18. Special Topics

18.1. Certificate of Confidentiality

Certificates of Confidentiality (COC) are issued by the Federal government to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the Federal, state, or local level. COCs may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

The COC goes beyond the consent form in ensuring confidentiality and anonymity. Without the COC, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects).

Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a COC. Federal funding is not a prerequisite for a COC.

18.1.1. Statutory Basis for Protection

Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service (PHS) Act 301(d), 42 USC. 241(d):

"the secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (research on mental health, research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of Individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such Individuals. Persons so authorized to protect the privacy of such Individuals may not be compelled in any Federal, state or local civil, criminal, administrative, legislative, or other proceedings to identify such Individuals."

18.1.2. Usage

A COC may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, a COC can help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects.
Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a COC. Research can be considered "sensitive" if it involves the collection of:

- Information about sexual attitudes, preferences, practices;
- Information about personal use of alcohol, drugs, or other addictive products;
- Information about illegal conduct;
- Information that could damage an Individual’s financial standing, employability, or reputation within the community;
- Information in a subject's medical record that could lead to social stigmatization or discrimination; or
- Information about a subject's psychological well-being or mental health.

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the Research Compliance Office (RCO) for help in applying for a COC.

In the consent form, investigators should tell research subjects that a COC is in effect. Subjects should be given a fair and clear explanation of the protection that it affords, including the limitations and exceptions noted below. Every research project that includes human research subjects should explain how identifiable information will be used or disclosed, regardless of whether or not a COC is in effect.

**18.1.3. Limitations**

The protection offered by a COC is not absolute. A COC protects research subjects only from legally compelled disclosure of their identity. It does not restrict voluntary disclosures.

For example, a COC does not prevent researchers from voluntarily disclosing to appropriate authorities such matters as child abuse, a subject's threatened violence to self or others, or from reporting a communicable disease. However, if researchers intend to make such disclosures, this should be clearly stated in the consent form which research subjects are asked to sign.

In addition, a COC does not authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if

- The subject (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;
- Authorized personnel of DHHS request such information for audit or program evaluation, or for investigation of DHHS grantees or contractors and their employees; or
- Release of such information is required by the FDA Act or regulations implementing that Act.
18.1.4. Application Procedures

Any person engaged in research collecting sensitive information from human research subjects may apply for a COC. For most research, certificates are obtained from NIH. If the NIH funds the research project, the investigator may apply through the specific funding institute. However, even if the research is not supported with NIH funding, the investigator may apply for a COC through the NIH Institute or Center (IC) funding the research in a scientific area similar to the project.

If the research is a sensitive research project that is covered by the agency for Healthcare Research and Quality (AHRQ) confidentiality statute [42 USC. 299a-1(c) entitled “Limitation on Use of Certain Information”] or the Department of Justice Confidentiality Statute [42USC 3789g], then a COC is not required.

If there is an Investigational New Drug (IND) application or an Investigational Drug Exemption (IDE), the sponsor can request a COC from the FDA.

For more information, see the NIH certificates of confidentiality kiosk (http://grants.NIH.gov/grants/policy/coc/INDex.htm).

18.2. Mandatory Reporting of Abuse and Neglect

18.2.1. Definitions

Child: a person who is younger than age 18 or who is not an emancipated minor

Child abuse: the infliction of physical, sexual, or mental injury against a child by any person eighteen years of age or older. For purposes of this section, abuse shall not include injury inflicted on a child by accidental means by a person with care, custody, or control of the child, or discipline of a child by a person with care, custody, or control of the child, including spanking, in a reasonable manner (562.060 Missouri revised statutes (RSMO))

Child neglect: “…failure to provide, by those responsible for the care, custody, and control of the child, the proper or necessary support, education as required by law, nutrition or medical, surgical, or any other care necessary for the child’s well-being.”

Elder: means an adult over the age of 60.

Elder abuse: the infliction, on an elder, of physical, sexual, or emotional injury or harm including financial exploitation by any person, firm, or corporation (660.250, RSMO).

