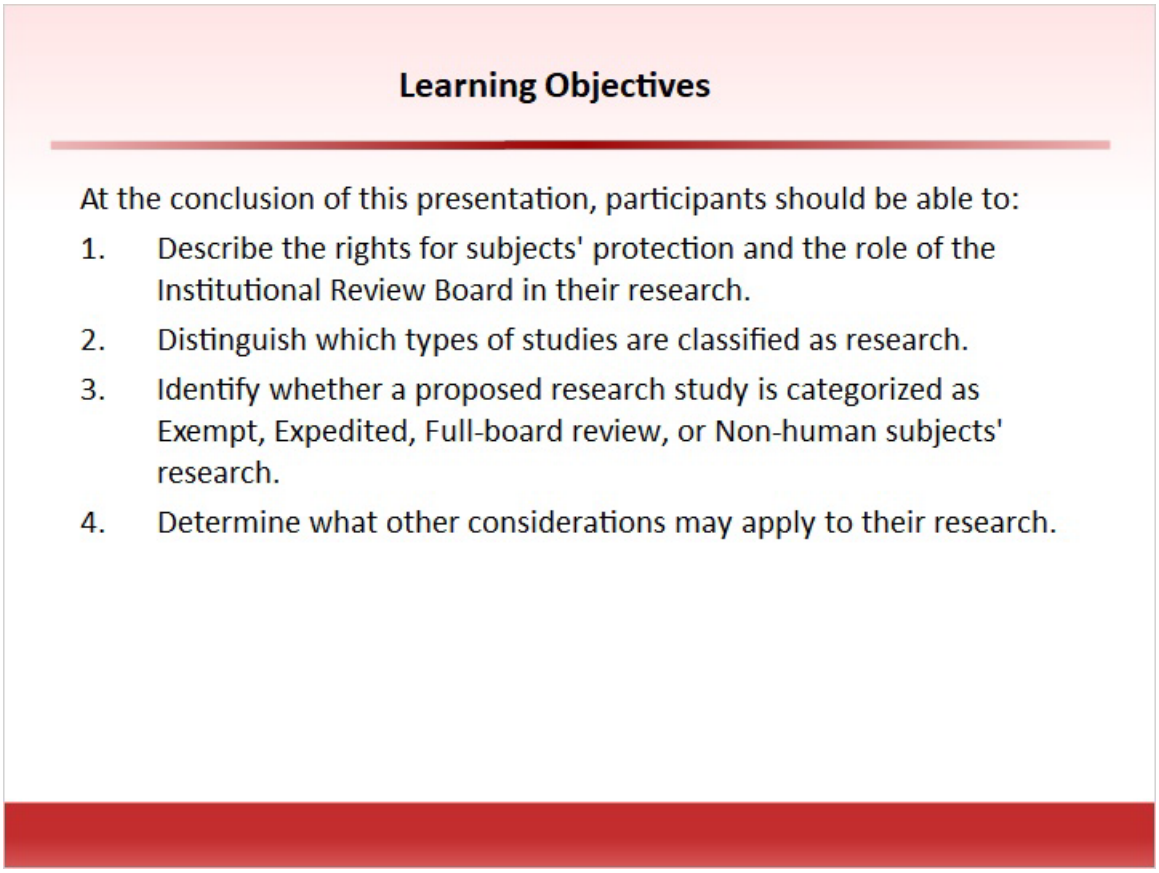
LABCC100 Lesson 41

1.1 Conducting ART Research:

Notes:

Welcome to the American Society for Reproductive Medicine's eLearning modules. The subject of this presentation is Conducting ART Research: The Institutional Review Board. The information presented in this module is based on regulations and practices in the United States. However, many other countries have adopted regulations based on these principles.

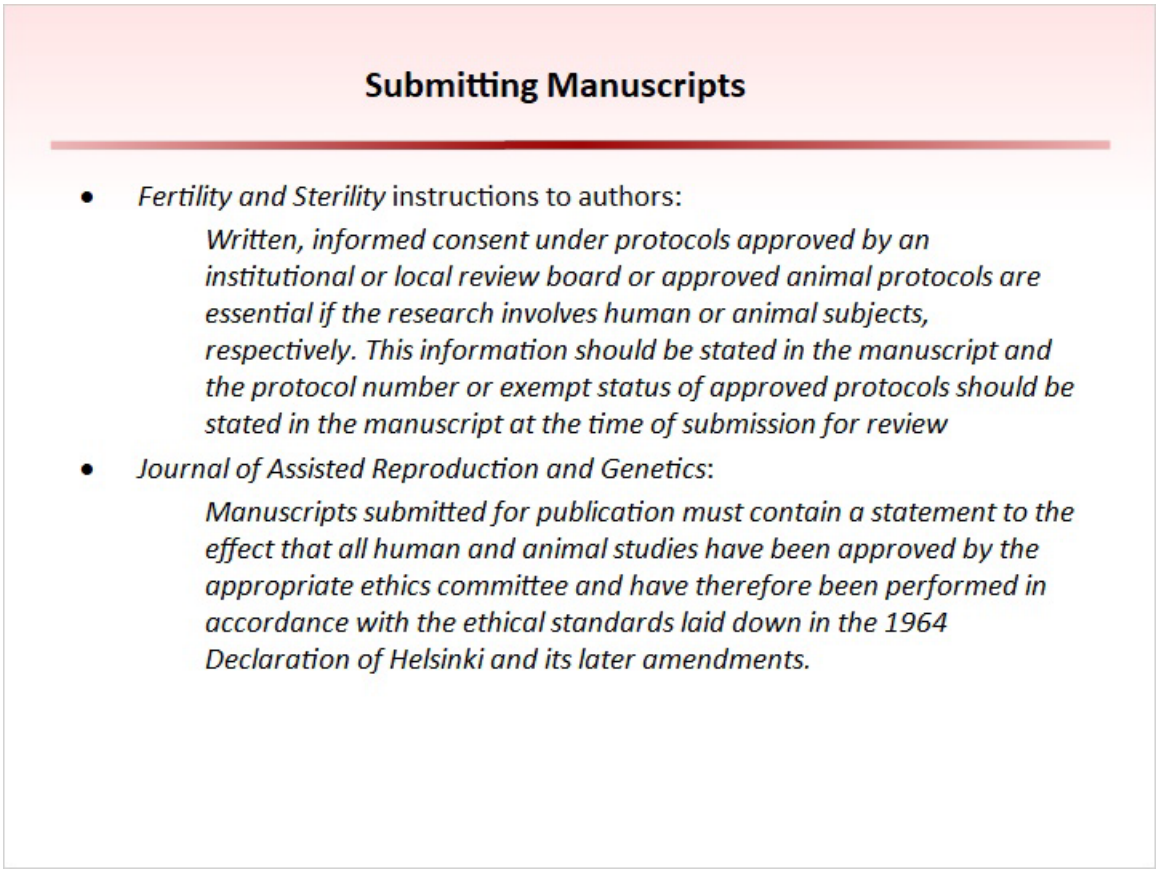
1.2 Learning Objectives



Notes:

At the conclusion of this presentation, participants should be able to:
1. Describe the rights for subjects' protection and the role of the Institutional Review Board in their research.
2. Distinguish which types of studies are classified as research versus quality improvement.
3. Identify whether a proposed research study is categorized as Exempt, Expedited, Full-board review, or Non-human subjects' research.
4. Determine what other considerations may apply to their research.

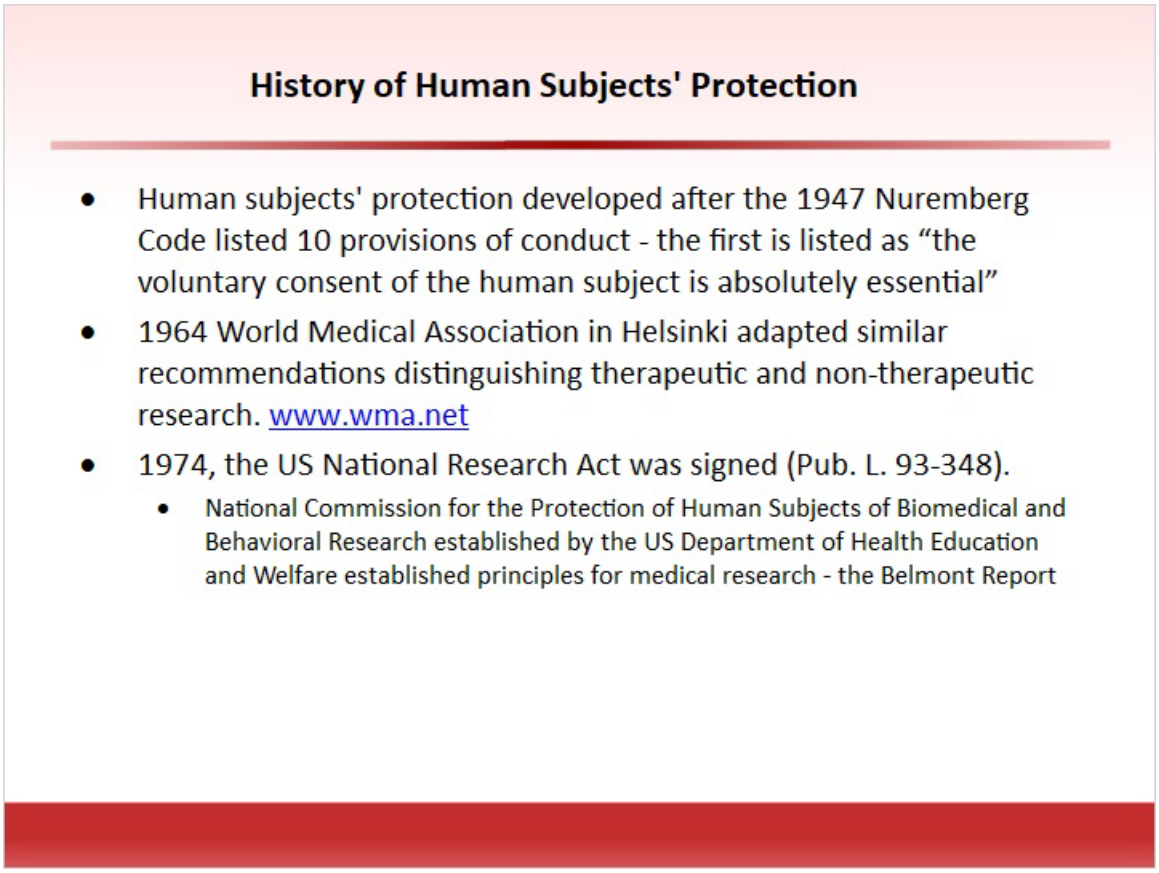
1.3 Submitting Manuscripts



Notes:

Many journals will state in the instructions to authors their requirements for institutional, ethics, or review board approval prior to the initiation of the research. The verbiage may cite the Belmont Report or the 1964 Declaration of Helsinki. But what exactly does that mean? This module will explain these documents and the types of approvals granted.

