Informed Consent	RSP.024.00
Effective Date	May 2016
Last Revision/Review	07/25/2023

1. Purpose

This policy provides information about the requirements for obtaining consent from research subjects or their legal guardian and defines the basic elements of informed consent. Information is also provided on waiver of informed consent.

Scope- All Burrell faculty, staff, and students involved in human subjects research.

2. Related Policy/Authority

B8530: Human Research Protection Program Statement of Compliance

3. Faculty/Staff Responsibilities

Responsible Official(s): Authorized Institutional Official for Research, Director of Research, IRB Chairperson, IRB Members.

4. Definitions/Abbreviations

Informed Consent: An agreement by the research subject to participate in the research only after all of the relevant facts regarding the project, including risks and benefits, are disclosed.

5. Procedural Steps

5.1 **Informed Consent:** Federal regulations for the protection of human subjects in research require that an investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless:

1. The research is exempt under 45 CFR 46.101(b).
2. The IRB finds and documents that informed consent can be waived (45 CFR 46.116(c) or (d)); or
3. The IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45CFR 46.101 (i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

5.2 **Documentation of Informed Consent:** When informed consent is required, it must be sought prospectively and documented to the extent required under HHS regulations at 45 CFR 46.117. Food and Drug Administration (FDA) regulations at 21 CFR 50 may also apply if the research involves a clinical investigation regulated by FDA. Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

5.3 **Waiver of Informed Consent:** The IRB may waive the requirement for obtaining informed consent or approve a consent procedure that leaves out or alters some or all of the elements of informed consent, provided that the IRB finds and documents that ALL of the following four criteria are met:

1. The research involves no more than minimal risk to the subjects.
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
3. The research could not practically be carried out without the waiver or alteration.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

5.4 **Basic Elements of Informed Consent:** The following basic information shall be provided to each subject unless specific exceptions have been reviewed and approved by the IRB.

1. A statement that the study involves research, and explanation of the purposes of the research and the expected duration of the subject's participation.
2. A description of the procedures to be followed, and identification of any experimental.
3. A description of any reasonably foreseeable risks or discomforts to the subject.
4. A description of any benefits to the subject or to others which may reasonably be expected from the research.
5. A disclosure of appropriate alternative procedures of courses of treatment, if any, that might be advantageous to the subject.
6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
7. For research involving more than minimal risk, an explanation of whether any compensation and medical treatments are available if injury occurs, and if so, what they consist of or where further information may be attained.
8. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

5.5 **Additional Elements of Informed Consent:** When appropriate, the IRB may require one or more additional elements of information to be provided to each subject. Additional elements include but are not limited to the following:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigators without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and
6. The approximate number of subjects involved in the study.

6. Reports/Charts/Forms/Attachments/Cross References

7. Maintenance

This SOP is reviewed no less than annually by the Office of Research.

8. Signature

Approved by	8/9/2023
Assistant Dean of Research	Date

9. Distribution List

Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/ Replacement Procedure? (if applicable)	Approval Date
7/25/2023		Converted from Policy Dated May 2016		8/9/2023