Elder neglect: the failure to provide services to an eligible elder by any person, firm or corporation with a legal or contractual duty to do so, when such failure presents either an imminent danger to the health, safety, or welfare of the elder or a substantial probability that death or serious physical harm would result (660.250, RSMO).
18.2.2. Reporting Obligation of Abuse & Neglect

When any physician, medical examiner, coroner, dentist, chiropractor, optometrist, podiatrist, resident, intern, nurse, hospital or clinic personnel that are engaged in the examination, care, treatment or research of persons, and any other health practitioner, psychologist, mental health professional, social worker, day care center worker or other child-care worker, juvenile officer, probation or parole officer, jail or detention center personnel, teacher, principal or other school official, minister as provided by section 352.400, RSMO, peace officer or law enforcement official, or other person with the responsibility for the care of children has reasonable cause to suspect that a child has been or may be subjected to abuse or neglect or observes a child being subjected to conditions or circumstances which would reasonably result in abuse or neglect, that person shall immediately report or cause a report to be made to the children’s division in accordance with the provisions of sections 210.109 to 210.183 of the RSMO.

Consistent with Missouri law, the Human Research Protection Program (HRPP) has established a policy and procedures to protect the health, safety, and well-being of children, neonates and elders who are involved as subjects in research under the purview of UMKC’s IRB. Mandated reporters suspecting abuse and neglect are required to follow the institutional policies under which they are identified as mandated reporters. Researchers who are not mandated reporters requesting additional information regarding reporting obligations or resources should contact Child Protective Services (“CPS”), Adult Protective Services (“APS”), the Department of Social Services, and/or Missouri Department of Health and Human Services (DHHS) with respect to suspected abuse or neglect.

18.3. UMKC Students and Employees as Subjects

When UMKC students and/or employees are being recruited as potential subjects, researchers must ensure that there are additional safeguards for these subjects. The voluntary nature of their participation must be primary and without undue influence on their decision. Researchers must emphasize to subjects that neither their academic status or grades, or their employment, will be affected by their participation decision.

Whenever possible, researchers should avoid using their own students if another population of subjects is equally suited to the research question, e.g., another class section not taught by the researcher, recruitment by another instructor, or blinded/coded data collected by an associate so that subjects are not identified to the instructor.

- Students should be given an opportunity to decline participation without jeopardy.
- Unless the research question is directly related to class material, or the study process is being used as a teaching opportunity, such as in a research methods class, the IRB discourages the use of class time to recruit subjects or class time used to complete study instruments, etc.
• Use of extra credit points as reward for research participation should be limited to established research pools such as the UMKC Psych Pool (Psychology Department) or specific circumstances where the research is closely tied to the course material. The number of points awarded should not be sufficient to augment a student's grade by a whole step, e.g., from b to a.

• Whenever possible, a teaching opportunity in the form of an "educational debriefing" should be employed. Students should know something about the IRB review process, the rationale for the study, the process of data collection, and intent of the researcher.

In these situations, investigators should solicit subjects through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes or laboratories other than their own. When entering a classroom to recruit students and conduct research (e.g. administer a survey), investigators must do so in the least intrusive manner possible (e.g. during a break, end of the class period, etc.) Thereby alleviating pressure to participate.

In certain research situations in which the use of the Principal Investigators (PI) students and/or employees as subjects is unavoidable, direct interaction/intervention by the principal investigator is highly discouraged and additional safeguards to protect subjects from coercion and/or undue influence must be in place.

18.4. Student Research

For additional Guidance on student research see Institutional Review Board for the Protection of Human Subjects (IRB) - Guidelines for Class Projects – See appendix 1

18.4.1. Human Subjects Research and Course Projects

Learning how to conduct ethical human subjects research is an important part of a student’s educational experience. Research activities that are designed as part of a course requirement for purposes of learning experience only and are not designed to develop or contribute to generalizable knowledge may not require IRB review.

Responsibility of the course instructor: the course instructor is responsible for communicating to the students the ethics of human subjects research, for ensuring the protection of human subjects (including having a process in place for obtaining voluntary consent from research subjects when appropriate), and for monitoring the students’ progress.

