRB should approve only research that is both valid and of value. The Committee may request an expert consultant review or defer to a scientific review committee.

The federal regulations allow the SHIRB to approve a study design that involves deception or withholding of information if the strategies are justified and the protocol provides for a post-study debriefing of the subjects. The SHIRB may grant a waiver of the debriefing requirement if the debriefing may prove harmful to the subjects. (Please see *Chapter 4, "Informed Consent Requirements: Deception and the Withholding of Information"*, for more information.)

#### ***Risks and Benefits:***

The SHIRB will assess whether the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects, and the importance of the knowledge reasonably expected to result from the research. The SHIRB will consider only those risks and benefits that may result from the research. The federal regulations do not allow the SHIRB to evaluate the possible long range effect of applying the knowledge gained through the research. [\[45 CFR 46.111\]](#) (Please see *Chapter 5, "Risk/Benefit Assessment"* for more information.)

The SHIRB is required to review any possible benefits a subject may derive from participation in research, and/or the benefits of new knowledge that may justify asking a person to undertake the risks of the study. Payment for participating in research is not considered a benefit.

#### ***Equitable selection of subjects:***

The selection of subjects should be equitable and free of coercion. The SHIRB will consider the purpose of the research and the setting of the research. The Committee will closely examine research involving vulnerable subject populations, such as children, prisoners, subjects with cognitive disorders, or economically or educationally disadvantaged subjects. Investigators should indicate in their submission how they will avoid the appearance of coercion in the recruitment of subjects. They should also detail any extra precautions taken to safeguard the rights and welfare of subject populations. (Please see *Chapter 8, "Special Classes of Research Subjects"* for additional information regarding vulnerable subject populations.)

#### ***Identification of Subjects and Confidentiality:***

The SHIRB is required to review the method for prospective identification of subjects. They will examine the means of identifying and contacting potential subjects and the methods for ensuring the subjects' privacy and confidentiality. Investigators are required to submit plans for ensuring the confidentiality of subjects. (Please see *Chapter 4, "Informed Consent Form Requirements: Confidentiality"*; *Chapter 6, "Selection & Recruitment of Subjects"* and *Chapter 7, Responsibilities of Principal Investigators: "Confidentiality"* for more information.

***The Informed Consent Process:***

The SHIRB will carefully review the informed consent process: when, where and how consent is obtained and any provisions for the ongoing consent of subjects. (Please see *Chapter 4, "Informed Consent Requirements"* for more information.)

***Qualifications:***

The SHIRB will examine the qualifications of investigators. Procedures requiring special skills on the part of the investigators, licensure, accreditation, and/or experience in qualifying the investigator for the performance of the proposed procedures are reviewed by the SHIRB. In addition, the SHIRB will consider the facilities and equipment used to conduct the research and maintain the rights and welfare of the subjects.

***Additional Review:***

The SHIRB will determine whether a project requires more than annual review and may require an appropriate monitoring procedure that could include monitoring of the consent process, observation of the research procedures, and review of research related records. In some instances, the SHIRB may refer review of the research to an additional committee, such as a Data Safety Monitoring Board (DSMB) for research with cognitively impaired subjects, or an Independent Safety Monitoring Board (ISMB) assigned by the SHIRB to monitor individual projects.

**LEVELS OF REVIEW**

Applications submitted to the Sunrise Health Institutional Board (SHIRB) may undergo one of two levels of Committee review or the Sunrise Health Office of Research Compliance (SHORC) may make a determination of exemption from SHIRB review. The two committee review levels are:

1. Full Committee
2. Expedited

**Full Committee Review**

Most protocols submitted to the SHIRB require full Board review. Please note that this level of review usually takes a minimum of 21 days from the date of submission until the Board identifies necessary clarifications and modifications. In the event that no additional information or modification is required, the SHIRB may approve a study within this time period. Investigators

should be aware that initial Board review most often does not result in outright approval of the research.

The SHIRB performs a detailed examination of the protocol, informed consent form, and all supporting documentation, including any questionnaires or survey instruments. Consideration, discussion, and a vote regarding the proposed research must occur during a properly convened meeting of an SHIRB. Results of SHIRB decisions are reflected in correspondence sent to investigators within approximately ten working days following the SHIRB meeting. Letters sent to investigators will justify any conditions required for approval, may request additional information, and will indicate the next step in the review process.

