SOUTH PIEDMONT COMMUNITY COLLEGE

Monroe • Polkton • Wadesboro

IRB Policies and Procedures

Mission Statement and Overview:

The South Piedmont Community College (SPCC) Institutional Review Board (IRB) exists to review and support ethical research involving human participants in order to ensure that the rights of all participants are protected. The IRB seeks to ensure that all research is ethical, confidential, voluntary, and poses minimal risk of harm to participants.

To assure the protection of human subjects and to comply with United States Federal law including the 45 CFR 46 statute, employee and student researchers at South Piedmont Community College must submit proposals for studies involving human subjects to the College's Institutional Review Board for review and approval prior to initiating a proposed study. External researchers wishing to solicit participation from SPCC students, staff, or alumni must also submit proposals for studies involving human subjects to the College's IRB for review and approval prior to initiating a proposed study. SPCC Policy 3.10 Institutional Research Board (IRB)

- The following principles apply to all research involving human subjects at South Piedmont Community College to ensure proper safeguards are provided:
    - The legal rights of all subjects will be respected based on federal and state regulations.
    - Risks to subjects must be reasonable relative to any anticipated benefits of results.
    - Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
    - Participation of human subjects must be voluntary and the right to withdraw at any time must be provided. Information provided to subjects in order to gain consent must be adequate, appropriate, and presented in language that is suitable and fitting to the subject population.
    - All research programs that involve human subjects must be reviewed by the IRB and must receive approval prior to initiation.
    - Compensation for any study should be kept to a maximum of $25. The IRB will approve or modify the amount of compensation on each application as deemed necessary.
    - In the rare instance that a study lasts longer than one year, an IRB Renewal Application must be submitted before the expiration date given on the IRB Project Review Certificate.

- Duties and Obligations of South Piedmont Community College's IRB:
    - To develop and revise IRB policies and/or procedures.
    - To distribute information to faculty, students, and other researchers regarding ethics, policies and/or procedures concerning research involving human subjects at SPCC.
    - To review human subject research requests submitted to the IRB involving SPCC staff or students including the review of informed consent and other documentation.
    - To keep records of, supervise, and track research involving human subjects at the college.
    - To suspend or terminate approval of a study, or to place restrictions on a study, when deemed to be in the best interest of the subjects in that study.

Regulations and Ethics for Protection of Human Subjects in Research

While scientific research involving human subjects can produce substantial benefits, it also has the potential for troubling ethical questions. Past abuses of the violations of the rights and welfare of human subjects have resulted in various codes and regulations at the Federal level. State and local regulations, as well as institutional policies, provide additional protection for research subjects.

Regulations are built on three ethical principles: respect for persons, beneficence, and justice. The principles govern much of the research with human subjects in the United States, as well as all research involving these subjects at South Piedmont Community College. SPCC will voluntarily adhere to the Common Rule of 45 CFR 46, which is the federal regulation administering research falling under the regulation of Department of Health and Human Services (DHHS).

Institutions that receive federal funds in support of research on human subjects are required by the DHHS to comply with federal regulations that govern such research. As part of the compliance requirements, institutions must establish an IRB that maintains responsibility for reviewing all research activities involving human subjects within the given institution, and for ensuring proper training in research ethics. **South Piedmont Community College will voluntarily enforce 45 CFR 46 as the minimum standard for all studies across the entire institution, whether or not the study is receiving governmental or external funding.**

Federal Regulations

Federal regulations are available online at www.hhs.gov/ohrp/regulations-and-policy/regulations

45 CFR 46- The National Research Act
The first federal regulation that became effective in 1974 and established the IRB system for work with human subjects.

The Belmont Report
The cornerstone statement of ethical principles for human subjects' protection. The three ethical principles of the Belmont report are:

- Respect for persons- pragmatically expressed through informed consent and through establishing protections for those with diminished autonomy. This also includes the right to confidentiality and the right to withdraw consent without consequence.
- Beneficence- the act of securing the well-being of research subjects. The researcher must do no harm and maximize possible benefits while minimizing potential harm.
- Justice- fairness in the distribution of the burdens and benefits of research. This is reflected in the regulations through review criteria requiring equitable selection of subjects.

21 CFR 50 and 21 CFR 56
These regulations require researchers seek approval from an IRB for investigational use of drugs, devices, and biologics.

The Common Rule
Though it has now been integrated into 45 CFR 46, The Common Rule provides the basis for regulations covering the protection of human subjects in research. The Common Rule was revised effective January 21, 2019.