When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should:

• Understand the elements of consent;
• Develop appropriate consent documents;
• Plan appropriate strategies for recruiting subjects;
• Identify and minimize potential risks to subjects;
• Assess the risk-benefit ratio for the project;
• Establish and maintain strict guidelines for protecting confidentiality; and
• Allow sufficient time for IRB review (if necessary) and completion of the project.

In making a determination of whether or not a class research project requires IRB review, the instructor is encouraged to err on the side of caution and to contact the RCO for assistance.

18.4.2. Individual Research Projects Conducted by Students

Independent study projects, senior theses, undergraduate research projects, masters and advanced degree research, and similar exercises that involve human subjects must be independently submitted for IRB review. It is important to keep in mind that any human subjects research activity that will ultimately contribute to part or all of a thesis, dissertation, or other type of publication or presentation must go through the IRB review process prior to enrolling human subjects and collecting data. IRB review cannot occur after a study has begun.

Students and advisors should contact the RCO with any questions.

UMKC policy and procedures, forms and related information can be found on the UMKC IRB website at: http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/adult-health-sciences-irb/standard-operating-procedures.

18.4.3. Independent Study, Theses and Dissertations

These research activities are considered to meet the Federal definition of human subject research and should be independently submitted to the IRB. However, when students conduct research as part of a course of study, a faculty member who services as the PI, ultimately is responsible for the protection of the subjects, even if the student is the primary researcher and actually directs the project. Students are not allowed to be PI(s). Advisers assume the responsibility for students engaged in Independent research, and instructors are responsible for research that is conducted as part of a course.

18.5. Oral History

The threshold question in determining whether or not an oral history is subject to human subject protections is whether or not the activity meets the definition of research. A decision whether oral history or other activities solely consisting of open ended qualitative type interviews are subject to the policies and regulations outlined in an institution’s Federal wide assurance (FWA) and HHS regulations for the protection of human subjects research is based on the prospective intent of the investigator and the definition of “research” under HHS regulations at 45 CFR 46.102(l); “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 purposes of this part, the following activities are deemed not to be research:

- 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.

Interviews conducted with questionnaires and anonymous sources, from which generalized conclusions are drawn, fit the definition of research. Open-ended, Individualistic interviewing about events that have occurred in the past represents a fundamentally different form of research than Federal regulations were intended to encompass.

Focus should be on the prospective intent of the PI and the definition of research (i.e., does it involve a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

An activity is considered to not be an oral history and not exempt if it satisfies both of the following requirements:

- The activity involves a prospective research plan which incorporates data collection, including qualitative data, and data analysis to answer a research question; and
- The activity is designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

When reviewing an activity to determine whether or not it is an oral history that qualifies for exempt review, the following general principles may be useful for evaluative purposes:

- Oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of Individuals without intent to draw conclusions or generalize findings would not constitute research.
  - Example: an oral history video recording of interviews with holocaust survivors is created for viewing in the holocaust museum. The creation of the video tape does not intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the holocaust and provide a venue for holocaust survivors to tell their stories.
- Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) would constitute research.
- Example: an open ended interview of surviving gulf war veterans to document their experiences, and to draw conclusions about their experiences, inform policy, or generalize findings.

- Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. This activity would constitute research since the intent of the archive is to create a repository of information for other investigators to conduct research.
  - Example: open ended interviews are conducted with surviving Negro league baseball players in order to create an archive for future research. The creation of such an archive would constitute research since the intent is to collect data for future research.

18.6. **Public Registration of Clinical Trials**

The FDA requires that certain trials be publicly registered at “clinicaltrials.gov” before any subjects are enrolled. The URL for the registration site is: [https://register.clinicaltrials.gov/](https://register.clinicaltrials.gov/)

18.6.1. **Who Must Register?**

The responsible party for registering applicable clinical trials is the sponsor of the clinical trial, which means the person who initiates a clinical investigation.

- For investigator-initiated trials, the lead PI responsible for initiating, conducting and coordinating the overall clinical trial is responsible for registration;
- For sponsor-initiated trials the sponsor is responsible for registration;
- For trials sponsored or funded wholly or in part by the NIH the grantee is responsible for registration; and
- For trials associated with investigational new drug (IND) or investigational device exemption (ide) applications with the FDA the IND/ide holder is responsible for registration.

