



Medaille College

Institutional Review Board Policies & Procedures Manual

Revised July 2019

An Introduction to the Medaille College Institutional Review Board

An Institutional Review Board (IRB) is a committee designated by an institution to review, to approve the initiation of, and to conduct the periodic review of research involving human participants (sometimes referred to as *human subjects*). The primary purpose of such review is to ensure the protection of both the rights and welfare of humans who participate in research.

After multiple research ethics violations came to light (e.g., Tuskegee Syphilis Study, 1932-1972; Willowbrook Study, 1956-1970), Institutional Review Boards, or IRBs, were established around the world to ensure that the rights and welfare of all human beings who participate in research are protected. In the United States, specifically, IRB establishment was an outgrowth of multiple Senate hearings that took place over the course of 1973, followed by Congress' passing of the 1974 National Research Act. IRBs are currently regulated by the Department of Health and Human Services' Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA).

The IRB acts as an advocate for the research participant. This means that the IRB, during its review of proposed and ongoing research studies, has the right and responsibility to ensure that:

- potential research participants are fully informed of the procedures that will be involved in a study and the potential risks and benefits associated with participating in a study
- that the researcher(s) has taken appropriate steps to minimize possible risks and that such risks are reasonable in relation to potential benefits
- that an appropriate plan for obtaining and documenting informed consent is in place
- that participant privacy and confidentiality are protected throughout the course of the research.

Medaille College IRB Website

<https://www.medaille.edu/institutional-review-board>

Medaille College IRB E-mail Address

IRB@medaille.edu

Ethics Training for Research With Human Participants

<https://about.citiprogram.org/en/homepage/>

Electronic Code of Federal Regulations Pertaining to Research With Human Participants

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

Medaille College Policy on Research Involving Human Participants

The policy of Medaille College is to respect and protect the rights and welfare of all humans who participate in research. In the conduct of research, actions of Medaille College will be guided, to the extent that they are applicable, by principles set forth in such nationally accepted documents as the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (April 18, 1979). Actions of Medaille College will also conform to applicable federal, state, and local laws and regulations.

In accordance with this policy, all Medaille College research activities which will involve human participants, regardless of the level of risk foreseen, require review and approval, prior to their initiation. The IRB shall have jurisdiction over all reviews and approvals. Depending upon the nature of the proposed research, the IRB may utilize different types of reviews. For instance, research that poses more than minimal risk to participants, or involves participants from a protected/vulnerable population (e.g., pregnant women, minors, individuals with cognitive impairments, etc.), or involves the use of deception must be reviewed at a convened IRB meeting. Other research activities may be reviewed in another manner as determined appropriate by the IRB under its procedures (e.g., expedited review). An individual is considered to be at more than minimal risk if exposed to the possibility of harm -- physical, psychological, social, legal, or other -- as a consequence of participation in any research activity which departs from the performance of routine physical or psychological examinations and/or tests, or which departs from established and accepted procedures necessary to meet the individual's needs, or which increases the probability or magnitude of risks ordinarily encountered in daily life.

This policy applies to all research activities and to all development, training, and improvement or other related activities containing a research and development component. Furthermore, it applies to any such activity performed on the premises of Medaille College and to any such activity performed elsewhere by faculty, students, or employees under Medaille College auspices. The IRB has the authority to approve, to require modification as a condition of approval, and to disapprove proposed research activities that are covered by this policy. Furthermore, the IRB has the authority to determine whether or not any activity is covered by the policy and whether it requires review by an IRB.

Responsibility for Human Participants Involved in Research at Medaille College

Associate Vice President for Research, Grants, & Assessment

- Advises IRB on federal, state, and local laws and regulations pertaining to research with human participants

IRB Co-Chairs

- Conduct preliminary reviews of incoming IRB applications to determine the type of review* needed
- Assign primary review teams to IRB applications that qualify for expedited reviews
- Create agendas for all full board IRB meetings, including
 - Exempt studies
 - Expedited studies
 - Studies requiring full board review
- Provide all materials to appropriate IRB members to conduct required reviews
- Communicate IRB decisions to Principal Investigators
- Facilitate communication among IRB members

IRB Members

- Attend full board meetings
- Review expedited studies when requested by the IRB Co-Chairs
- Review all studies requiring full board review

Researchers Affiliated with Medaille College (e.g., faculty, staff, students, etc.)