South Piedmont Community College Members and Faculty involved in Research

The IRB is composed of a minimum of five voting members. Alternate and non-voting members may be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are designated to alternate.

No person shall be excluded from serving on the IRB. SPCC will assure diversity of representation on the IRB, including race, gender, cultural background, and academic discipline. In the instance of subjects with diminished autonomy, the IRB for that particular application may include someone with the knowledge of or experience with that population.

The IRB reserves the right to exclude a member from participation in the initial or continuing review of any project in which the member has a conflicting interest.

The IRB will include at least one member from each of the following fields:

1. An institutional research representative from the Department of Institutional Effectiveness
2. A representative from the Division of Student Services
3. A faculty member from a science area (i.e. biology, chemistry, psychology)
4. A faculty member from a non-science area (i.e. history, English, philosophy)
5. A member who is not otherwise affiliated with SPCC, or its foundation, and who is not part of the immediate family of a person who is affiliated with the college

More voting members may be appointed as deemed necessary by the President of the College or the Chief Academic Officer. The IRB Chair will be selected by the IRB membership.

Research studies at SPCC may be conducted by parties who are internal or external to the college. For studies conducted by undergraduate students, a faculty member must facilitate the study. The faculty member will be responsible for leading the study and will be known as the Principal Investigator, or PI. An undergraduate student may be named an associate PI but must have a faculty member as the PI on the study. The ultimate safety and welfare of subject's rests with the PI. The PI must design studies that are scientifically sound and that will yield valid results. He/she must also be appropriately qualified to conduct the research. PIs must ensure that research is conducted responsibly and that all research personnel are adequately trained and supervised during research.

It is the responsibility of the PI to disclose to the IRB any potential conflict of interest. If granted approval to conduct the research, he/she must execute the study according to the protocol stated by the IRB. Any new information, modifications, or adverse events must be reported to the IRB immediately.

PIs must ensure completion of the IRB process, which includes receipt of all necessary documents and obtaining an IRB approval. Research is initiated when researchers begin recruiting or contacting participants and is not permissible without IRB approval.

Operations of the IRB

1. Procedures
    a. The IRB Chair may appoint a designee from among the IRB membership to complete the following activities as needed to facilitate the timely completion of the board's activities.
    b. The IRB Chair will review all materials received and notify the PI if the application is not complete. Applications will not be reviewed until the application is completed and all required documents have been submitted.
    c. The IRB Chair will send completed applications to a second IRB member (based on area of expertise) for initial review.
    d. Both reviewers will use the decision tree in Appendix A to determine the type of review that is appropriate for the study. A third IRB member may be included if a consensus cannot be reached.
    e. Previously approved applications with minor changes will undergo Expedited Review (see criteria for minor changes in Appendix A under Expedited Review).
    f. Previously approved applications with major changes will undergo the same evaluation process as outlined in Appendix A to determine the review type.
    g. Renewal Applications, Closure Applications, and Unexpected Event Reports will be governed by the same review type as the initial application (with the same reviewers if possible).
    h. The IRB reserves the right to include additional members or the full board in the review process if criteria are unclear.
    i. Researchers will be provided a copy of the IRB Project Review Certificate, which provides the committees decision in writing. The IRB Chair will also provide any applicable feedback pertaining to modifications needed or rationale for a deferred or denied research proposal.
    j. For research proposals that require modifications, the PI has two weeks to respond to the IRB request. The IRB Chair will review the submitted information for review and approval. The PI will be contacted in writing with the final decision
    k. Any approvals made outside the full board must be shared at the next convened meeting.

2. Meetings
    a. IRB meetings are scheduled as needed.
    b. Members may participate in meetings via teleconference if participants receive full meeting materials electronically. Any members participating via teleconference must be noted in the meeting minutes. Members may not vote on proposed research outside of a convened meeting (e.g. via email prior to the convened meeting).
    c. Minutes of IRB meetings must include:
        i. Attendance at the meetings
        ii. Actions taken by the IRB (separately for each research proposal)
        iii. The vote on these actions, including specifically the number voting for, against, and abstaining
        iv. The basis for any changes required of the research or for research that is not approved.
        v. Discussion of controverted issues and how they were resolved

3. Voting Requirements
    a. In order for research to be approved, it must receive the approval of the majority of voting members.
    b. Exempt and Expedited research will require a vote from two IRB members. A third member may be asked to vote in the case a consensus cannot be reached. Decisions made for Exempt or Expedited review will be shared with the full IRB during the next convened meeting.
    c. For research requiring full review, all members present (or alternates if necessary) must vote on each proposal. A majority of IRB members must be present, including at least one member from a nonscientific area. A vote cannot take place if a quorum is not met because of member absence or recusal due to conflict of interest.
    d. Principal investigators, including those who may also be IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting.
    e. Materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. Members will be asked to sign a confidentiality form when joining the board.