1.4 History of Human Subjects' Protection



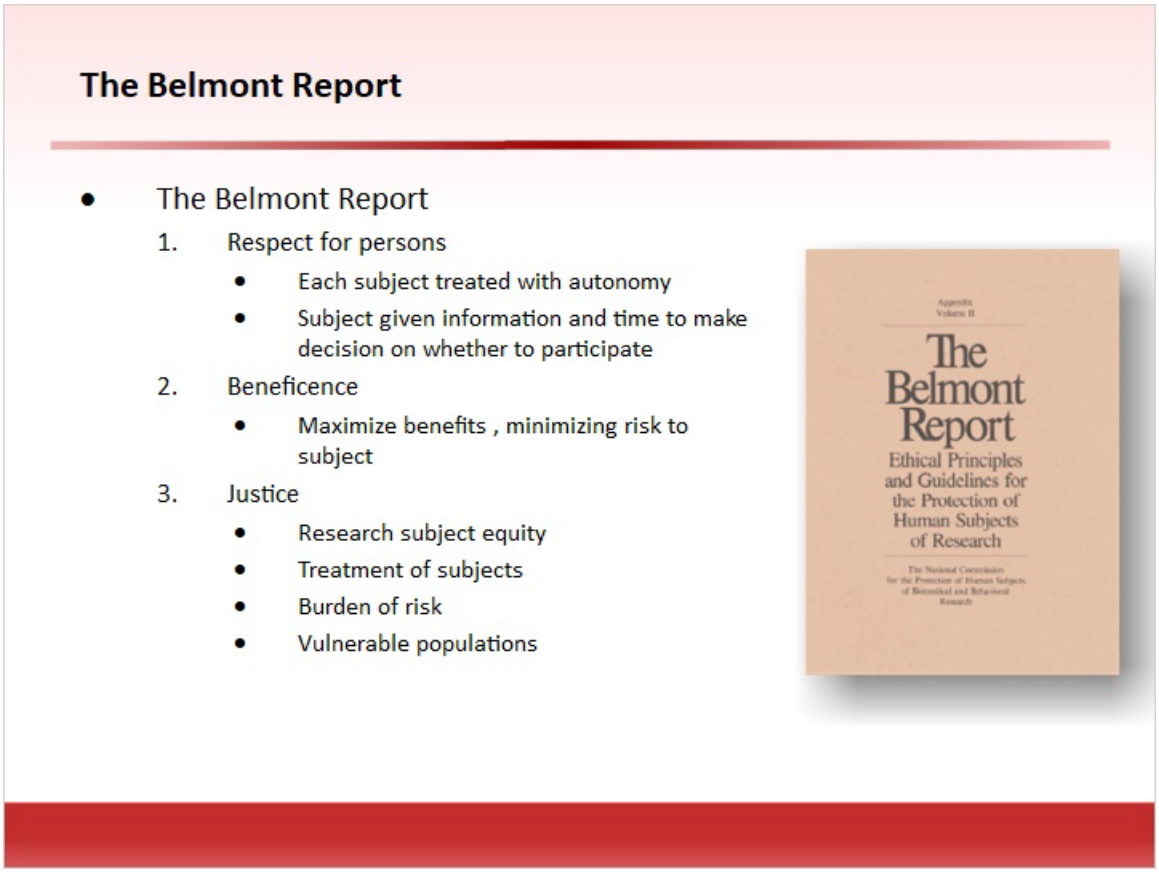
Notes:

Fifteen years after the 1932 Tuskegee syphilis studies in African Americans, the need for human subjects' protection finally escalated due to the development of the Nuremberg Code in response to experimentation by the Nazis. A code of conduct was established listing 10 principles. The first principle states that "the voluntary consent of the human subject is absolutely essential."

The World Medical Association established a similar code known as the Helsinki Declaration, so named after their 1964 meeting in Finland. Those principles for medical research can be found on the Association's website at www.wma.net.

In 1974, the United States signed into law the National Research Act. This act established a commission for the protection of human subjects of biomedical and behavioral research. The commission met in the Belmont Conference center of the Smithsonian Institute to determine the basic principles of conducting research using human subjects. Their proceedings became known as the Belmont Report.

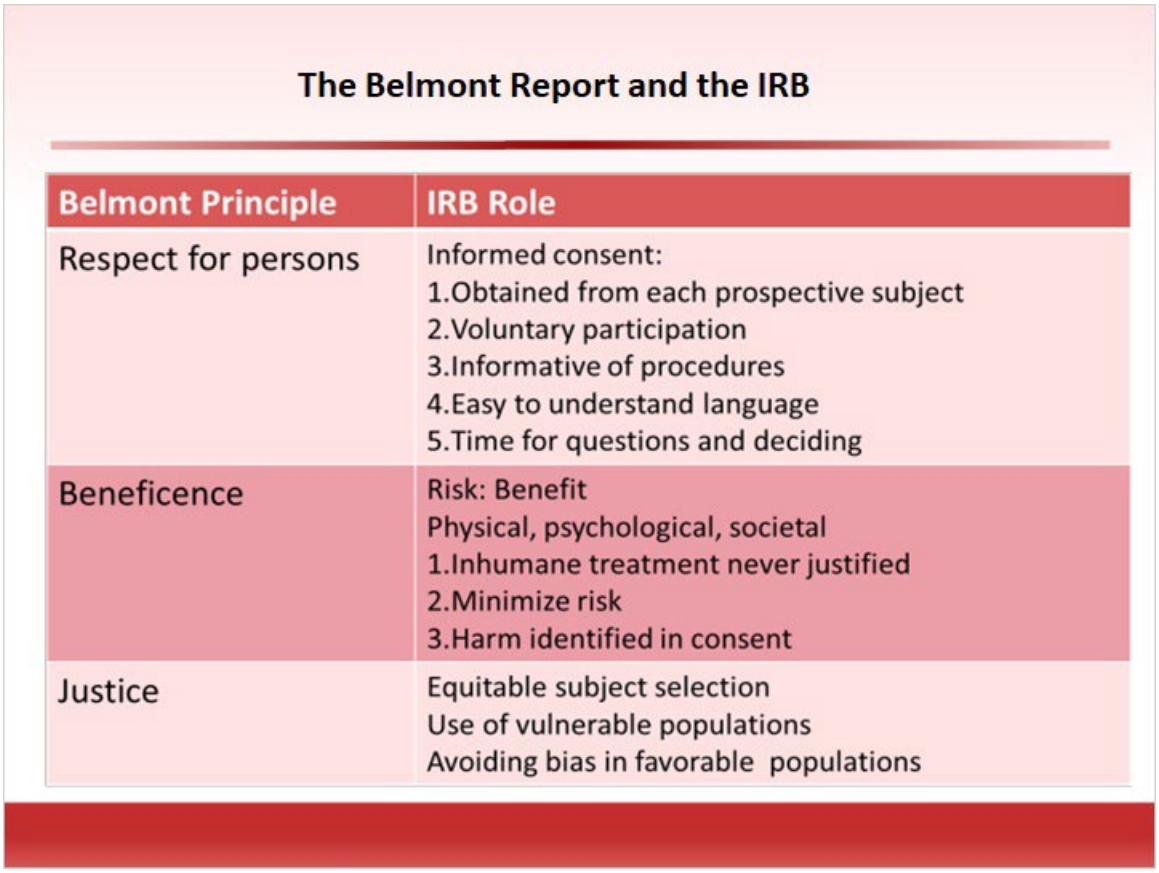
1.5 The Belmont Report



Notes:

The Belmont report follows three fundamental principles of ethics:
The first is Respect for persons. This means that each subject is treated with autonomy- they or their legal representative are capable of making their own decisions. They should be given the information and time to make the decision on whether to participate in the research. The subject must not be coerced into participating in activities that may cause them harm.
The second principle is Beneficence. Researchers should maximize the benefits of participation in research studies while minimizing the risk to the subject. This also means that the participant should not be subjected to harm that would outweigh the benefit.
The third principle of the Belmont Report is Justice. The following questions need to be answered. Who should be a research subject? Is there equity in choosing? How are research subjects treated? Who bears the burden of possible risks? What are the rights of vulnerable populations such as the poor, incarcerated, and similar.

1.6 The Belmont Report and the IRB

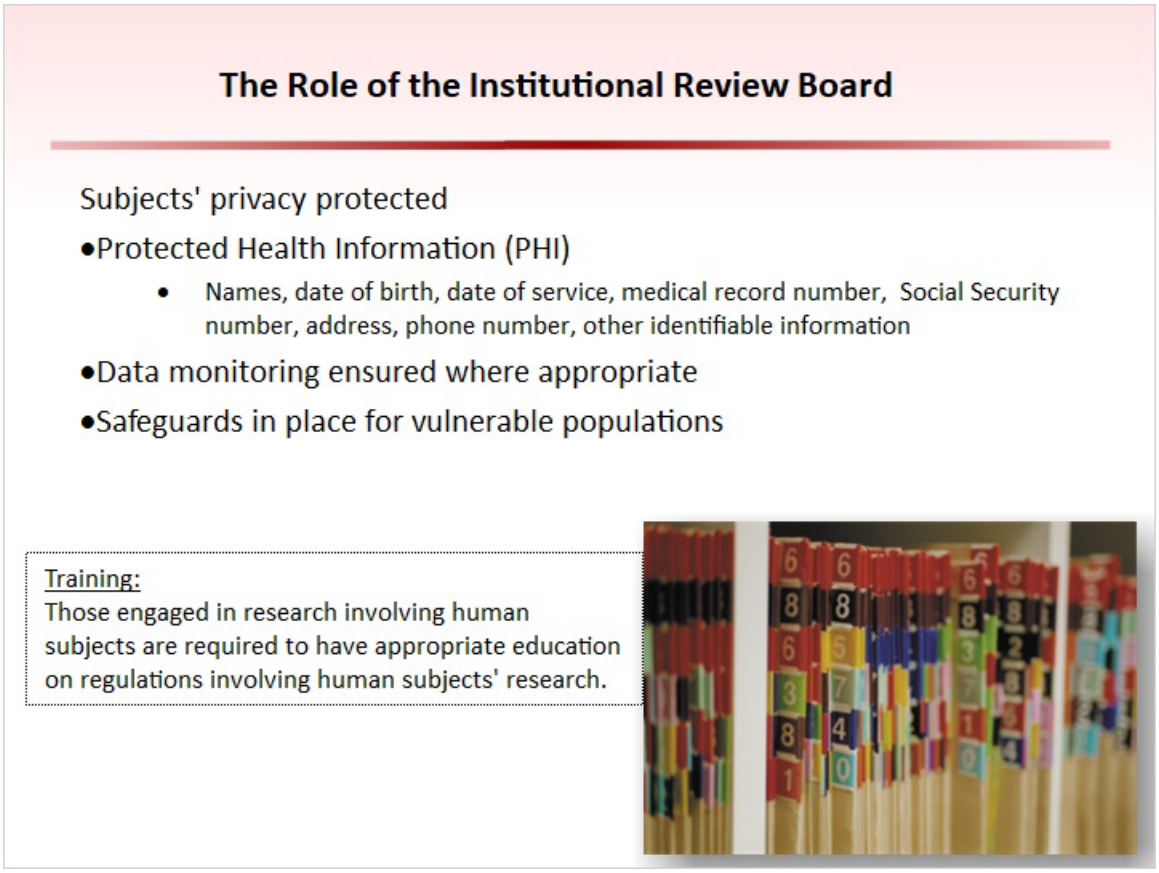


Notes:

The Institutional Review Board or IRB has several roles to ensure that the principles of the Belmont report are followed. For the first principle, respect for persons, the IRB is charged with ensuring that informed consent is obtained from each prospective subject or their legal guardian or authorized representative. Their participation is voluntary. The consent must inform the participant of the research procedures and alternatives. The consent must also be written in lay language or in terms that the participant can understand in their native language. The process of informed consent must allow for the participant to ask questions and time to make their decision.
In order to ensure beneficence, the IRB evaluates the risk:benefit ratio of the study. Do the benefits outweigh the possible harm? This includes physical and psychological harm. In addition, will society benefit from this research? Inhumane treatment is never justified. Any risk should be minimized whenever possible and the benefit must outweigh risk, especially in the case of impairment. All this must be explicitly stated in the informed consent. The principle of justice is covered by the IRB's evaluation of subject selection. If a vulnerable population, such as children or the poor or the incarcerated, is used as human subjects, what is the justification? Favorable populations should not sway the outcome of the research as to mislead the interpretation of results.

The selection of subjects should be equitable for race, sex, social, and cultural biases.

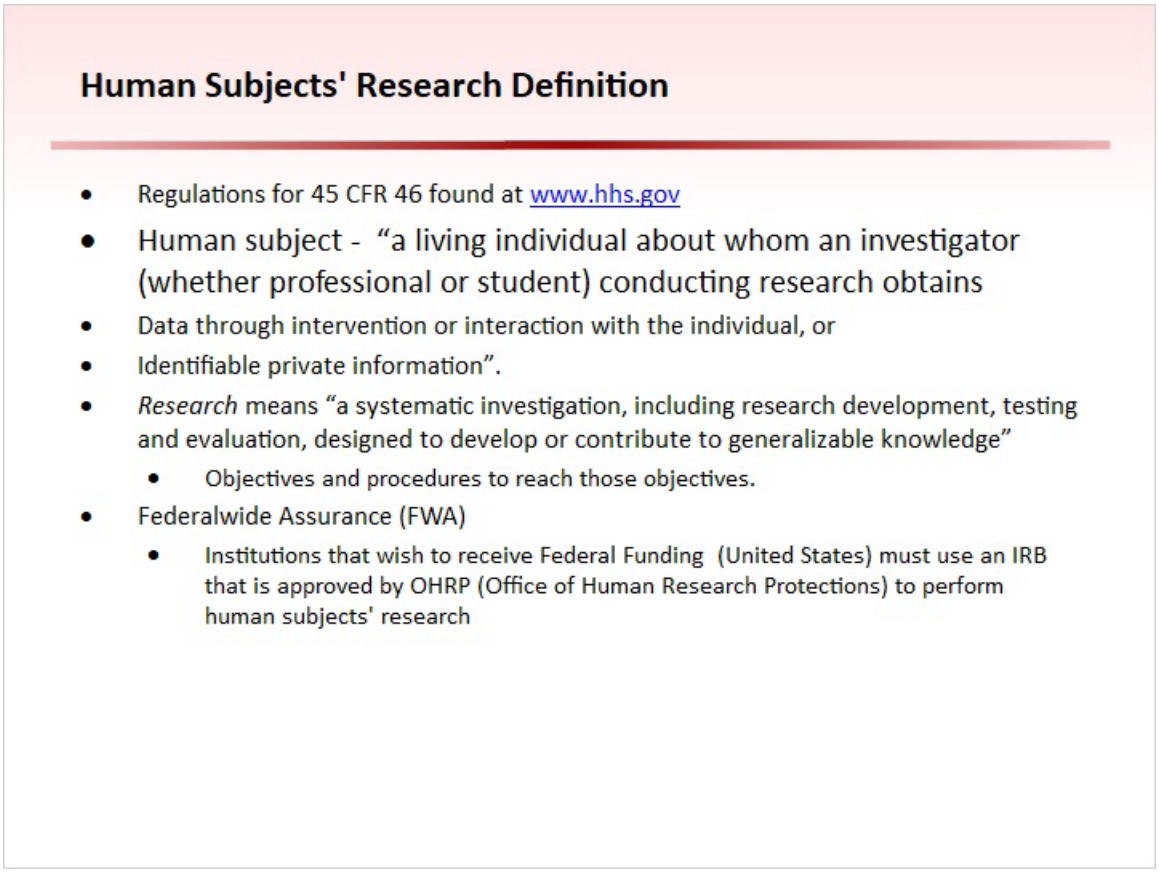
1.7 The Role of the Institutional Review Board



Notes:

The role of the IRB is to protect human subjects. The IRB should ensure that the privacy of the subject is protected. This includes the inadvertent release of protected health information (PHI). Protecting a person's name, Social Security number and date of birth seems so obvious, but few realize that the date of service is also protected information. Even zip codes can be considered protected health information if the first three digits are from populations of less than 20,000 people.
The IRB ensures appropriate data monitoring for the safety of the subjects. This includes adherence to protocol, equitable subject selection, and safeguards are in place.
All those who are engaged in research involving human subjects must have appropriate education and refresher courses on the regulations involving human subjects' research. This can be achieved by online modules or other courses; most academic institutions will have a system in place for training.

1.8 Human Subjects' Research Definition



Notes:

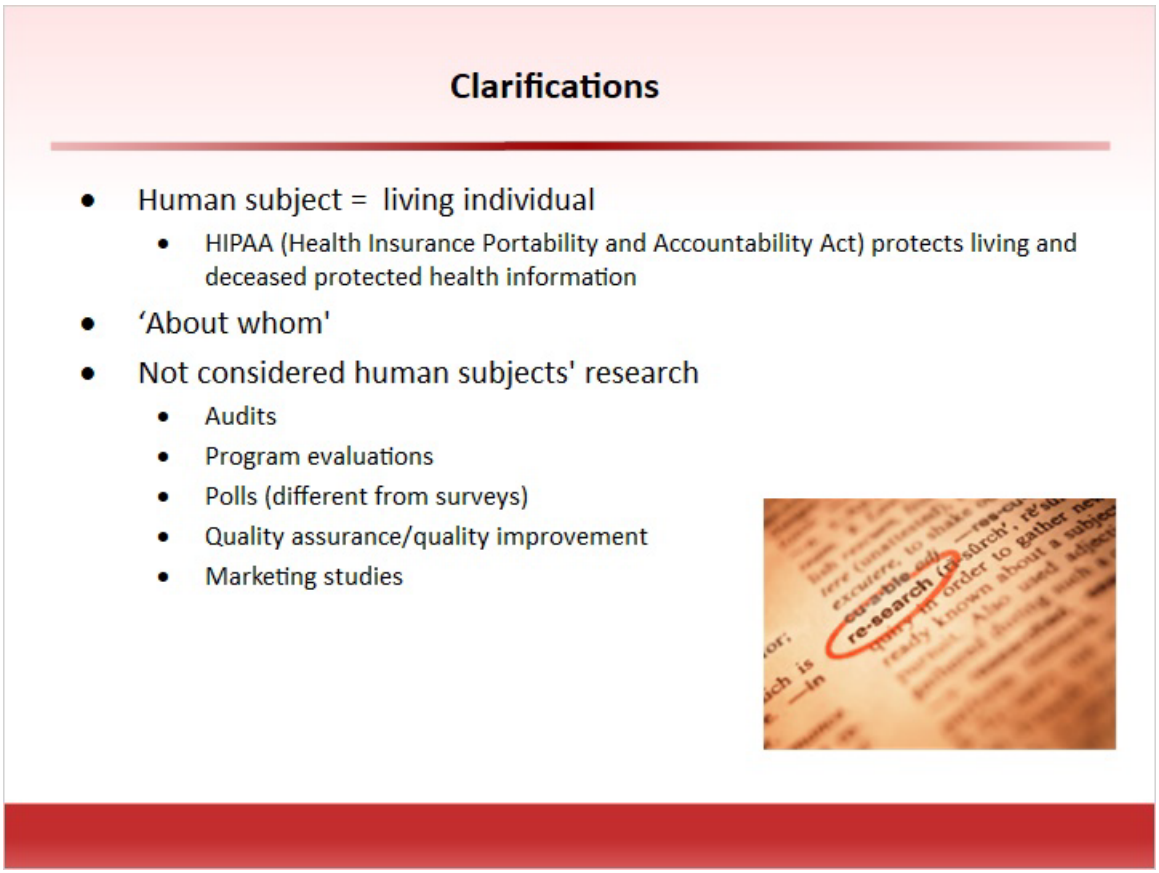
It is important to understand the terminology of 'research' and of 'human subjects' and where those terms apply. The United States code for federal regulations, 45CFR46, that discusses IRB regulations can be found at www.hhs.gov. These regulations apply to Department of Health and Human Services-supported or conducted research involving human subjects at any institution, defined as a public or private entity. This means that if your institution receives federal funding, even if the project specifically is not federally funded, most institutional policies require that the human subjects' research be submitted to the IRB. This is one way the institution ensures that all human subjects' research complies with federal regulations. As previously stated, many publications also require a statement of a review board's approval.