- Review the Medaille College IRB Policies and Procedures Manual
- Complete required ethics training
- Obtain IRB approval for proposed research involving human participants
- Follow IRB-approved protocols for the duration of the research
- Be aware of IRB deadlines. Proposals must be turned in by the first of the month to be reviewed during that month.
- Notify the IRB at the conclusion of the research

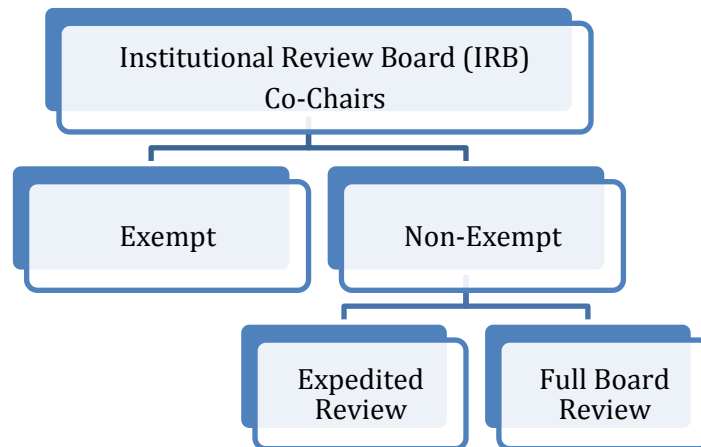
Researchers Not Affiliated with Medaille College

- Researchers who are not part of the Medaille College community, but who wish to conduct research projects involving faculty, staff, or students on the campus, are required to submit an application to the Medaille College IRB for review and approval. This includes individuals seeking to conduct either written or electronic surveys, interviews, or focus groups, in addition to other types of research activities. In addition, we ask that a faculty member or administrator formally affiliated with Medaille College be identified as a co-investigator on the application.

**Please see "Categories of IRB Review" for additional details regarding the Medaille College IRB review process.*

Categories of IRB Review

The Medaille College IRB is responsible for reviewing all proposals for research that will involve human participants. When a new IRB application is submitted, the IRB Co-Chairs conduct a preliminary review to determine whether the proposed research qualifies as *exempt* or *non-exempt*. If the research is found to be *non-exempt*, the IRB Co-Chairs determine whether the protocol is eligible for an *expedited review* or whether a *full board review* is required. Each of these terms is described in further detail below.



1. *Exempt*

Following their preliminary review, the IRB Co-Chairs may determine that a proposed research study qualifies as exempt, meaning (a) it requires no further review beyond the IRB Co-Chairs, and (b) it is exempt from certain federal regulations (e.g., the need to obtain informed consent from participants). Once the proposed research is declared exempt, the Principal Investigator listed on the IRB application will be notified and the research can commence. The categories of research that qualify as exempt are shown in Appendix A. Please note, researchers do not have the authority to determine whether a particular research project involving human participants is exempt.

2. *Non-Exempt, Expedited Review*

Certain types of research are eligible for expedited review. An expedited review procedure can be utilized when the only involvement of human participants will be in one or more of the Expedited Review Categories listed in Appendix B and when the proposed research will involve no more than minimal risk to the participants. According to the Office for Human Research Protections, *minimal risk* is defined as follows: “*The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*”

In an expedited review, the application is forwarded to one or two IRB members for review. The response(s) is returned to the IRB Co-Chairs for their review. The Principal Investigator often needs to revise the initial application to address specific concerns raised by the expedited reviewer(s). When the Principal Investigator satisfactorily revises the application, the IRB Co-Chairs can grant final approval of the proposed research. The IRB is kept informed of all protocols approved by expedited review.

3. Non-Exempt, Full Board Review

If a proposed research study will involve more than minimal risk to human participants, it must be reviewed by IRB members at a convened monthly meeting. After the full board review, the Principal Investigator may need to revise the application to address specific concerns raised by the IRB. These changes will then need to be reviewed again by the full board at another convened IRB meeting.

Instructions for IRB Applicants

The Medaille College IRB meets during the third week of the month. IRB application submissions must be e-mailed to IRB@medaille.edu by the first of the month to be reviewed at that month's IRB meeting.