4. Decisions Available
    a. Approval: The activity may start as soon as approval is received if all other relevant SPCC requirements have been met.
    b. Approval Pending with Required Modifications: Approval of a protocol will be granted by the IRB Chair after addition or removal of contingencies that are identified by the IRB during its convened meeting. Return to the full board is not required.
    c. Deferred: The protocol requires extensive modifications and must be resubmitted to the IRB for reconsideration after modifications are made.
    d. Denied: The activity may not be conducted as proposed. The researcher will be provided with written documentation of the reasons for the IRB's decision. A new application may be submitted for consideration after being revised to address the reasons for denial.
    e. Referral to Full Board: The IRB Chair may elect to send the protocol to the full board for review.

5. Documentation
   The IRB prepares and maintains adequate documentation of IRB activities, including, but not limited to:
    a. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.
    b. Copies of all correspondence between the IRB and the investigators.
    c. Other correspondence or documents generated by the IRB.

6. Document Retention
    a. All documents and records required to be saved will be retained for a minimum of three (3) years after the completion of the research.
    b. The IRB Chair will maintain a list of the current IRB members and written procedures for the IRB.

7. Conflict of Interest
   All IRB members are responsible for identifying and avoiding any situations in which they, either personally or by virtue of their position, might have a conflict of interest, or may be perceived as having a conflict of interest, in connection with a matter before an IRB of which they are a member.

   A conflict of interest may arise if an IRB member, or an immediate family member/significant other, have a financial or intellectual interest in or are receiving compensation related to a research project under review by the SPCC IRB. A conflict may also occur if an IRB member has or anticipates a financial relationship (e.g. consulting, speaking, advisory boards, patents, equity, options) that could be perceived to overlap or present a conflict of interest with a proposal under review of the SPCC IRB.

8. Training
   All IRB members will complete training regarding the protection of human research participants at least every four (4) years. Members will submit a copy of the completion certificate to the IRB Chair to be retained with IRB documents and records.

9. Non-Compliance
   Any non-compliance with IRB policies and procedures will be investigated by the Chair of the IRB. Any actions against the violator will be taken as deemed necessary.

Appendix A: Decision Tree for Research Project Review Type

This information is provided for review and consideration only. The final decision rests with the IRB. In addition to this review, the IRB will also evaluate for compliance with FERPA and HIPAA requirements.

Step 1: Is this project human subject research?

- **If no**, the IRB Chair contacts the PI via email. This study does not need to be reviewed by the IRB and the PI may proceed.
- **If yes**, continue to step 2.

- **Definition of research:**
  - Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed **not to be research**:
    - (1) **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
    - (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
    - (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
    - (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

- **Definition of human subjects:**
  - Human subject means a **living individual** about whom an investigator (whether professional or student) conducting research:
    - (1) Obtains information or biospecimens **through intervention or interaction with the individual**, and uses, studies, or analyzes the information or biospecimens; **or**
    - (2) **Obtains**, uses, studies, analyzes, or generates **identifiable private information** or identifiable biospecimens.

Step 2: Is this project exempt with no review required?

- **If yes**, the IRB Chair contacts the PI via email and provides the Project Review Certificate showing Exempt review and Approval. Use of the IRB Project Review Checklist is not required.
- **If no**, continue to step 3.

- Examples of projects that may qualify as exempt with no review required:
  - Evaluation of instructional methods
  - Assessment of student attitudes about school or learning
  - Anonymous survey with adults, regardless of content

SPCC does not utilize broad consent at this time, which is referenced in the Common Rule exemptions 7 and 8. The exemptions in this section apply to prisoners if the research is aimed at involving a broader subject population that only incidentally includes prisoners.

Exempt Review Criteria:

(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.

(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) **<u>if at least one of the following</u>** criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the **identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;

(ii) **Any disclosure** of the human subjects' responses outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** to make the determination required by §46.111(a)(7).

