# Burrell College of Osteopathic Medicine

**Research Activities That Require IRB Review And Approval**

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## 1. Purpose

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

## 2. Related Policy/Authority

- B8530 Human Research Protection Program Statement of Compliance
- 45 CFR 46: Subpart A

## 3. Faculty/Staff Responsibilities

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

## 4. Definitions/Abbreviations

- **Research** - is defined in the [BCOM Human Research Program Statement of Compliance, B8530](#). Activities which meet this definition constitute research for purposes of this SOP, whether or not 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.

- **Human Subjects** - is defined in the [BCOM Human Research Program Statement of Compliance, B8530](#).

- **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.

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

- **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 for obtaining the information to constitute research involving human subjects.

4.6 IRB- means an institutional review board established in accord with and for the purposes expressed in this policy.

4.7 IRB approval- means 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.

5. Procedural Steps

5.1 Investigator Responsibilities

5.1.1 It is the investigator’s responsibility to make sure that IRB review and approval 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. At BCOM, the I.O. is the Assistant Dean for Research.

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 member 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 make a determination as to the level of review. The IRB chair may consult the IRB Vice Chair, other members of the IRB or Institutional Official for advice if necessary. In the event of conflicts of interest by the IRB Chair, the IRB Chair shall recuse 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 for the decision with the understanding that the IRB Chair’s decision may include protocol specific reasons for classification of the proposal for review and may not always follow the decision charts.

5.2.1.2 Levels of Review

5.2.1.3 Exempt Review: Research activities in which the only involvement of human subjects present no greater than minimal risk to subjects and fit 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 or 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:

A. **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.

B. **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.

C. **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.

D. **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.

E. **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.

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

G. **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.

H. **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.

5.2.1.4 **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. 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.

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

5.2.1.5 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, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum), 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 actions or votes unless the quorum can be restored.

5.2.2 Institutional Review Board (IRB)
   5.2.2.1 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 as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

The following charts are provided in subsequent pages:

- Chart 1: Is an Activity Research Involving Human Subjects?
- Chart 2: Is the Research Involving Human Subjects Eligible of Exemption Under 45 CFR 46.101(b)?
- Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?
- Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?
- Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?
- Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?
- Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?
- Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?
- Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?
- Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?
- Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here.

Is it research?

Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge? [45 CFR 46.102(d)]

YES

Activity is research. Does the research involve human subjects?

Does the research involve **obtaining information about living individuals**? [45 CFR 46.102(f)]

NO

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

NO

The research is not research, so 45 CFR part 46 does not apply.

YES

Does the research involve **intervention** or **interaction** with the individuals? [45 CFR 46.102(f)(1), (2)]

NO

NO

BUT

Yes

Activity is research involving human subjects. Is it covered by the regulations?

Is it **conducted or supported by HHS**? [45 CFR 46.101(a)(1)]

YES

NO

Does the institution hold an FWA under which it applies 45 CFR 46 to all of its human subjects research regardless of the source of support?

YES

The research involving human subjects is **covered by the regulations**.

NO

The research involving human subjects is **NOT covered by the regulations**.

NO

BUT

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

GO TO Chart 2

Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A applies to the research, and as appropriate subparts B, C, and D also apply.

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Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

**NO**

Will the only** involvement of human subjects be in one or more of the following categories?

Research conducted in established or commonly accepted educational settings, involving normal education practices?

- Yes → Exemption 45 CFR 46.101(b)(1) may apply → Go to Chart 3

- If not exempt under (b)(1)
  - Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
    - Yes → Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply → Go to Chart 4
    - If not exempt under (b)(2) or (b)(3)
      - Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?
        - Yes → Exemption 45 CFR 46.101(b)(4) may apply → Go to Chart 5
        - If not exempt under (b)(4)
          - Research studying, evaluating, or examining public benefit or service programs?
            - Yes → Exemption 45 CFR 46.101(b)(5) may apply → Go to Chart 6
            - If not exempt under (b)(5)
              - Research involving taste and food quality evaluation or consumer acceptance studies?
                - Yes → Exemption 45 CFR 46.101(b)(6) may apply → Go to Chart 7
                - If not exempt under (b)(6)

**NO**

**“Only”** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

**YES**

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research **only** conducted in **established or commonly accepted**
educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

**"Only"** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.

NO

Research is not eligible for 45 CFR 46.101(b)(1) exemption.

YES

Does the research study involve only **normal education practices**? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)

NO

Return to Chart 2 and consider whether 45 CFR 46.101(b)(2) exemption applies.

YES

Research is eligible for 45 CFR 46.101(b)(1) exemption from 45 CFR part 46 requirements.

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Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

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Does the research involve only* the use of educational tests, survey procedures, interview procedures, or observation of public behavior? **"Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

Does the research involve children to whom 45 CFR part 46, subpart D applies?

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects’ responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation?

**Research is not eligible for exemption under 45 CFR 46.101(b)(2).**

Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

**Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.**

Return to Chart 2 and consider whether 45 CFR 46.101(b)(4) exemption applies.
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?