New Research Proposals

Any individual who wishes to conduct research with human participants must obtain IRB approval prior to the initiation of any research-related activities. In order to submit a research proposal to the Medaille College IRB for review:

- 1) Complete the official **Medaille College IRB Application Form**, available for download through the Medaille College IRB website. Be sure to complete the entire application (all sections and questions).
- 2) Create an original consent form for the research study. A consent form template is provided on the Medaille College IRB website and can be used as a guide. Additional information on the consent process is provided under the heading "Informed Consent."
- 3) Determine whether your proposed study will involve a vulnerable/protected population of participants (e.g., pregnant women, minors, individuals who are imprisoned, etc.). See "Special Protections for Vulnerable/Protected Populations" for additional details. If so, complete the **Research Involving Vulnerable Populations Form**, available for download through the Medaille College IRB Website.
- 4) Have all members of the research team (e.g., Principal Investigator, Student Principal Investigator, Co-Investigators, Research Assistants, etc.) complete their required ethics training. Proof of ethics training (such as a copy of a **CITI Completion Report**) must be included for each member of the research team when submitting an application to the Medaille College IRB for review. Additional information on Medaille's required ethics training is provided under the heading "Ethics Training Requirement."
- 5) Students who are conducting research must have their faculty advisor review their completed IRB application and all supporting materials prior to submitting them to the Medaille College IRB for review. After the faculty advisor reviews the student's application package, they should complete and sign the **Faculty Advisor Sign-Off Form**, available for download through the Medaille College IRB website. The faculty advisor should return the completed/signed form to the student who must scan it so that it can be included as an attachment when submitting the final IRB application package for review.
- 6) After completing the above steps, the IRB application package is ready for submission. Please forward the final IRB Application Form and all supporting materials in one single email to the Medaille College IRB at IRB@medaille.edu.

Requests for Amendments/Modifications to IRB-Approved Research in Progress

Researchers must follow their IRB-approved protocols. If a researcher wishes to change their existing protocol in any way, the researcher must complete an **Amendment Request Form** explaining the proposed change(s). This form, which is available for download through the Medaille College IRB Website, must be submitted, along with any other necessary supplementary materials, to IRB@medaille.edu for approval by the Medaille College IRB before the proposed change can be implemented.

Research Study Expiration or Extension

All studies granted approval through the Medaille College IRB will be assigned an expiration date (generally, one year from the date of IRB approval). One month prior to this expiration date, researchers must submit one of two forms to the Medaille College IRB:

- **Study is Complete:** A study is considered “complete” when all aspects of the research have concluded. This means that data collection has ceased, participants are no longer being recruited or enrolled, no further contact/follow-up with participants is necessary, data are no longer being coded, and analysis of personally-identifiable data is complete. If a study is complete (or the researcher has voluntarily chosen to end the study), the researcher must submit a **Study Completion Form**, available for download through the Medaille College IRB Website.
- **Study is Not Yet Complete:** If a study is not yet complete and the researcher wishes to continue it, the researcher must request an extension by completing a **Study Extension Request Form**, available for download through the Medaille College IRB website.

IRB Forms

Provided below are the names and descriptions of a number of helpful forms that are available for download on the Medaille College IRB Website:

- **Medaille College IRB Application Form:** This is the official application form that must be completed in order to request permission to conduct research involving human participants.
- **Faculty Member Sign-Off Form:** This form is for students who plan to conduct research. Upon completing an IRB application, the student must give this form to their faculty advisor along with a copy of their completed IRB application and supporting materials. The faculty advisor should review the student's IRB application package to ensure that it is complete and accurate. When the faculty advisor is satisfied with the student's application, the faculty advisor should complete and sign this form and return it to the student. The student must scan the completed/signed copy of this form so it can be included as an attachment when submitting their final IRB application package for review.
- **Amendment Request Form:** This form is used to request a revision or modification to a currently active research protocol that previously received approval through the Medaille College IRB. Amendments can be requested at any time during the approval period.
- **Study Extension Request Form:** This form is used to request an extension for currently active research. This form should be completed and submitted to the IRB one month prior to the research study expiration date.
- **Study Completion Form:** This form must be submitted when all aspects of the research have concluded. This means that data collection has ceased, participants are no longer being recruited or enrolled, no further contact/follow-up with participants is necessary, data are no longer being coded, and analysis of personally identifiable data is complete.
- **Research Involving Vulnerable Populations Form:** This form must be included when the proposed research will involve a group of participants who may be vulnerable to coercion or undue influence and/or who are considered part of a protected/vulnerable population (i.e., pregnant women, minors, individuals who are imprisoned, individuals with impaired decision-making capacities, and economically or educationally disadvantaged persons). Additional information on vulnerable/protected populations is provided in the section named "Special Protections for Vulnerable/Protected Populations."

Ethics Training Requirement

Medaille College's Ethics Training Requirement

In order to ensure that all research activities which will involve human participants are conducted in an ethical manner, every individual listed as a member of the research team on a **Medaille College IRB Application Form** is required to complete an educational training focused on ethical considerations important to the conduct of research with human participants. This “ethics training” can be completed through the Collaborative Institutional Training Initiative, or CITI, Program. Instructions for creating a CITI account and accessing CITI’s ethics training course are provided on the Medaille College IRB website. Be sure to follow these instructions so that you can access the CITI training *free of charge*.

