Burrell College of Osteopathic Medicine Research Activities That Require IRB Review And Approval	SOP #: RSP.009.03
Effective Date	11/11/19
Last Revision/Review	07/09/2020, 11/30/2021 4/1/2023, 11/06/2025

1. Purpose

To document the procedures and provide guidance for the Burrell College Institutional Review Board to determine whether an activity requires IRB review and approval.

2. Related Policy/Authority

Statements of Regulatory Compliance
45 CFR 46: Subpart A
RSP.001_Case-Report-and-Case-Series-3

3. Faculty/Staff Responsibilities

Execution of SOP: Principal Investigator (PI)/Study Personnel, Assistant Dean of Research and Sponsored Programs, IRB Chairperson, IRB Members, ORSP Staff, Institutional Official (I.O.) for Research.

4. Definitions/Abbreviations

4.1 Human subject- a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens: or (ii) Obtains, uses studies, analyzes or generates identifiable private information or identifiable biospecimens.

4.2 Intervention- includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

4.3 Interaction- includes communication or interpersonal contact between investigator and subject.

4.4 Private Information- includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to obtain the information to constitute research involving human subjects.

4.5 IRB- an institutional review board established in accordance with and for the purposes expressed in this SOP.

4.6 IRB approval- the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

4.7 IRB exempt determination- research activities in which involvement of human subjects falls within one or more of the Exempt Categories (Exempt Category I-VIII), in accordance with 45 CFR 46.104. The determination of exempt status is made by the IRB Chairperson or designee.

4.8 IRB expedited review- review procedure conducted by the Chairperson or by one or more experienced IRB members designated by the Chairperson rather than by the full convened IRB. Research activities meeting the criteria of presenting no more than minimal risk to human subjects and involving only procedures listed in specified categories, may undergo expedited review, in accordance with 45 CFR 46.110 and 21 CFR 56.110. The review follows specific categories established by the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA).

4.9 Full Board/Committee Review- review of research involving human subjects that does not qualify for exempt or expedited review procedures. Such research is reviewed at a convened meeting of the IRB, at which a majority of the members are present (including at least one member whose primary concerns are in nonscientific areas), and approval is granted only when a majority of those present vote in favor. This review process is conducted in accordance with 45 CFR 46.108 and 21 CFR 56.108.

5. Procedural Steps

The College shall ensure the protection of human subjects in research through the College's Office of Research & Sponsored Programs (ORSP). The ORSP shall provide administrative oversight of all research conducted at the College and ensures institutional compliance with appropriate federal, state, and local regulations as well as College policies as stated in Burrell College Statements of Regulatory Compliance, whether they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

5.1 Investigator Responsibilities

5.1.1 It is the investigator's responsibility to make sure that IRB review and approval or an exempt status determination is obtained prior to initiation of any research involving human subjects.

5.1.2 It is the investigator's responsibility to make a preliminary assessment as to whether or not the information collected will be used to contribute to generalizable knowledge.

5.1.3 If the investigator is not sure whether his/her project qualifies as "human subjects and research", the investigator must contact the IRB Chair or Authorized Institutional Official (I.O.) for Research for advice.

5.1.4 The IRB Chair will make a final determination whether the project requires or does not require IRB review or approval. The IRB Chair may seek input from members of the IRB and will delegate this responsibility to the IRB Vice-Chair or other IRB members in the event of conflicts of interest.

5.1.5 The IRB Chair communicates with the investigator in writing. Copies of the correspondence are kept on file in the IRB files with the protocol.

5.2 IRB Responsibilities

5.2.1 IRB Chair

5.2.1.1 The IRB Chair will review the protocol upon receipt and decide as to the level of review. The IRB chair may consult the IRB Vice Chair, other members of the IRB or the I.O., for advice if necessary. In the event a conflict of interest exists, the IRB Chair shall recuse themselves from this stage of the review process, and the responsibilities will be handled by the IRB Vice-Chair or another member of the

IRB who does not have a conflict with the proposal. The Decision Charts for IRB developed by the NIH Office of Human Research Protection serve as guidance with the understanding that the IRB Chair's decision may include protocol-specific reasons and may not always follow the charts.