A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research establishes objectives and lays out procedures to reach those objectives.

In order for an institution to receive federal funding, a Federalwide Assurance (FWA) must be issued to an IRB that is approved by the Office of Human Research protections.

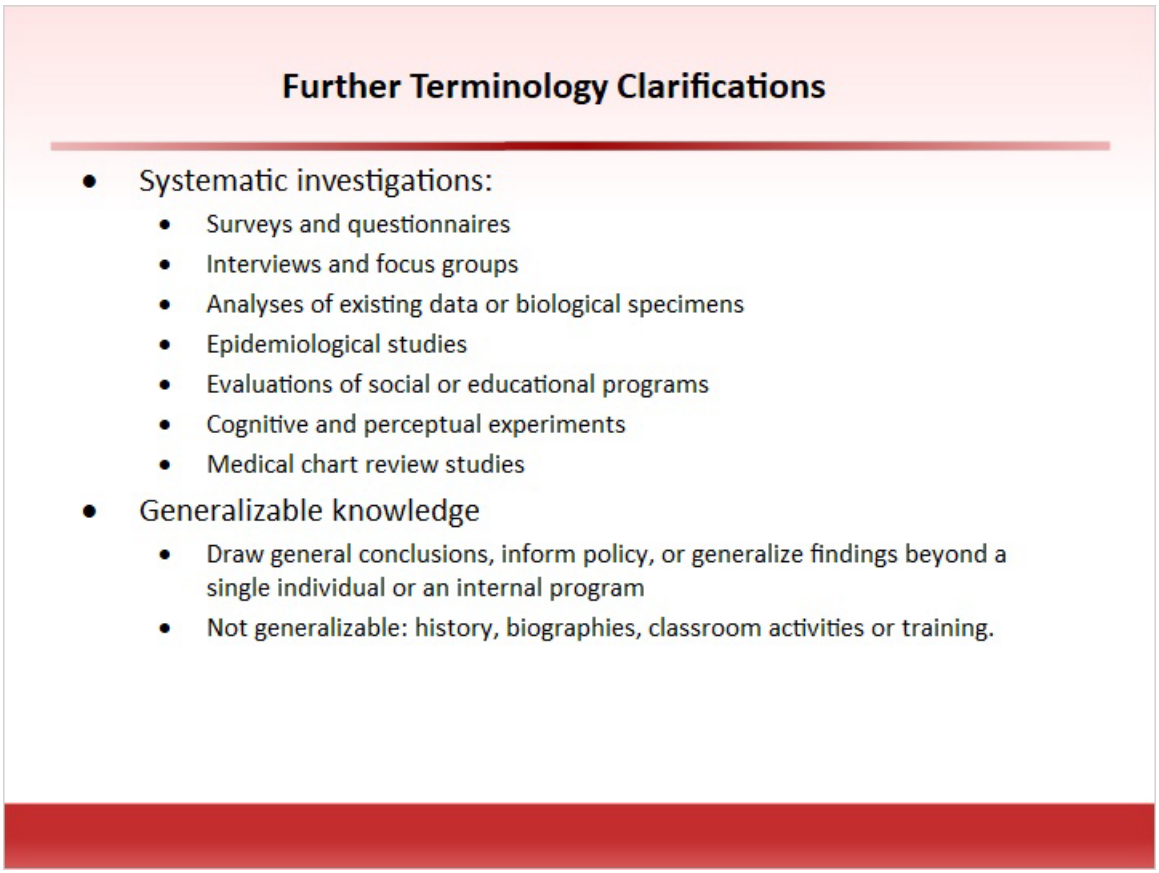
1.9 Clarifications



Notes:

To further clarify, the definition of a human subject is a living individual; thus federal regulations for human subjects' research only apply to a living person. However, it is important to note that protected health information for both the living and deceased are protected by HIPAA, the Health Insurance Portability and Accountability Act.
The definition states an individual ***about whom*** the investigator obtains information. For example, if a survey is conducted that asks ***you*** about ***your experiences*** while learning how to perform ICSI, that is about you as an individual. However, if the survey asks if your laboratory performs ICSI and what training program is in place, that is not about a specific person or their experiences.
Lastly, studies not considered human subjects' research include audits, program evaluations, polls, marketing studies, and quality assurance or quality improvement programs.

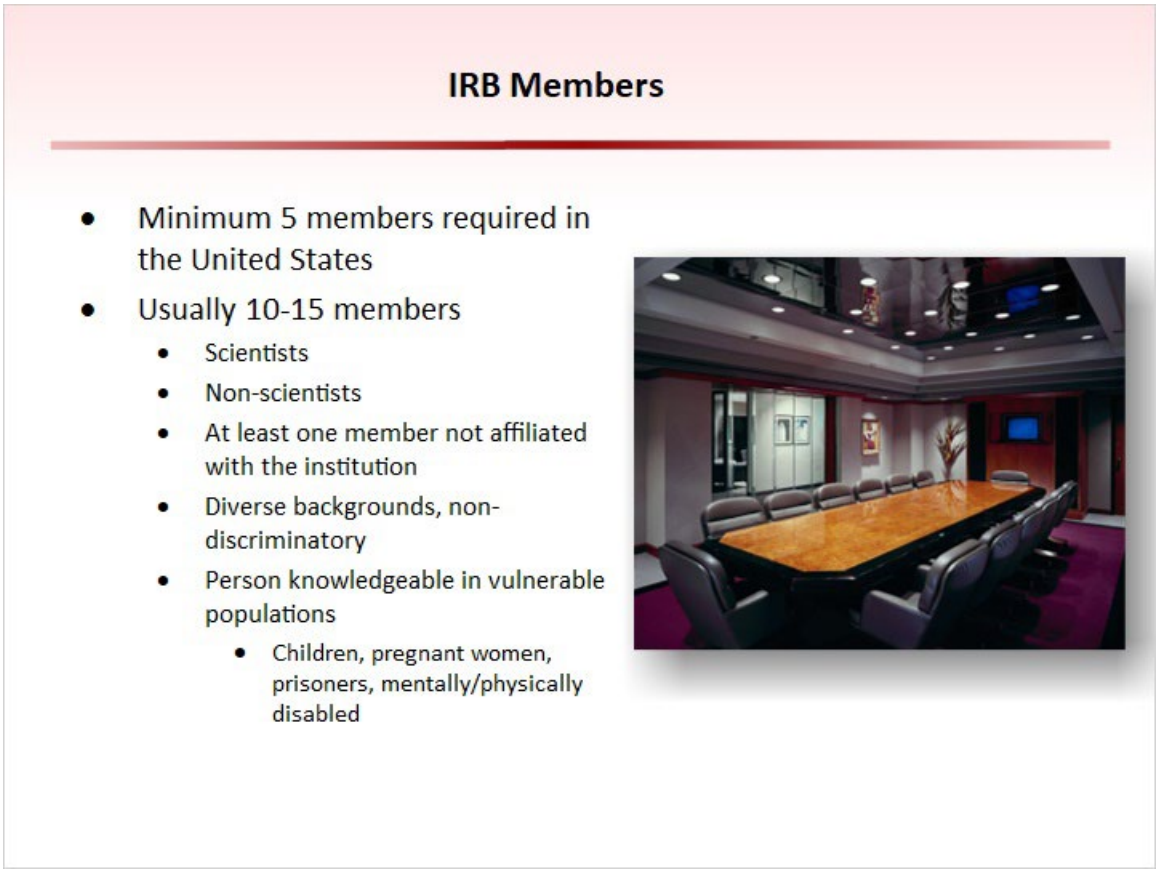
1.10 Further Terminology Clarifications



Notes:

Listed are examples of systematic reviews to clarify. Generalizable knowledge does not necessarily mean that the information is publishable. Rather, it is the ability to draw conclusions about the findings that are beyond the scope of the individual or internal process. Some examples of ‘not generalizable knowledge' would be histories or biographies, or classroom activities for training purposes.

1.11 IRB Members

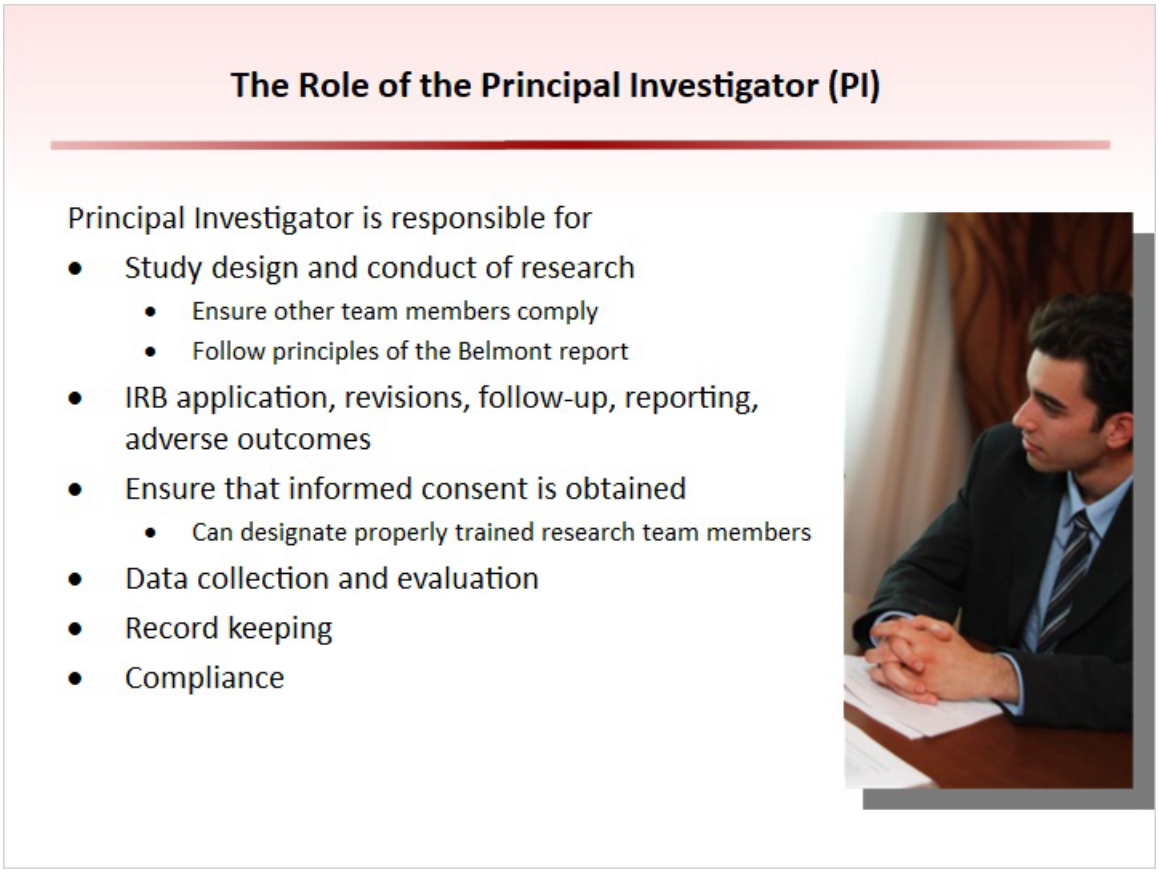


Notes:

In the United States, IRBs are required to have a minimum of 5 members, although usually there are 10 to 15 members. These individuals have both scientific and non-scientific backgrounds as well as at least one member who is not affiliated with the institution. A member should be designated as someone knowledgeable regarding subjects considered to be a vulnerable population, such as research involving children less than the age of 18 years, pregnant women, prisoners, or others who are mentally or physically disabled.