To complete CITI’s ethics training course, you will be required to work your way through a number of different training modules and quizzes. Once you have completed all of the required modules and quizzes, your course will be complete and CITI will allow you to download and save a copy of your “CITI Completion Report,” as proof that you have completed the required ethics training. Again, a CITI Completion Report must be included for each member of the research team when submitting an application to the Medaille College IRB for review.

Although ethics courses are available through other organizations besides CITI, please email IRB@medaille.edu with the name of the course so that the Medaille IRB can ensure the course meets necessary training requirements.

NIH's Ethics Training Requirement (only necessary for NIH Applications & Grants)

In 2000 the National Institutes of Health (NIH) enacted a policy requiring education on the protection of human research participants for all investigators/researchers submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human participants. The new policy requires that all “key personnel” in the proposed research be documented by their institution as having completed education on the protection of human research participants. According to NIH, “key personnel” are defined as “all individuals responsible for the design and conduct of the study.” In addition, NIH announced that documentation should be in the form of a letter containing (1) the names of all key personnel who are responsible for the design and conduct of the study, and (2) the title of the education program completed by each named personnel plus a one sentence description of the program. This letter must be signed by an institutional official. In keeping with NIH's “just-in-time” procedures, NIH will request this letter before an award is issued.

Student Research

Students at Medaille College who are interested in conducting research with human participants must go through the same process as faculty members or other Medaille College employees who are conducting research in order to secure IRB approval for their proposed work.

Importantly, a student conducting research cannot be listed as a research study's Principal Investigator. That role belongs to the student's faculty advisor or another faculty member who has agreed to supervise the student's research activities. When filling out a **Medaille College IRB Application Form** for a newly proposed study, the student's advisor or other faculty member must be listed on the *Principal Investigator* line of the application. The student may then be listed on the *Student Principal Investigator* line. Students may also be listed on the *Research Assistant* or *Other* line, if appropriate.

In addition, before a student can submit an IRB application for review, the student must have the faculty member who has agreed to supervise them review their completed IRB application package and document that they have done so by completing the **Faculty Advisor Sign-Off Form**, available for download through the Medaille College IRB website. After the faculty advisor has completed and signed this form, the student must scan the form and include it as an attachment when submitting their final IRB application package to the Medaille College IRB for review.

Important Message for Students Completing Theses

- All requests for permission to conduct research that will involve human participants must be obtained before beginning any research-related activities.
- Retroactive approval from Medaille's IRB will not be granted.

Informed Consent

As required by federal regulations (Code of Federal Regulations, Title 21 Part 50-Protection of Human Subjects), the IRB must review and approve the plan for obtaining informed consent from all individuals who agree to participate in research. Importantly, consent is not simply a form that a researcher has a participant sign – It is a process as well.

Consent as a Process: The consent process includes sharing important information about the study itself with potential participants, answering questions individuals have about the study, allowing individuals sufficient time to decide whether they want to participate in the study, obtaining the voluntary agreement of individuals who consent to participate in the study, and ensuring that individuals understand their ongoing rights as participants in the study (e.g., that they can withdraw from the study at any time, without penalty; that they can ask questions at any time; that they can refuse to answer specific questions or participate in certain research activities, if they choose). Every IRB application submitted for review to the Medaille College IRB must include a detailed description of the process that will be used to obtain informed consent and identify which member(s) of the research team will be responsible for this process.

Documentation of Consent: Typically, researchers are required to document consent (in writing or, if more appropriate, through another IRB-approved method) to provide a record that the consent process took place. In the case of written documentation, researchers are responsible for creating an official consent form for their study and including it as part of the IRB application they submit for review to Medaille's IRB. A template of a consent form, provided on the Medaille College IRB Website, can be used as a guide.

Privacy & Confidentiality

The IRB is responsible for ensuring that researchers have adequate provisions in place for protecting the privacy of participants and maintaining the confidentiality of their data. Thus, a researcher's IRB application must include a number of details related to how privacy and confidentiality will be protected. Will personally identifiable data (e.g., names) be collected from participants and, if so, how will such data be secured? How and where will data be stored? How long will data be retained and how will the researcher dispose of the data following study completion? Who, specifically, will have access to the research data? These are some of the questions related to privacy and confidentiality that must be addressed in the IRB application.