The SHIRB may come to one of four determinations regarding an application:

1. Approved without questions or requests for modifications;
2. Contingent Approval (Acceptable with requests for clarification and/or modifications.)  
The SHIRB will draft correspondence to investigators requesting clarification of minor points and/or modifications to the informed consent form. An investigator's response to SHIRB correspondence may be approved by a designated Board member or sub-committee without review by the full Board. The designated member or sub-committee may not disapprove a response, instead, they may request additional information from the investigator or refer the response to the full Board for review;
3. Deferred. Studies are deferred when the SHIRB has substantive concerns or significant requests for clarification. Responses to SHIRB correspondence in this category must return to the full Board for deliberation.
4. Disapproved.

Investigators have the right to discuss SHIRB requests for revision and decisions of disapproval directly with the Committee. The SHIRB, however, retains the final authority for approval of proposed research with human subjects.

The Committee review process allows investigators various levels of appeal from the time a study receives initial review through approval or disapproval. Any and all SHIRB decisions are contingent upon the response of the investigator. If the Board finds that the negotiation is at an impasse, it may request an intramural and/or extramural independent consultant review. The SHIRB wishes to respect the investigator's intellectual property, therefore, prior to assigning a consultant, investigators are asked if there is anyone they would NOT like to review their study.

**NOTE:** Written responses to SHIRB correspondence should be submitted directly to the Sunrise Health Office of Research Compliance (SHORC). Materials for the SHIRB are only reviewed in the SHORC. Submitting SHIRB materials to any office other than the SHORC will lead to a delay in the review process and may lead to the loss of the submission.

## **IRB Meetings**

When submitting a study for full Board review, investigators should allow enough lead time for processing of the human subjects application by the SHORC prior to the SHIRB meeting. The

SHORC staff logs-in each submission and checks to ensure it fulfills all of the application requirements. The staff will inform investigators by telephone or e-mail if the application is missing elements. All complete applications are distributed to the Board. A thorough and intelligent analysis of the application requires that each Board member receive a complete set of materials to review prior to the meeting. A typical meeting agenda includes at least thirty discussion items. The members receive materials six to eight days prior to the scheduled meeting.

Investigators should be aware that it may take at least three weeks from submission to full Board review to initial correspondence.

Investigators are urged to contact the SHORC regarding SHIRB submission deadlines and the current SHIRB meeting schedule. The SHIRB meeting dates/times are determined by the end of each year for the following year. Usually, SHIRB meetings are conducted monthly, on the 1<sup>st</sup> Wednesday at 11:30 a.m. Meetings include discussions of new, continuing, and renewal applications, amendments to approved projects, reviews of adverse events, complaints from subjects, and possible violations. The Board also discusses current ethical issues, new regulations, and national trends in the field of human subject research.

### **Expedited Review**

Expedited review as defined by [45 CFR 46](#) allows an individual Committee member or a designated sub-committee of the SHIRB to evaluate and approve specific types of research. All studies received by the SHIRB are evaluated for possible expedited review. Research that involves no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories may receive expedited review. Reviewers conducting an expedited review may exercise all of the authority of the SHIRB except that they may not disapprove a study. When a reviewer or sub-committee cannot approve the research under expedited review, the study is referred to the full Board for review at the next scheduled meeting. Investigators should note that some of the expedited review categories may not apply to "vulnerable" populations, such as pregnant women, in vitro fertilization, children, prisoners, or mentally incompetent persons. (Please see *Chapter 8, "Special Classes of Research Subjects,"* for an explanation of vulnerable populations).

Interim requests or addenda, submitted between scheduled continuing reviews, that involve only minor changes in previously approved protocols or minor changes in consent forms also may qualify for expedited review. Only changes that do not increase the risk to research subjects may receive an expedited review. Modifications to approved protocols that may affect the risk to subjects are forwarded to the full Board for review.

Investigators will receive written notification of SHIRB action resulting from an expedited review. Such action may include approval or a request for further information. All research approved under expedited review must receive ratification during a legally convened meeting of the full Board.