It is important that there is diversity in the IRB and that members are from different races, gender, and cultural backgrounds that may be sensitive to the issues of research studies presented.

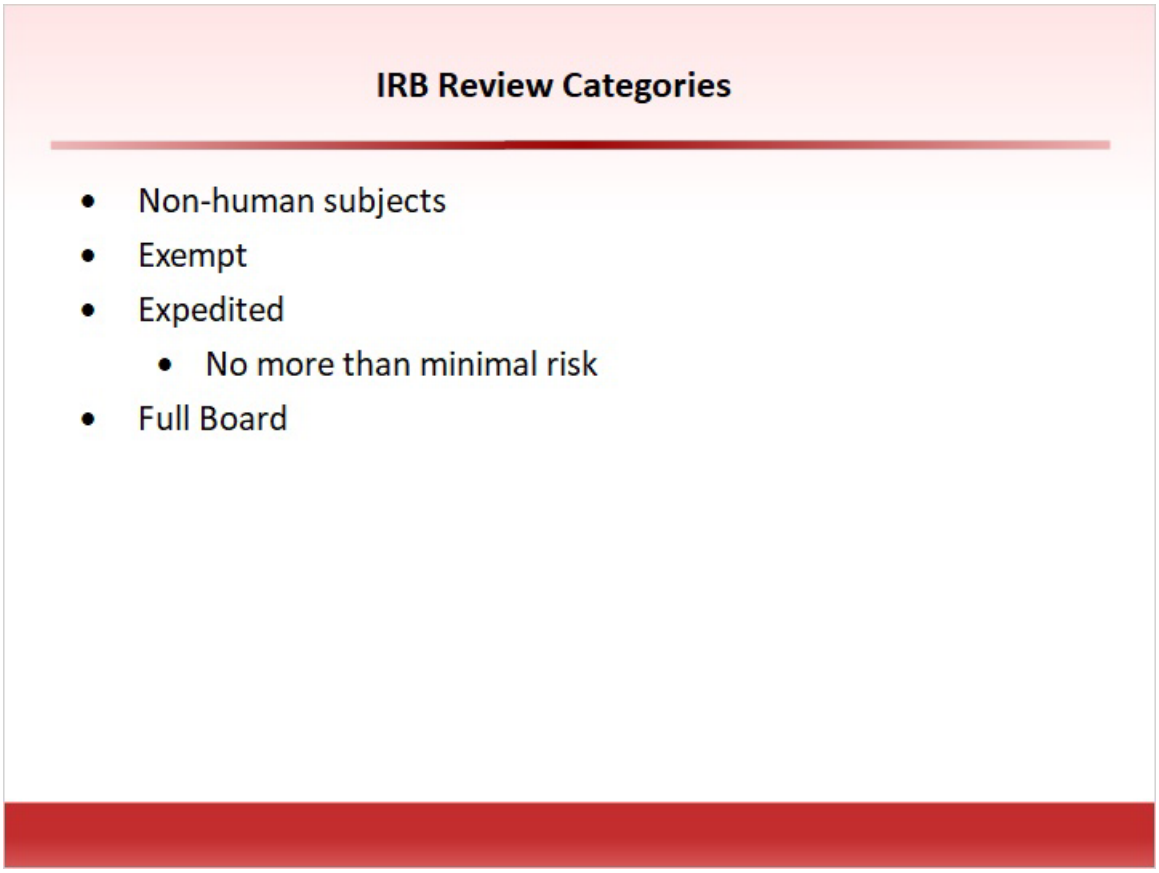
1.12 The Role of the Principal Investigator (PI)



Notes:

The principal investigator or PI is responsible for the study design and to ensure that the research is carried out in a manner that follows the federal, state, local, and institutional guidelines and ethical principles.
The PI is also responsible for the application to the IRB, any revisions, amendments, follow-up, or other reporting involved with the research. This also includes the immediate reporting of any adverse outcomes that occur in the study.
The PI does not have to be the sole person obtaining the informed consent, but the IRB application should list which other team members will be designated to do so. The PI is however, then responsible to ensure that those research team members are properly trained in the elements of the informed consent so that the subjects can be fully informed to give their voluntary consent.
The PI also is responsible for the maintenance of research data and evaluation and other compliance.

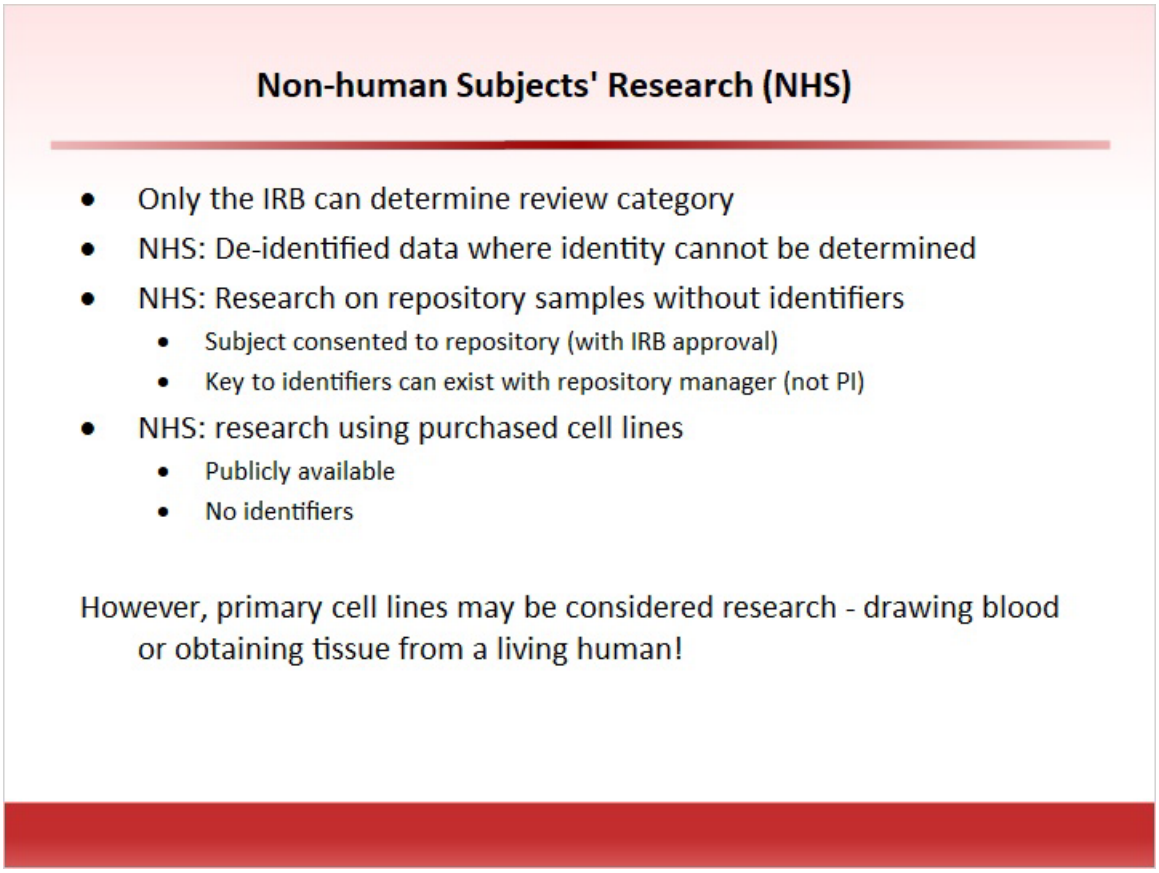
1.13 IRB Review Categories



Notes:

Several categories of IRB review exist and will be explained. It is important to remember that it is the IRB, and not the investigator that makes the determination of the level of review. Even if the research is classified as non-human subjects, it is the IRB's responsibility to determine that.