Special Protections for Vulnerable Populations

In compliance with federal regulations (45 CFR 46), the Medaille College IRB will ensure that additional safeguards are in place to protect the rights and welfare of research participants who may be vulnerable to coercion or undue influence. Such participants are sometimes referred to as *vulnerable or protected populations* and include, but are not limited to, the following categories: pregnant women, minors, individuals who are imprisoned or on parole, individuals with impaired decision-making capacities, and economically or educationally disadvantaged persons.

When proposed research will involve a category of individuals who may be vulnerable to coercion or undue influence, the Medaille College IRB will require researchers to complete the **Research Involving Vulnerable Populations Form**. This is a required supplemental form that a researcher must include when submitting his/her IRB application for review. Furthermore, when reviewing an IRB application that will involve a potentially vulnerable/protected group of participants, the IRB will include in its reviewing body one or more individuals who are knowledgeable about and/or experienced in working with this particular group.

In addition to the required ethics training (see “Ethics Training Requirement”), we recommend that anyone planning to conduct research with a population that may be considered vulnerable to coercion or undue influence complete an additional training course through CITI titled: *Research with Vulnerable Populations and Consent Topics*.

Frequently Asked Questions

When is the submission deadline for my proposed research?

Proposed research must be submitted by the first of the month in order to be reviewed during that month.

When do I need to submit a proposal to the IRB?

All proposed research which will involve the use of human participants requires review and approval by the Medaille College IRB *prior to the initiation* of any research-related activities (this includes participant recruitment, data collection, etc.). Because the IRB review process involves multiple phases of review by a number of different parties (Co-Chairs, IRB members, external reviewers, etc.) and because applicants are frequently asked to revise their initial applications to address reviewers' concerns, new IRB applications should be submitted to Medaille's IRB well in advance of the proposed start date of the research.

How long does it take to receive a decision on a study?

This depends on a variety of factors, including the completeness of the application, the type of proposed research, and the complexity of the proposed research. The IRB will generally issue its initial decision (e.g., approving the proposed study, requiring modifications/revisions before granting approval of the proposed study, or rejecting the proposed study) within 4-6 weeks of receiving the initial IRB application and all required supporting materials. Studies requiring revisions will take longer.

Does all research involving human participants need to be reviewed?

YES. All research that will involve human participants must be reviewed in one form or another. Federal law requires that federally funded research or research involving more than minimal risk be reviewed and approved by the full IRB before research can be initiated.

If my research qualifies as “exempt,” do I still need to submit an IRB application?

YES. Exempt does not mean exempt from review. "Exempt" means the proposed research (a) requires no further review beyond the IRB Co-Chairs and (b) is exempt from certain federal regulations (e.g., the need to obtain informed consent). See Appendix A for a list of categories of research that qualify as exempt. Please note, researchers do not have the authority to determine whether a particular research project involving human participants qualifies as exempt.

What if my research will not be federally funded? Does it still need to be reviewed?

YES. It still needs to be reviewed. If your research poses no more than minimal risk, it may qualify for an expedited review, meaning it can be reviewed by a subset of the IRB. If your research poses more than minimal risk, it must be reviewed by the full IRB at a convened meeting.

What is Minimal Risk?

According to the Office for Human Research Protections, *minimal risk* is defined as follows: “*The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*”

Who makes up the Medaille College IRB?

The IRB consists of members from diverse fields which may include biology, criminal justice, education, and psychology. Members are drawn from within and outside the Campus community.

On what basis are IRB applications reviewed?

Review of proposed research involving human participants is broadly based on three factors: (1) Informed Consent (information, comprehension, and voluntariness of the proposed research), (2) Assessment of Risks and Benefits, and (3) Selection of Participants. All procedures must be fair at both individual and social levels.

Appendix A

Exemption Categories

(Revised to comply with Federal Common Rule, August 19, 1991)

Remember, exempt does not mean exempt from review. "Exempt" means the proposed research (a) requires no further review beyond the IRB Co-Chairs and (b) is exempt from certain federal regulations (e.g., the need to obtain informed consent). Please note that the exemption categories below do not apply to research that will involve individuals who are members of a vulnerable/protected population (e.g., pregnant women, minors, etc.).

- 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. This exemption category for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.
- 3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is **not exempt under paragraph 2 (above) if**: (a) the human participants are elected or appointed public officials or candidates for public office; or (b) the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g, or for the National Center for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.
- 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
- 5) Research and demonstration projects which are conducted by or participant to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
- 6) Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed or (b) 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 U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Appendix B

Expedited Review Procedure Categories

The IRB may use an expedited review procedure when the proposed research will involve no more than minimal risk to participants and the only involvement of participants will be in one or more of the following categories:

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