The sponsor, grantee, contractor, or awardee may designate the principal investigator of a clinical trial as the responsible party, provided that the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for submitting information under the law.

Once a trial is registered, the responsible person must ensure on an ongoing basis that the information is complete, accurate and updated. This includes reviewing the listing and making necessary changes every 6 months or more frequently if significant changes occur. The responsible person is also responsible for noting when enrollment ceases.
If unclear who is responsible for registering an applicable clinical trial, investigators should consult with the sponsor, funding agency, and/or other study investigators to define who the responsible party will be.

18.6.2. Which Studies Must be Registered?

Registration is required for any research study that:

- Prospectively assigns human subjects to intervention and at least one concurrent control or comparison groups; and
- Uses a drug, biologic, or device as the intervention or control/comparison; and
- Studies the safety, efficacy or cause-and-effect relationship between an intervention and a health outcome.

The registration requirement does not apply to:

- The use of FDA approved, marketed products used in the course of medical practice;
- Phase I clinical investigations of drugs or biologics;
- Small clinical trials to determine the feasibility of a device or clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes;
- FDA required pediatric post-marketing surveillance of devices;
- Purely observational studies, meaning those studies where the assignment of the intervention is not at the discretion of the investigator;
- Investigators and sponsors are encouraged to register all clinical trials to ensure they meet the publication requirements of the International Committee of Medical Journal Editors (“ICMJE”) and to promote transparency in clinical research.

18.6.3. When Must the Information be Submitted?

Information about new protocols open for enrollment must be registered not later than 21 days after protocol approval. [42 USC. 282(j)(3)]. Supplemental information can be submitted at 30-day intervals. The FDA strongly encourages you to update information about trials that are unexpectedly closed (e.g., clinical hold) within 10 days after the closing or sooner if possible.

18.6.4. How to Register a Clinical Trial?

Search clinicaltrials.gov to ensure that the trial is not already listed. NIH-sponsored clinical trials and many industry-sponsored trials have already been registered on the clinicaltrials.gov site. If the trial is not listed, continue with registration.

Establish an account with clinicaltrials.gov. You will receive an e-mail message from clinicaltrials.gov containing your login name and temporary password.
Once you have received your login information, register the trial. This process will take approximately 1 hour, and it will be helpful to have the protocol, consent document, and IRB approval (if available) on hand. IRB approval is not required to register a trial. Note that this system offers the option to save data if you do not have time to complete the entire process.

Some suggestions for completing certain items that you might not have available are:

- **Unique protocol ID**: the UMKC IRB number is recommended. An IRB number is generated by starting an IRB application. IRB approval is not required to register a trial.
- **Secondary IDs**: the grant number, funding agency number or other funding source number is recommended.
- **Board name**: (full name of the approving human subjects review board).
- **Board contact**: (contact information for the human subjects review board):
  - **Name**: Chris Winders, Director of Research Compliance
  - **Phone**: 816 235-5370
  - **Email**: windersc@UMKC.edu
  - **Address**: 5319 Rockhill Road, Kansas City, MO, 64110

Information should be reviewed and updated as needed every 6 months or more frequently if changes occur.

### 18.6.5. What Information Must be Submitted?

The following are examples of information to be submitted:

- **Descriptive information**
  - Brief title (in lay language)
  - Brief summary (in lay language)
  - Study design/study phase/study type
  - Condition or disease
  - Intervention

- **Recruitment information**
  - Study status information including
  - Overall study status (e.g., recruiting, no longer recruiting)
  - Individual site status
  - Eligibility criteria/gender/age

- **Location and contact information**
  - Location of trial
  - Contact information (includes an option to list a central contact person for all trial sites)
• **Administrative data**
  - Unique protocol id number
  - Study sponsor
  - Verification date

18.6.6. Who Receives the Submitted Information?

The DHHS Secretary acting through the NIH Director receives information submitted to clinicaltrials.gov.