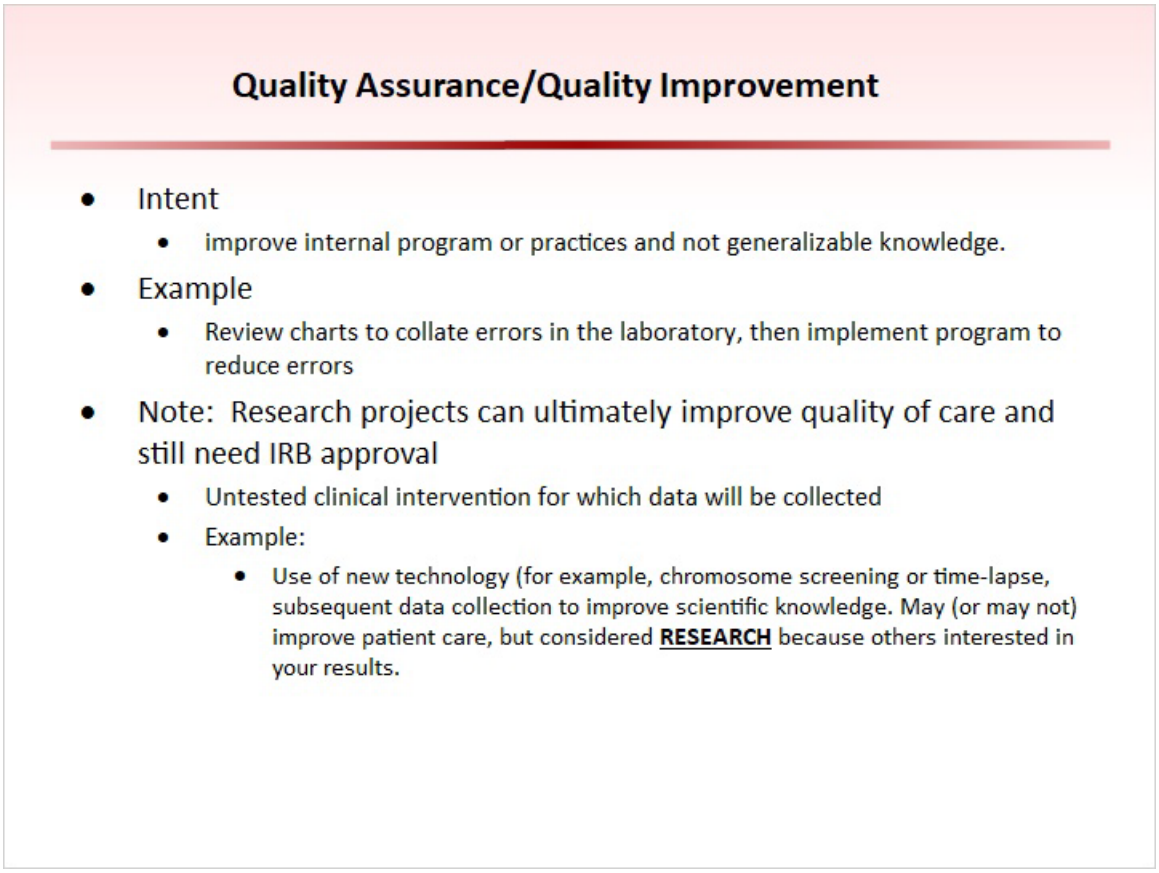
1.14 Non-human Subjects' Research (NHS)



Notes:

Listed here are several examples of what might be classified as non-human subjects' research.
This includes the use of de-identified data where the identity cannot be determined or research on repository samples that have no identifiers.
Purchased cell lines from commercial companies are also considered in this category. However, if the investigator obtained blood or tissue to establish a primary cell culture, more than likely that is considered human subjects' research since an intervention with a living person occurred.

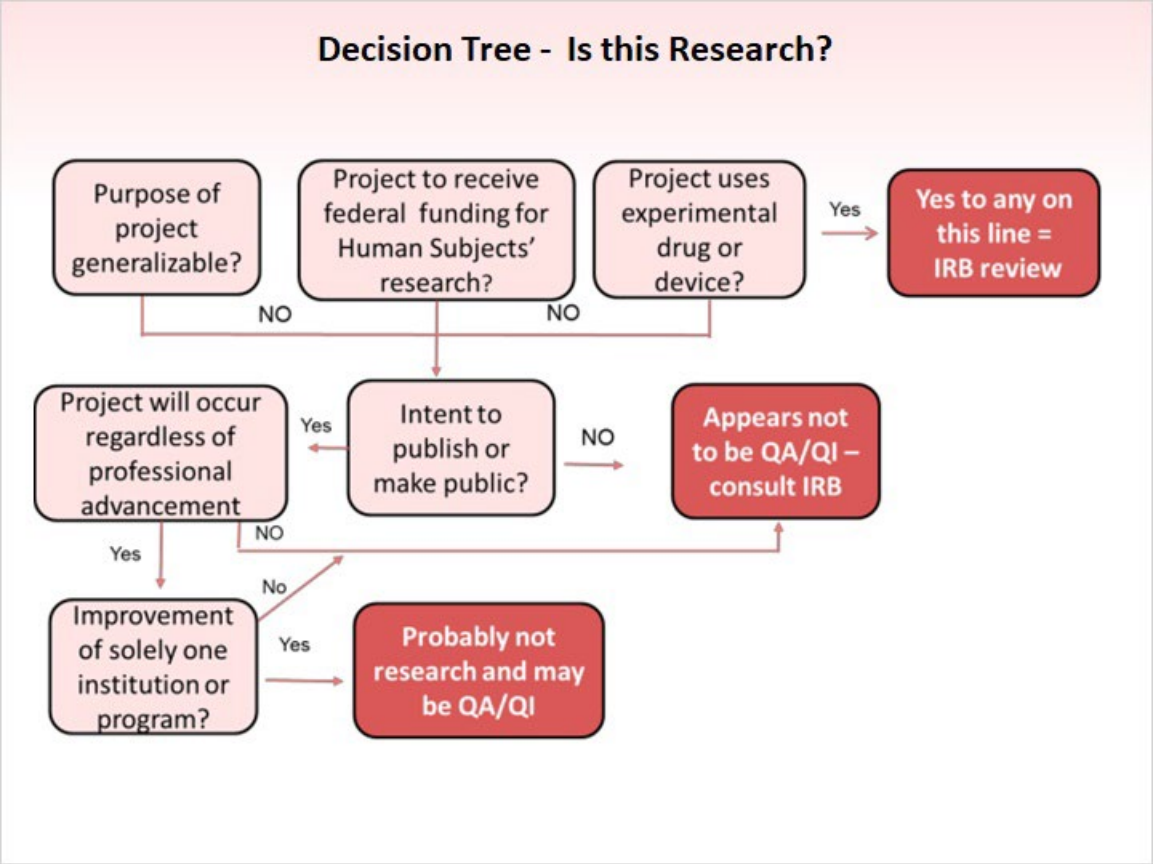
1.15 Quality Assurance/Quality Improvement



Notes:

The intent of quality improvement or program evaluation is to improve internal practices at a single institution and the results are not generalizable. For example, an IVF lab may review its patient charts to collate the errors that have occurred, then use the information to implement a program to minimize those errors.
Projects can ultimately have the possibility to improve patient care as well as be considered generalizable knowledge. For example, time-lapse morphokinetics may be used to determine if it will (or may not) improve patient care at a clinic. That can be a clinical decision to use; however, the research aspect is when cycle data such as embryo development and pregnancy rates are collected and evaluated on those patients in which it was used.

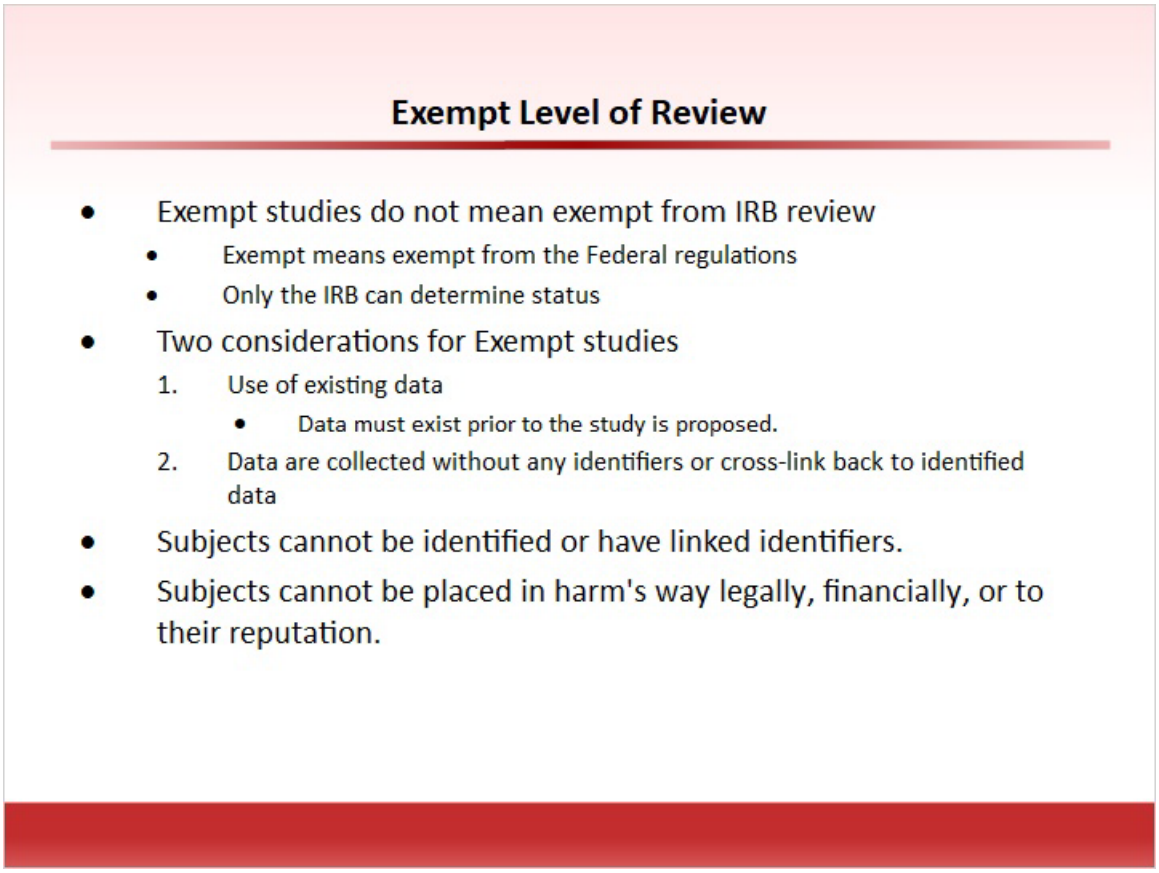
1.16 Decision Tree – Is this Research?



Notes:

A decision tree can provide guidance when trying to ascertain whether or not a project might involve research. The IRB still needs to be able to make that determination, but having some guidance may help in the submission process. Answering "Yes" to any of the questions in the top boxes means that it is likely that the IRB needs to review the project.