From Chart 2

Does the research involve only** the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? **
("Existing" means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

YES

Are these sources publicly available?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

Return to Chart 2 and consider whether 45 CFR 46.101(b)(5) exemption applies.

* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html, and on coded data or specimens at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html for further information on those topics.

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Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.

YES

Does the research or demonstration project involve **only** the study, evaluation, or examination of:

Public benefit or service programs;

YES

Procedures for obtaining benefits or services under public benefit or service programs;

YES

Research is eligible for exemption under 45 CFR 46.101(b)(5) from 45 CFR part 46 requirements.*

NO

NO

NO

Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs;

YES

Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs?

YES

Return to Chart 2 and consider whether 45 CFR 46.101(b)(6) exemption applies.

NO

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(5).

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

From Chart 2

Does the research involve only** a taste and food quality evaluation or a food consumer acceptance study?

- **YES**: Are wholesome foods without additives consumed?
  - **YES**: Research is eligible for exemption under 45 CFR 46.101(b)(6) from 45 CFR part 46 requirements.
  - **NO**: Is food consumed that contains a food ingredient, agricultural chemical, or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture?
    - **YES**: Research is not eligible for exemption under 45 CFR 46.101(b)(6).
    - **NO**: Other Federal, State, and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

- **NO**: Go to Chart 8

**“Only”** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

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Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

1. From Chart 2, or 7
   - Has the research been *previously reviewed* and approved by the IRB?
     - YES
     - Is the review a *continuing review*? [45 CFR 46.100(d)]
       - NO
       - Does the research present *no more than minimal risk* to human subjects? *and* does the research involve *only procedures included in categories 1 through 7* on the list of categories of research that may be reviewed through an expedited review procedure? [45 CFR 46.110(b)(1)]
         - NO
         - Go to Chart 9
         - YES
         - Review by convened IRB is required.
           - YES
           - Are measures in place to make risks no more than minimal?
             - NO
             - Go to Chart 10
             - YES
     - NO
       - Is the research *classified*? [Paragraph (D) of Categories of Research That May Be Reviewed By an IRB through an Expedited Review Procedure.]
         - NO
         - Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging? [Paragraph (C) of Categories.]
           - YES
           - Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution’s or IRB’s use of the expedited review procedure. [45 CFR 46.110(d)]
             - NO
   - NO


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Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

From Chart 8

Has the research been previously reviewed and approved by the IRB using expedited procedures?

YES

Have conditions changed such that the research is no longer eligible for expedited review (e.g., protocol change, or experience shows research to be of greater than minimal risk)?

YES

Review by convened IRB is required.

NO

Go to Chart 10

NO

Have any additional risks been identified since IRB review at a convened meeting?

YES

NO

Research is eligible for IRB review through expedited procedures.

NO

Category 8

(a) For this site: Is the research permanently closed to enrollment of new subjects? and Have all subjects completed all research-related interventions? and Does the research at this site remain active only for long-term follow-up of subjects?

YES

(b) Have no subjects been enrolled at this site? and Have no additional risks been identified anywhere?

NO

(c) Are the remaining research activities at this site limited to data analysis?

YES

NO

Category 9

Is the research conducted under an IND or IDE?

February 16, 2016
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

**(Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])

From Chart 8 or 9

Will the research or demonstration project be conducted by or subject to the approval of state or local government officials? [45 CFR 46.116(c)(1)]

YES

Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs? [45 CFR 46.116(c)(1)]

NO

Will the research involve greater than minimal risk, as defined in Section 46.102(i)? [45 CFR 46.116(d)(1)]

NO

Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(d)(3)]

YES

No waiver of informed consent or alteration of consent elements is allowed.*

NO

Will waiving or altering the informed consent adversely affect the subjects’ rights and welfare? [45 CFR 46.116(d)(2)]

YES

Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(c)(2)]

NO

Go to Chart 11

NO

If informed consent is not waived entirely

Will pertinent information be provided to subjects later, if appropriate? [45 CFR 46.116(d)(4)]

NO

Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.

YES

* Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html for further information on emergency research informed consent waiver.

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Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

From Chart 10

Would the consent document be the only record linking the subject and the research and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(c)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

AND

IRB may require investigator to provide subjects with a written statement regarding the research. [45 CFR 46.117(c)]

END

NO

IRB may NOT waive the requirement for a signed consent form for any subjects.

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research. [45 CFR 46.117(c)(1)]

Subject’s wishes will govern whether informed consent is documented. [45 CFR 46.117(c)(1)]

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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: Select Chart 1: Is an Activity Research Involving Human Subjects?
- Office for Human Research Protections (OHRP)

7. Maintenance

Assistant Dean for Research, IRB

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

8. Signature

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<tr>
<th>Signature on File</th>
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<tr>
<td>Joseph Benoit, PHD</td>
<td>11/11/2019</td>
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9. Distribution List

Internal/External

10. Revision History

<table>
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<tr>
<th>Revision Date</th>
<th>Subsection #</th>
<th>Summary of Changes</th>
<th>New/Cancellation/Replacement Procedure? (if applicable)</th>
<th>Approval Date</th>
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<tr>
<td>1</td>
<td>[e.g., 3.1]</td>
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