18.6.7. Who Can Access the Registered Information?

Studies will be made available to the public through clinicaltrials.gov within two to five days after submission by the sponsor. Except for the IND number, serial number, and FDA center designation, all information submitted through the Protocol Registration System (PRS) is made available to the public.

18.6.8. Must Information be Included about Foreign Trial Sites?

Yes. A sponsor must include information about foreign trials when those trials are conducted under an IND submitted to the FDA and the trial meets the criteria for submission to the clinical trials data bank. [42 USC. 282(j)(3)]. Sponsors may voluntarily conduct a foreign trial under the IND regulations. Sponsors are not required to submit information to the clinical trials data bank when a foreign trial is not conducted under an IND.

18.6.9. Can Intermediaries Act on Behalf of a Sponsor?

Yes. For example, in some cases a sponsor might want to contract with an information management company to serve as an intermediary in preparing data for inclusion in clinicaltrials.gov. The information management company, when authorized by the sponsor, could act on behalf of the sponsor for this purpose.

18.6.10. Can Sponsors Designate Multiple Individuals to be Data Providers?

Yes. When sponsors register to become a PRS data provider, they will be given information, including instructions, for creating additional users for their accounts. A sponsor can control access to the account by designating users and administrators for the account.

18.6.11. What are the NIH Requirements for Clinicaltrials.gov Registration Information in Applications and Progress Reports?

On September 27, 2007 Congress enacted US public law 110-85 (also known as HR 3580, or Food and Drug Administration Amendments Act of 2007). This Act mandates the expansion of clinicaltrials.gov, expands the required submission elements, and establishes penalties for not listing a trial. Investigators and sponsors must ensure that applicable drug, biologic and device
trials are registered within 21 days of enrollment of the first subject and preferable before first subject enrollment. The legislation also requires applications or progress reports for any clinical trials required to be registered which are funded in whole or in part by a grant from any agency of the DHHS to contain specific registration information in clinicaltrials.gov.

18.6.12. How do the FDA Registration Requirements Affect NIH Funded Studies?

Competing renewal applications that include studies that are required to be registered must include as part of the human subjects section of the research plan the following items:

- A statement that “this application includes a trial which requires registration in clinicaltrials.gov;”
- The National Clinical Trial (“NCT”) number (i.e. The clinicaltrials.gov number);
- Brief title as listed in clinicaltrials.gov; and
- The name of the Individual or entity responsible for registering the study (responsible party) for each study being conducted under the application (as grantee, UMKC designates the principal investigator of the trial as the responsible party).

New applications capture in the general checklist whether the application requires registering on clinicaltrials.gov.

18.6.13. Do the FDA Regulations have any Special Requirements for IND, IDE or Biologics License Application (BLA) Studies?

Studies conducted under an IND or IDE must include in the consent document(s) and the consent process a statement that clinical trial information for the study has been or will be submitted for inclusion in clinicaltrials.gov as required by FDA regulations.

A certification must accompany human drug, biological, and device product submissions made to the FDA. At the time of submission of an IND, IDE or BLA application or submission of a report, amendment, supplement or resubmission, such application or submission must be accompanied by a certification that all applicable requirements related to clinical trial registration have been met. Where available, such certification must include the appropriate NCT numbers.

The official certification form, Form FDA 3674 entitled "Certification of Compliance with Requirements of Clinicaltrials.gov Data Bank”, is available on FDA's web site.

For sponsor held INDs, IDEs and BLAs the sponsor must provide the certification. For investigator held INDs, IDEs and BLAs the Individual holding the IND, IDE or BLA must provide the certification.

18.7. Genetic Studies
Genetic research studies may create special risks to human subjects and their relatives. These involve medical, psychosocial, and economic risks, such as the possible loss of privacy, insurability, and employability, change in immigration status and limits on education options, and may create a social stigma. Knowledge of one's genetic make-up may also affect one's knowledge of the disease risk status of family members.

- In studies involving genetic testing, several questions need to be addressed, including:
  - Will test results be given?
  - Will disease risk be quantified, including the limits on certainty of the testing?
  - Will a change in a family relationship be disclosed, such as mistaken paternity?
  - Does the subject or family member have the option not to know the results? How will this decision be recorded?
  - Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?
  - Do any practical limitations exist on the subject's right to withdraw from the research, withdraw data, and/or withdraw DNA?
  - Is the subject permitted to participate in the study while refusing to have genetic testing (such as in a treatment study with a genetic testing component)?