1.17 Exempt Level of Review



Notes:

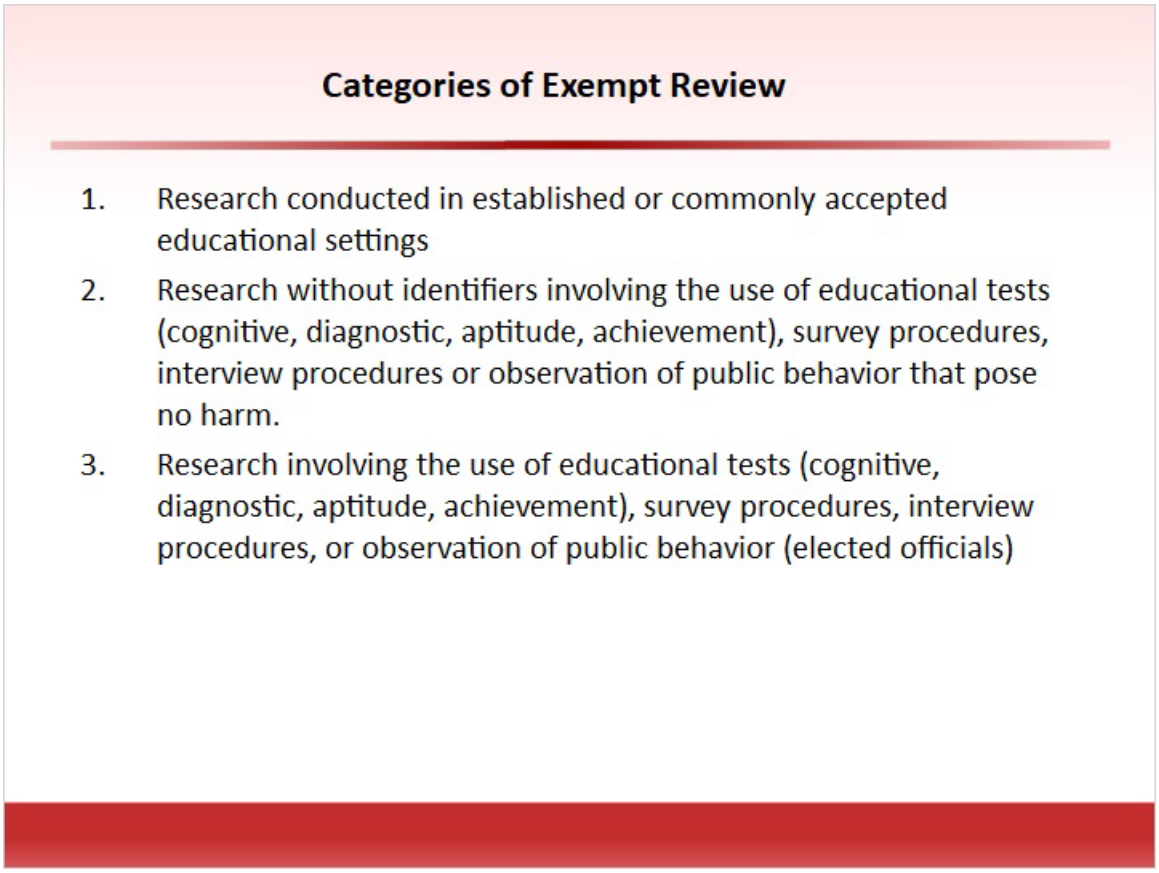
The classification 'Exempt' may be confusing and it does not mean that the study is exempt from IRB review. Rather, the term 'exempt' means that a study is exempt from the Federal regulations. Only an IRB can determine the appropriate necessity and level or review.

There are two considerations for Exempt review to proceed. First, the study must use existing data. Federal regulations define that the data must exist ***prior*** to the submission of the study to the IRB. An example of this is a study for retrospective chart review submitted to the IRB on January 1 and is approved February 1, then only data that existed prior to January 1 may be used.

The second consideration for exempt status is that no cross reference can exist-once the data are collected, there is no way to identify the subject.

Even if exempt status is granted, the principles of the Belmont Report must be followed.

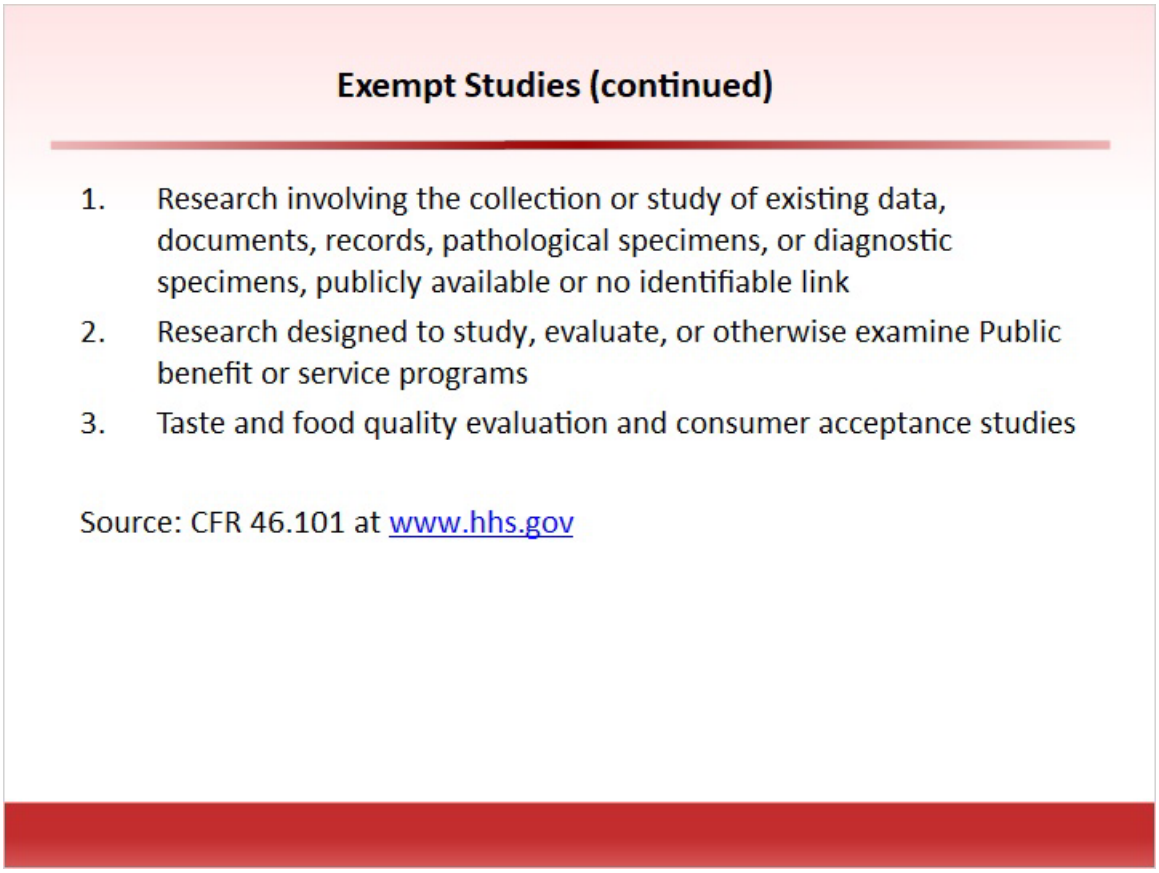
1.18 Categories of Exempt Review



Notes:

There are 6 categories of research that an IRB can deem as exempt from Federal Regulation. These are:
(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless they pose harm.
(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if the human subjects are elected or appointed public officials or candidates for public office.

1.19 Exempt Studies (continued)

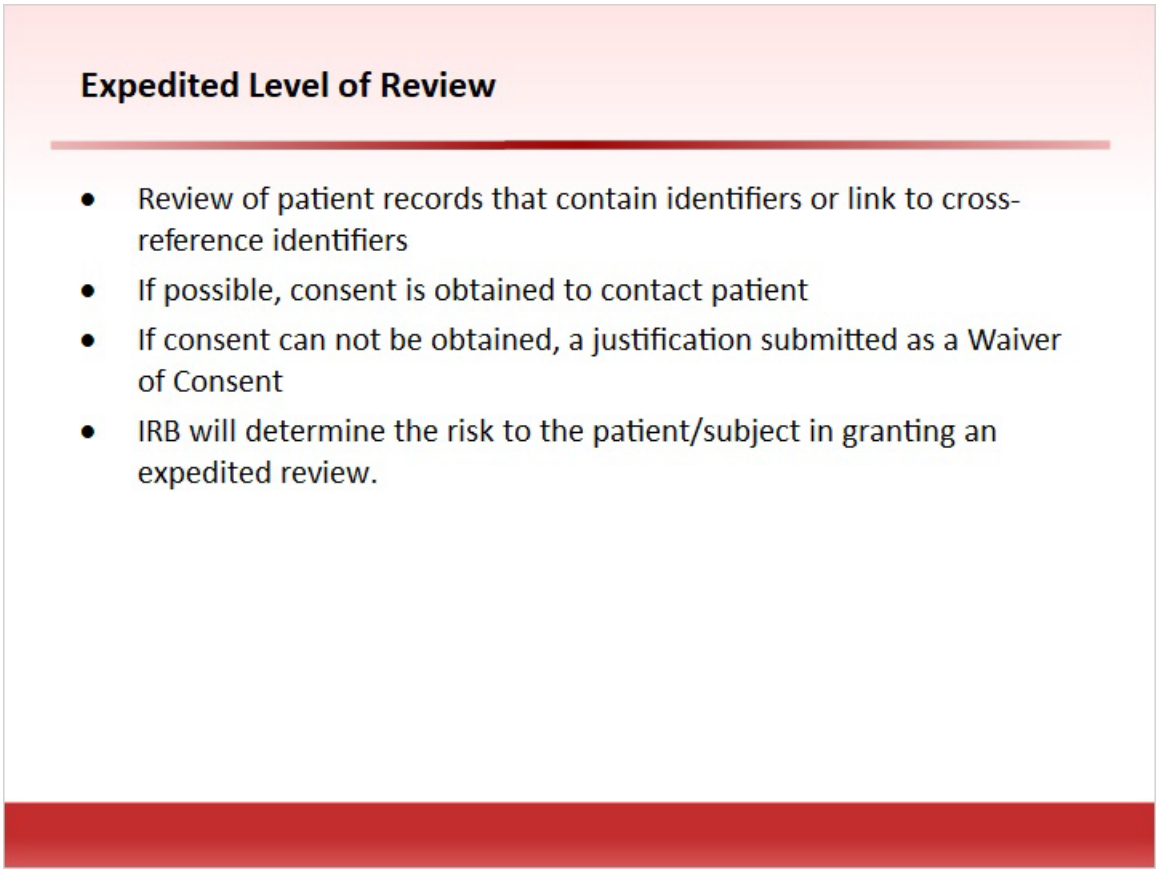


Notes:

(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 subjects cannot be identified either directly or through identifiers linked to the subjects. This is a key to differentiate between exempt and expedited reviews as to whether an identifiable link exists.
(5) Research and demonstration projects, that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine Public benefit or service programs
(6) Taste and food quality evaluation and consumer acceptance studies.

Further information regarding these determinations can be found in the Code of Federal Regulations.