The categories eligible for expedited review in accordance with [45 CFR 46.110](#) are:

1. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, and placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using non invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week from subjects 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra- and sub-gingival dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recordings made for research purposes such as research of speech defects.
7. Moderate exercise by healthy volunteers.
8. The study of existing data documents, records, pathological specimens, or diagnostic specimens.
9. Research on individual or group behavior or characteristics or individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

**EXEMPT FROM SHIRB REVIEW**

Research activities in which the only involvement of human subjects is in one or more of the categories listed below may qualify for a Claim of Exemption from review by the SHIRB. **These exempt categories do not apply to research involving:**

- a. **deception of subjects where the investigator does not disclose the true purpose of the research and/or the results of the subject's participation in the study** (Please see *Chapter 4, "Informed Consent Requirements: Deception or Withholding Information"* for more information);
- b. **sensitive behavioral research, or research involving pregnant women, in vitro fertilization, prisoners, the mentally disabled, or other "vulnerable" populations** (Please see *Chapter 8, Special Classes of Research Subjects* for more information).

In order to fulfill federal requirements for the proper review of research, investigators cannot "self-exempt" from SHIRB review. Determination of exempt status is performed by the SHORC in consultation with the SHIRB. Investigators are urged to consult with the SHORC staff before applying for exemption from Committee review.

**NOTE:** A Claim of Exemption does not necessarily exempt investigators from the requirement of gaining written informed consent from subjects. Most research requires the use of an informed consent form. For studies where there are no subject identifiers, i.e., anonymous data is collected; an information sheet or cover sheet is usually required. (Please see *Chapter 4, "Informed Consent Requirements"* for more information.)

Exempt categories include the following:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special educational strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Educational research proposals are exempt providing all of the following conditions are met:
  - a. All of the research is conducted in a commonly accepted educational setting (e.g., private or public school).
  - b. The research involves normal educational practices (e.g., comparison of instructional techniques).
  - c. The study procedures do not entail a significant deviation in time or effort from those educational practices already existent in the study site.
  - d. The study procedures do not involve an increase in the level of risk or discomfort beyond normal, routine educational practices.

- e. The study procedures do not involve sensitive topics such as sexual behavior of individual subjects. A sensitive survey is one that deals with socially questionable or highly personal issues or drug abuse.
- f. Provisions are made to ensure the existence of a non-coercive environment for all students, including those who choose not to participate.
- g. The school or other institution grants written approval for the research to be conducted.

Educational tests that are exempt from SHIRB review are tests of:

a) knowledge; b) mastery; and c) skills. For example the following assessment program does not include individual subject identifiers or ask sensitive information from the subjects:

*In order to evaluate the effectiveness of a high school AIDS prevention curriculum an investigator may ask questions such as:*

*"(a) Is the HIV virus carried in saliva? (b) Can condoms block the transmission of HIV? (c) Can HIV be caught by kissing?"*

*The test qualifies for a Claim of Exemption since the test is an objective assessment of knowledge that does not include individual subject identifiers or ask sensitive information from the subjects.*

The following AIDS awareness prevention evaluation requires specific sensitive behavioral disclosures on the part of the subject and would not qualify for a Claim of Exemption unless all participation is anonymous:

*(a) Have you used or will you use condoms? (b) Do you feel good about your sexuality?*

- 2. Research involving the use of educational tests (cognitive, diagnostic aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. The SHIRB is required to review copies of the informed consent form and proposed questionnaires or survey instrument(s) prior to approval and implementation.

***Anonymous data:***

Investigators should note that a survey is anonymous when there is no possible way to identify the participants from the data collected. Data are not anonymous if accessing a computer database will identify the subject. In most specific identifiers, instances, the omission of names or other data such as social security numbers, is sufficient to qualify a study as anonymous.