5.2.1.2 Levels of Review

Exempt Review: Research activities in which the only involvement of human subjects presents no greater than minimal risk to subjects and fits into one or more categories defined below may be exempt from requirements of 45 CFR 46. The determination of Exempt status must be made by the IRB chairperson, designee, or knowledgeable ORSP staff member upon review of a request for determination of exempt status and shortened application from the investigator. If the research is found to be exempt, it need not receive full committee or expedited review. The research may not begin until the investigator has received notification by a formal determination letter that the research qualified for exemption. The following types of research may be eligible for exempt review:

Exemption 1: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if additional criteria of 45 CFR 46 are met.

Exemption 3: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection if additional criteria of 45 CFR 46 are met.

Exemption 4: Secondary research for which consent is not required or Secondary research that uses identifiable private information or identifiable biospecimens, if additional criteria of 45 CFR 46 are addressed.

Exemption 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study,

evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies, if additional criteria of 45 CFR 46 are addressed.

Exemption 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.

Exemption 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if additional criteria of 45 CFR 46 are met.

Expedited Review: Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46 and 21 CFR 56. The expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46. Categories eligible for expedited review are:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
    b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and

the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;(c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected

solely for non research purposes (such as medical treatment or diagnosis) that is not exempt. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior that is not exempt (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Committee Review: Review of research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present (i.e., a quorum), including at least one member whose primary concerns are in nonscientific areas, except where expedited or exempt review is appropriate as defined in 45 CFR 46. Approval of research is by a majority vote of this quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further official actions or votes unless the quorum can be restored.

5.2.2 Institutional Review Board (IRB)

The IRB, in their deliberations of protocols, will utilize resources listed under

Sections 5.3 of this document for guidance in deliberations and actions on protocols. In interpreting regulations, the IRB will interpret mandatory items as those preceded by the terms “shall” and “must”. Mandatory items must be followed according to federal regulations. Items preceded by “should” are viewed as suggestions which are typically discussed more in the context of best practices, institutional practices, and protocol specifics.

5.3 NIH Office of Human Research Protection Decision Charts for IRB

5.3.1 Human Subject Regulations Decision Charts

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The charts address decisions on the following:

- whether an activity **is research** that must be reviewed by an IRB
- whether the research is eligible for an **exemption**
- whether the review may be performed by **expedited procedures**, and
- whether **informed consent** or its documentation may be waived.

5.3.2 Considerations for Use of Charts

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. The charts do not address requirements that may be imposed by other organizations, such the Food and Drug as Administration, National Institutes of Health, other sponsors, or state or local governments.

The relevant decision charts are provided here for reference: Human Subject Regulations Decision Charts: 2018 Requirements

HUMAN SUBJECT REGULATIONS DECISION CHARTS: 2018 REQUIREMENTS

OHRP Office for Human Research Protections

NOTE: This guidance is consistent with the 2018 Requirements (i.e., the revised Common Rule).

For use after January 20, 2019

SCOPE: The following graphic charts are intended to aid those who need to decide if an activity is research involving human subjects that must be reviewed by an institutional review board (IRB) and whether informed consent or the documentation of informed consent can be waived under the 2018 Requirements found for the U.S. Department of Health and Human Services (HHS) at 45 CFR part 46, Subpart A.

TARGET AUDIENCE: IRBs, institutions, investigators, and others

CONSIDERATIONS: These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html. OHRP cautions that the full text of an applicable regulatory provision should be considered in making final decisions. The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, the National Institutes of Health, other sponsors, or state or local governments.

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

Applicable Rules and Regulations:

- 21 CFR 56.102
- 21 CFR 50
- 45 CFR 46
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
- Human Subject Regulations Decision Charts
- Office for Human Research Protections (OHRP)

7. Maintenance

Assistant Dean of Research and Sponsored Programs, IRB Chairperson

The SOP will be reviewed as needed but not less than annually.

8. Signature

Signature on File	11/06/2025
Department Head of Research and Sponsored Programs	Date

9. Distribution List

Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/ Replacement Procedure? (if applicable)	Approval Date
1	5.3.2	NIH Revised Charts Inserted		07/09/2020
11/30/2021		Reviewed: No Changes Needed		12/06/2021
11/07/2025	All	Revised SOP: Added working links to related policies, included additional definitions, updated procedural steps, formatting, clarification, added link to decision charts, removed inserted charts, updated responsible party titles.		11/07/2025