Exemption 2 does not apply to research with minors except for research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed. Data must also be recorded without individual identifiers or disclosure of the recorded responses would not place subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

(3) (i) 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 **<u>and at least one of the following</u>** criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the **identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, **benign behavioral interventions** are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves **deceiving the subjects** regarding the nature or purposes of the research, **this exemption is not applicable** unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) **Secondary research** for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, **if at least one of the following** criteria is met:

(i) The identifiable private information or identifiable biospecimens are **publicly available**;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that **the identity of the human subjects cannot readily be ascertained** directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);

(iv) The research is **conducted by, or on behalf of, a Federal department** or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(6) **Taste and food quality** evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or 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.

Step 3: Is this project exempt with limited review required?

- **If yes,** two IRB members review the research project using only the "Privacy, Confidentiality, and Data Management" portion of the IRB Project Review Checklist.
  - If approved, the IRB Chair contacts the PI via email and provides the Project Review Certificate showing Exempt with Limited Review and Approval.
  - If approved pending modifications, the IRB Chair contacts the PI via email and provides a description of the changes needed.
    - The IRB Chair reviews the modifications submitted by the PI and determines approval. The IRB Chair may also forward the materials to the second reviewer for a determination of satisfactory changes.
  - If deferred or denied, refer to the Full Board for Review.
- **If no,** continue to step 4.

Limited review ensures that adequate protections are in place to protect the privacy and confidentiality of data. This means that the IRB must review and approve procedures for data management and security where sensitive information is collected with direct identifiers (e.g., name, address, email, phone number, social security number, student ID, patient ID) or indirect identifiers such as a code that can link back to a subject, or data elements that could be combined to readily re-identify a subject (e.g., dates, employment history, etc.).

Limited IRB Review Criteria:

- Exemption 2, iii (page 8). Research that **only includes interactions involving educational tests**, **survey** procedures, **interview** procedures, or **observation of public behavior** where the information obtained is recorded by the investigator in such a manner that **the identity of the human subjects can readily be ascertained**, directly or through identifiers linked to the subjects.

- Exemption 3, i, C (page 8). Research involving **benign behavioral interventions** in conjunction with the collection of information from an **adult subject** through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information collection and the information obtained is recorded by the investigator in such a manner that **the identity of the human subjects can readily be ascertained**, directly or through identifiers linked to the subjects.

Step 4: Is this project an expedited study?

- **If yes,** two IRB members review the research project using all of the criteria in the IRB Project Review Checklist.
  - If approved, the IRB Chair contacts the PI via email and provides the Project Review Certificate showing Expedited review and Approval.
  - If approved pending modifications, the IRB Chair contacts the PI via email and provides a description of the changes needed.
    - The IRB Chair reviews the modifications submitted by the PI and determines approval. The IRB Chair may also forward the materials to the second reviewer for a determination of satisfactory changes.
  - If deferred or denied, refer to the Full Board for Review.
- **If no,** continue to step 5.

- Examples of projects that may qualify for expedited review:
  - Minor changes to already approved research projects.
    - Minor changes include small changes in dollar amount of incentive or slight wording changes in recruitment documents that do not substantially change participant involvement, scope of project, or confidentiality protections.

Expedited Criteria:

A. Research activities that present no more than **minimal risk** to human subjects, and **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 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the IRB.

F. Categories one (1) through six (6) pertain to both initial and renewal IRB review.

Expedited Research Categories:

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. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   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.
   b. From other adults and children, 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.
   a. Examples: (a) hair and nail clippings in a non-disfiguring 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.)
   a. 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 nonresearch purposes (such as medical treatment or diagnosis).

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

7. Research on individual or group characteristics or behavior (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.

8. Continuing review of research previously approved by the convened IRB as follows:
   a. (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.
   b. No subjects have been enrolled and no additional risks have been identified.
   c. 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.

Step 5: Does this study require full board review?

- Convene a full IRB meeting to review the proposal and vote.
  - If approved, the IRB Chair contacts the PI via email and provides the Project Review Certificate showing Full Board review and Approval.
  - If approved pending modifications, the IRB Chair contacts the PI via email and provides a description of the changes needed.
    - The IRB Chair reviews the modifications submitted by the PI and determines approval. The IRB Chair may also forward the materials to a second reviewer or the full board for a determination of satisfactory changes.
  - If deferred or denied, the IRB Chair contacts the PI via email and provides the rationale for deferral or denial. The PI may submit a new application and/or dispute the IRB's feedback.