Sometimes an investigator may preserve a subject's anonymity while still retaining data on individual characteristics such as age, gender, ethnic origin, occupation, or diagnosis. Anonymity is possible only when studying large samples or populations. When the number of potential participants is small or the research setting is identified, anonymity can be threatened or compromised even when names are removed from the data. A case in point:

*A study consists of a survey of sociology students at a large university. The survey does not ask subjects to identify themselves by name or social security number. Subjects, however, may be easily identified by their citizenship, age, or ethnicity, which serve as markers that may compromise their anonymity.*

**NOTE TO INVESTIGATORS:** Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, is not exempt. Similarly, sensitive survey research is seldom exempt from SHIRB review (see below for exceptions). A sensitive survey includes questions about illegal activities or highly personal aspects of the subjects' behavior, life experiences, or attitudes. Examples include chemical substance abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, detailed health history, etc. *The potential for provoking a negative emotional reaction from subjects is a principal determining factor of sensitive survey research.*

Additional consideration for exemption includes whether there is a risk associated with a possible breach of confidentiality (i.e., accidental disclosure of drug use to law enforcement personnel). In surveys with potential psychological risk, review for exemption includes risks associated with surveys about sensitive topics as well as those resulting from a breach of confidentiality. When confidentiality is an issue, the presence or absence of subject identifiers may be a decisive factor.

Questionnaires or surveys covering sensitive topics may qualify for a Claim of Exemption if they fulfill the following:

- a. anonymity of the subject is guaranteed,
- b. potential subjects are informed of the sensitive nature of the topics prior to their participation, and
- c. the study does not exceed minimal risk.

(Please see *Chapter 5, "Risk/Benefit Assessment,"* for a discussion of the terms "benefit," "risk," and "minimal risk".)

In a few studies, there is a potential for identifying participants through other descriptions in the data set. The following study, if it contains sensitive content, would not qualify for a Claim of Exemption:

*A survey instrument asks college professors for their field of study and their date of degree. Some participants would be identifiable from the data alone.*

**NOTE TO INVESTIGATORS:** Research using survey or interview procedures *does not* qualify for a Claim of Exemption if children are involved as subjects. In addition, observation of children is not exempt from SHIRB review if the researcher participates in or influences the observed activities.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) (b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office or (b) federal statutes(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **Copies of the informed consent form and questionnaires or survey instrument(s) to be used must be forwarded to the SHORC for review.**
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. **The source of data, documents, records, pathological specimens or diagnostic specimens must be provided to the SHIRB.**

The term "existing" refers to the time period that the data and/or material was obtained and does not necessarily mean that the data and/or material was obtained for clinical or diagnostic purposes. The SHORC has informed the SHIRB that the term "existing" refers to material or tissue that is "archived" or "on the shelf" prior to SHIRB review of the research. The federal regulations also require that the SHIRB distinguish between *residual* material or tissue and *extra* material or tissue gathered from diagnostic or clinical procedures to be used in research.

#### ***Residual Biological Material or Tissue/A Prospective Study:***

The SHIRB is required to review research requesting the use of residual biological material, i.e., blood, tissue, other bodily fluids, etc., that is no longer needed for clinical/diagnostic purposes ("archived" or "on the shelf") if the material or tissue is not archived prior to submitting the protocol for SHIRB consideration. Exemption status is based upon whether the material is archived or exists prior to submission of the protocol for SHIRB review. For example:

*Dr. Jones knows that Dr. Smith will perform a tumor biopsy on her cancer patients. Dr. Jones wants to analyze tumor tissue in order to test a theory. Dr. Jones requests the use of the residual material, without subject identifiers, that Dr. Smith will otherwise dispose of over the next year. The research proposed by Dr. Jones will not qualify for a Claim of Exemption because the material he requests is not available until after SHIRB review of the project. In other words, the material is not archived at the time of the SHIRB review of the research.*

Since Dr. Jones' research does not qualify for a Claim of Exemption he should submit the *Application to Conduct Human Research* and other materials appropriate to the SHIRB review of the project.

The SHIRB is also required to review research with residual material where the investigator intends to identify the patient/subject donor with the acquired sample, either for future purposes or with the intent that the research results may have implications for diagnostic or clinical decisions. Please submit the *Application to Conduct Human Research* and other appropriate materials to the IRB for review of the project.