- For DNA banking studies, several questions need to be addressed, including:
  - Will DNA be stored or shared? If shared, will the subject's identity be known by the new recipient investigator?
  - Will the subject be contacted in the future by the investigator to obtain updated clinical information?
  - How can the subject opt out of any distribution or subsequent use of his/her genetic material?

- Written consent for use of genetic samples for research purposes only must include the following:
  - A Statement that the sample will be used for future genetic tests;
  - A Statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
  - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
  - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
18.8. Research Involving Coded Private Information or Biological Specimens

UMKC policy is based on the OHRP Guidance document entitled, “Guidance on Research Involving Coded Private Information or Biological Specimens” (October 16, 2008 http://www.HHS.gov/OHRP/policy/cdebiol.html). This document:

- Provides Guidance as to when research involving coded private information or specimens is or is not research involving human subjects, as defined under HHS regulations for the protection of human subjects research [45 CFR part 46];
- Reaffirms OHRP policy that, under certain limited conditions, research involving only coded private information or specimens is not human subjects research; and
- Provides Guidance on who should determine whether or not human subjects are involved in research.

In general, private information or specimens are considered to be individually identifiable when they can be linked to specific Individuals by the investigator(s) either directly or indirectly through coding systems. Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific Individuals by the investigator(s) either directly or indirectly through coding systems.

Research involving only coded private information (or specimens) do not involve human subjects if the following conditions are both met:

- The private information (or specimens) were not collected specifically for the currently proposed research project through an interaction or intervention with living Individuals; and
The investigator(s) cannot readily ascertain the identity of the Individual(s) to whom the coded private information (or specimens) pertains. Example of how this might arise include:

- The key to decipher the code is destroyed before the research begins;
- The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the Individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement) or pursuant to a data use agreement;
- There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the Individuals are deceased; or
- There are other legal requirements prohibiting the release of the key to the investigators, until the Individuals are deceased.

In some cases an investigator who obtains coded private information (or specimens) about living Individuals under one of the conditions cited in 2(a)-(d) above may either (1) unexpectedly learn the identity of one or more living Individuals, or (2) for previously unforeseen reasons, now believe that it is important to identify the Individual(s).

If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the Individuals to whom the previously obtained private information (or specimens) pertains, then the research activity now would involve human subjects. Unless this human subject research is determined to be exempt (see section 3.2.4), IRB review of the research would be required. Informed consent of the subjects also would be required unless the IRB approved a waiver of consent (see section 5.4.7).

### 18.8.1. Who Determines if Coded Private Information (or Specimens) Constitutes Human Subjects Research?

The PI in consultation with the IRB Chair or RCO will determine if the research involving coded information or specimens requires IRB review. If the request is verbal (by phone or in person) or by e-mail, it is the PI’s responsibility to maintain documentation of such a decision. If the PI submits a formal submission, the request must include sufficient documentation of the activity to support the determination. Formal submissions will be responded to in writing and a copy of the submitted materials and determination letter will be kept on file.

### 18.9. Case Reports Requiring IRB Review

In general, an anecdotal report on a series of patients seen in one’s own practice and a comparison of these patients to existing reports in the literature is not research and would not
require IRB approval. Going beyond one’s own practice to seek out and report cases seen by other clinicians creates the appearance of a systematic investigation with the intent to contribute to generalizable knowledge and therefore would be considered research and would require IRB approval.

18.10. Audio, Video, Photographic Recording

Recording the voice and/or image of an Individual creates a type of record that requires unique handling and storage, particularly if the content may be considered sensitive. As with all research procedures, the dignity of human subjects should be respected. Therefore, only what is necessary for the purpose of the study should be recorded.

Research subjects must be informed prospectively that such recording will occur, and be provided with information about the storage, confidentiality, and future use of the resulting recording.