***Residual Biological Material or Tissue/A Retrospective Study:***

A study that proposes to retrospectively examine archived or residual material that does not contain patient/donor identifiers may qualify for a Claim of Exemption. For example:

*Dr. Jones knows that Dr. Smith performed tumor biopsies on her cancer patients. Dr. Jones wants to analyze tumor tissue in order to test a theory. Dr. Jones requests the use of the residual samples without patient/donor identifiers that Dr. Smith obtained through clinical biopsy over the last six months. Since Dr. Jones proposes a retrospective study of archived material without patient/donor identifiers, the project does qualify for a Claim of Exemption.*

***Extra Biological Material or Tissue/A Prospective Study:***

Requests for additional material, i.e., blood, tissue, bodily fluid, from a patient or subject who is scheduled for a diagnostic or clinical procedure are **not** exempt from SHIRB review. This type of study would prospectively, or prior to the procedure, request for research purposes, the obtaining of extra material. SHIRB review is required regardless of the amount of extra material requested and regardless of the purpose for which it is procured. Please submit the *Application to Conduct Human Research* and other appropriate materials to the SHIRB for review of the project.

**NOTE TO INVESTIGATORS:** research involving human ova (fertilized or not) is not exempt.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternative to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

This category may also be applied to service/program evaluations of State, City or County programs providing: (a) the program being studied delivers public benefits or services; (b) there is specific statutory authority over the program; (c) there is

no statutory requirement that the program evaluation plan be reviewed by an IRB; and (d) there is no significant intrusion or invasion of the privacy of the participant.

6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspections Service of the U.S. Department of Agriculture.

## **STUDY OF EXISTING DATA OR HUMAN BIOLOGICAL SPECIMENS FOR NON-GENETIC RESEARCH**

### **Existing Material/Data**

[Federal regulations](#) stipulate that "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" may qualify as exempt from SHIRB review. (Please see the previous section of this chapter, "The SHIRB Review Process, Exempt from SHIRB Review, Exemption Category #4" for more information).

For example, research using medical records would be exempt from SHIRB review under the federal regulations if the records

1. exist prior to the initiation of the research project; and if
2. the investigator records the information in such a manner that subjects cannot be identified directly or through identifiers.

For example: *Dr. Smith requests records from the State Department of Health regarding people who have used a specific service. The research may qualify for a Claim of Exemption if the investigator receives records from the agency that do not include any subject identifiers, such as names, social security numbers, addresses, etc.*

*If Dr. Smith receives the data from the State with social security numbers, the identifying numbers pose a potential breach of privacy and confidentiality, are no longer anonymous, and require review by the SHIRB.*

Archived pathology or diagnostic specimens that are considered *residual biological material* and are destined to be destroyed can be used in research and are considered exempt from SHIRB review if there are no patient identifiers linked to the specimen and if the data is not intended to be used in the diagnosis or treatment of a patient. If either of these conditions applies, consent of the research subject is required and the study is not exempt from SHIRB review. (Please see the previous section of this chapter, "The SHIRB Review Process, Exempt from SHIRB Review," for more information.)

<b>NOTE:</b>	If the data/specimens are collected after the submission of the SHIRB application, the data is not pre-existing or "archived". When the data/specimen is not "archived" or if the information is recorded with direct or indirect identifying links to subjects, the protocol requires SHIRB review and may require written informed consent.
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Research which includes review of private records involving access to and/or recording of identifiable information is *not exempt* from SHIRB review and *requires prior written consent* from the subject. The review of pre-existing public records does not require prior consent of subjects.

Records considered *private* based on federal and State statutes, including medical, insurance, and educational records, require written release by the individual subject or by the *custodian of the record* and prospective SHIRB review to be used in research.

### **Extra Material**

Specimens received as *extra material or extra specimens* requested from a physician conducting a clinical procedure are not pre-existing or "archived" and thus require written informed consent from the subject and review by the SHIRB. If there is a link to the patient's identity and a possibility that the patient may be contacted in the future, an informed consent document is required. Furthermore, informed consent is required if there is a link to the patient's identity and a possibility that the research may result in commercial or economic value.

<b>NOTE:</b>	This section does not apply to human biological specimens collected or used for genetic research. There are additional ethical concerns for genetic research that may not apply for other types of research with biological specimens. Please contact the SHORC at (702) 731-8559 for additional information.
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