If a research protocol involves the recording of research subjects, the principal investigator must include the following elements for consideration, in his/her protocol and consent form for submission to and review by the IRB:

- Type of recording that will be utilized;
- Specific identifiers that will be recorded, e.g., partial facial features, full facial features, subject’s name;
- People who will have access to the recording(s);
- Mechanisms in place to protect the confidentiality of the person(s) being recorded;
- Clear Indication of when the recording(s) will be destroyed or that recording(s) will be kept Indefinitely;
- Use(s) of the recording(s), including educational or commercial purposes, analysis by the research team; or future unspecified use;
- Compensation, if any, to subjects for allowing themselves to be taped.

If the taping is an integral part of the research and not an optional procedure, separate consent is not required. However, documentation of the considerations listed above must be included, as appropriate, within the body of the consent document for the overall study. It is important that this information be clearly stated so that it is clear to the subject that a recording will be made.

If the recording is not required as part of the research procedures, then the consent document must include a specific statement indicating that participation in the research study is not contingent upon agreeing to be recorded. A separate consent signature for permission to record will be necessary. This permission can be in the form of a consent addendum, which includes the considerations listed above, as appropriate, or a separate signature line on the consent document labeled specifically for permission to record.
Appendix 1

Student Class Project Guidelines

To ensure ethical conduct of research projects, instructors and faculty who assign projects involving individuals as research subjects are expected to review students’ plans prior to subject recruitment and data collection.

Training

If the class project qualifies as Human Subjects Research, Instructors and students are required to complete the CITI training.

Criteria

An activity qualifies for the designation of student class project if:

- It is an activity designed as part of a course requirement for purposes of learning research methods and;
- The results and data will not be presented, posted, or published outside of the classroom.

A student class project does not meet the definition of human subject research because the project is intended only for classroom purposes. The student cannot use the project for any presentation, conference, publication, thesis, dissertation, or report outside of the course for which it is assigned.

The student must submit an IRB application if they intend to use the project outside of the classroom. This application must be approved before the student starts the project. Instructors should make this clear to their students.

Consent

Obtaining consent is important to the ethical conduct of research. It is strongly recommended students obtain either verbal or signed consent from participants in their projects. In most cases it is better to use a consent document to give to project participants. However, students may use a verbal script/information sheet to inform project participants instead. If students choose to use scripts/information sheets instead of consent forms, instructors should make sure that the scripts/information sheets accurately reflect the plans of the project.

Red Flags

- The student expresses intent to use the project for a presentation, conference, publication, thesis, or dissertation (they must submit an IRB application).
- The project’s activities expose participants to more than “minimal risk” (minimal risk means no more risk than everyday life).
• The project involves sensitive/private information such as sexual attitudes or behaviors, illegal behaviors, and/or the use of alcohol or drugs.
  o The project uses vulnerable populations (e.g., children under the age of 18, institutionalized persons, prisoners, persons who are “decisionally” impaired, etc.) or members of a “Subject Pool” as subjects.
  o Results of the project activities or data collected are recorded in such a way that the subjects are identifiable (images in videotapes or photographs and voices on audiotape are identifiable).
  o There is no consent process in place.
  o Subjects are under the direction or supervision of students collecting data (e.g. TAs collecting data from their own students or supervisors collecting data from employees).
  o Students do not plan to maintain confidentiality of the data (e.g. using subjects’ real names, inability to store consent forms in locked office/cabinet, etc.).
  o Subjects are forced to participate or are ostracized if they do not participate.

Helpful Tips

• The IRB is most concerned with protection of human subjects and their data. Thus the application should be detailed in describing: source of subjects, recruitment methods of subjects, interaction with subjects, informed consent processes, maintaining confidentiality of data, and data storage. These areas of the application, if executed well, will ensure faster processing.
• The IRB does NOT need robust literature reviews and lengthy background information details. The literature review should be no more than two paragraphs and it should cite three to ten references.
• Data collection instruments that are not solidified can be submitted as “semi-structured” and updated later.
• An instructor who expects students to use the class project toward a publication or presentation outside of the classroom may assist students by having them work in pairs, or by creating strict parameters for the class so that the project can be submitted under one application where the instructor is PI and the students are listed as co-investigators.