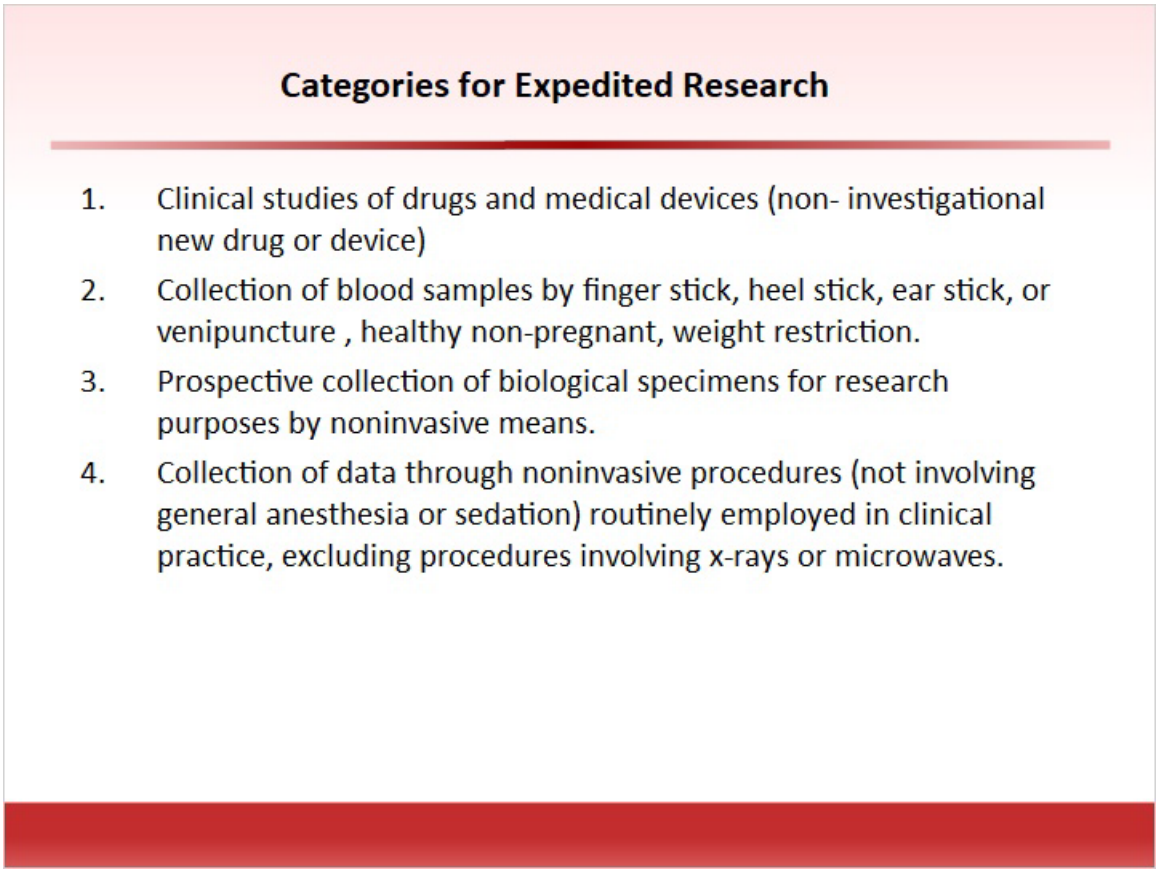
1.20 Expedited Level of Review



Notes:

An example of expedited review is a retrospective chart review that contains identifiers or can be cross-referenced back to a patient. If possible, consent should be obtained, but a waiver of consent can be applied for. The IRB determines the risk to the subject in granting this level of review.

1.21 Categories for Expedited Research



Notes:

There are 7 categories for expedited research. Each category has more specific information that can be obtained at www.hhs.gov

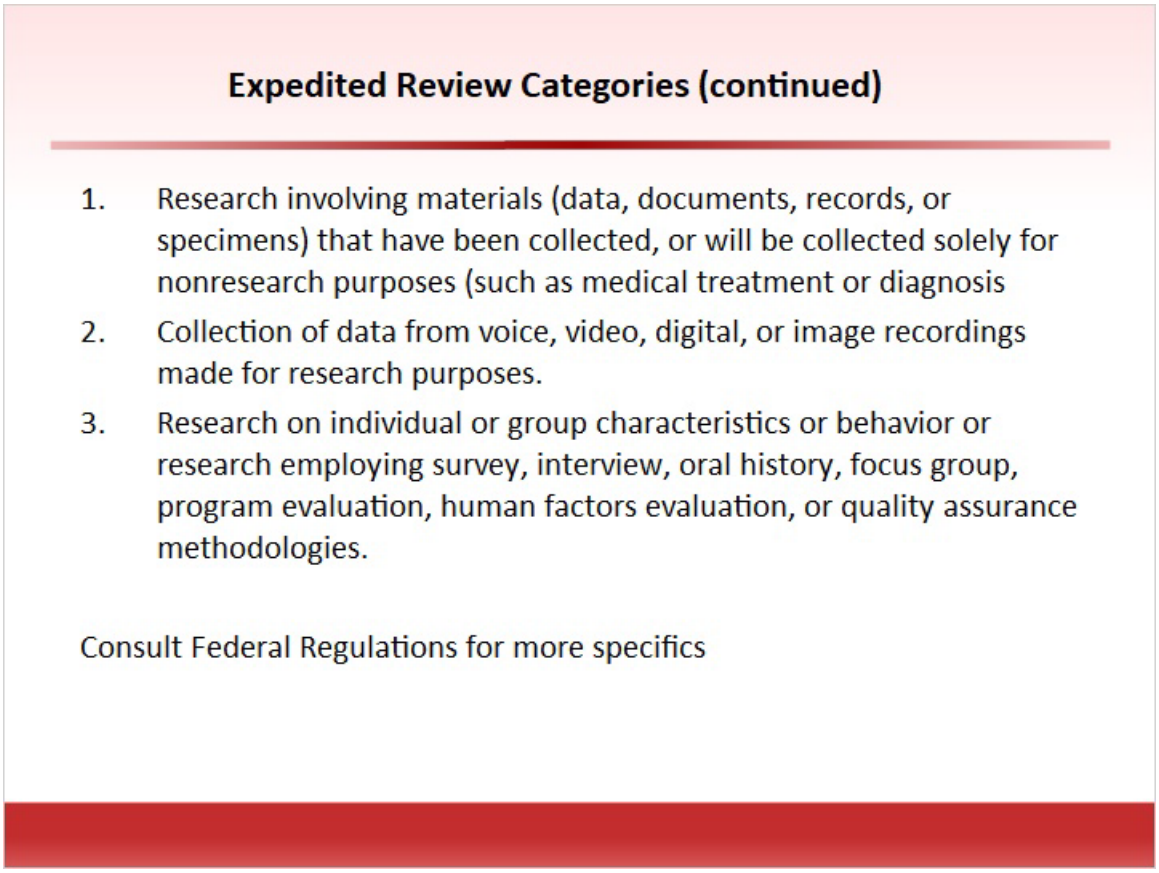
1.Clinical studies of drugs and medical devices that do not need an investigational new drug or device rating.

2.Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

3.Prospective collection of biological specimens for research purposes by noninvasive means

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves

1.22 Expedited Review Categories (continued)

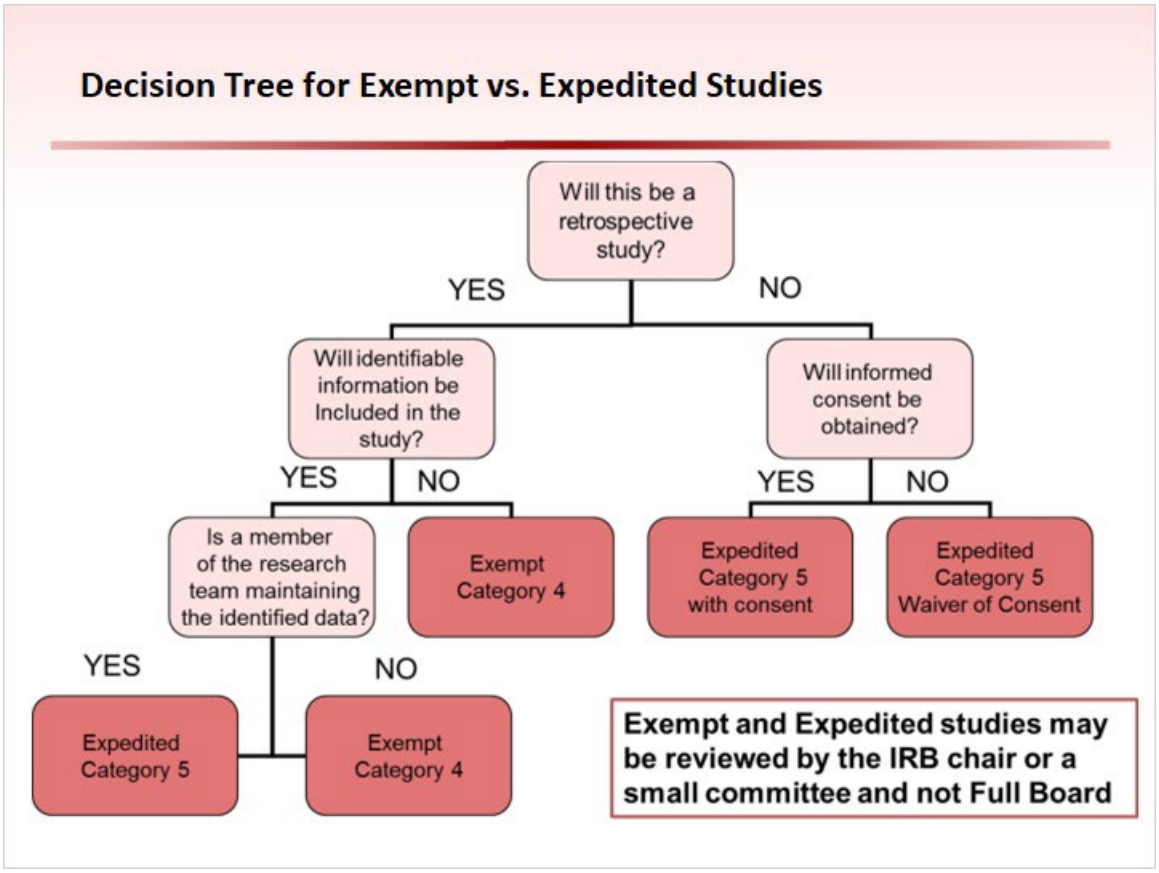


Notes:

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.

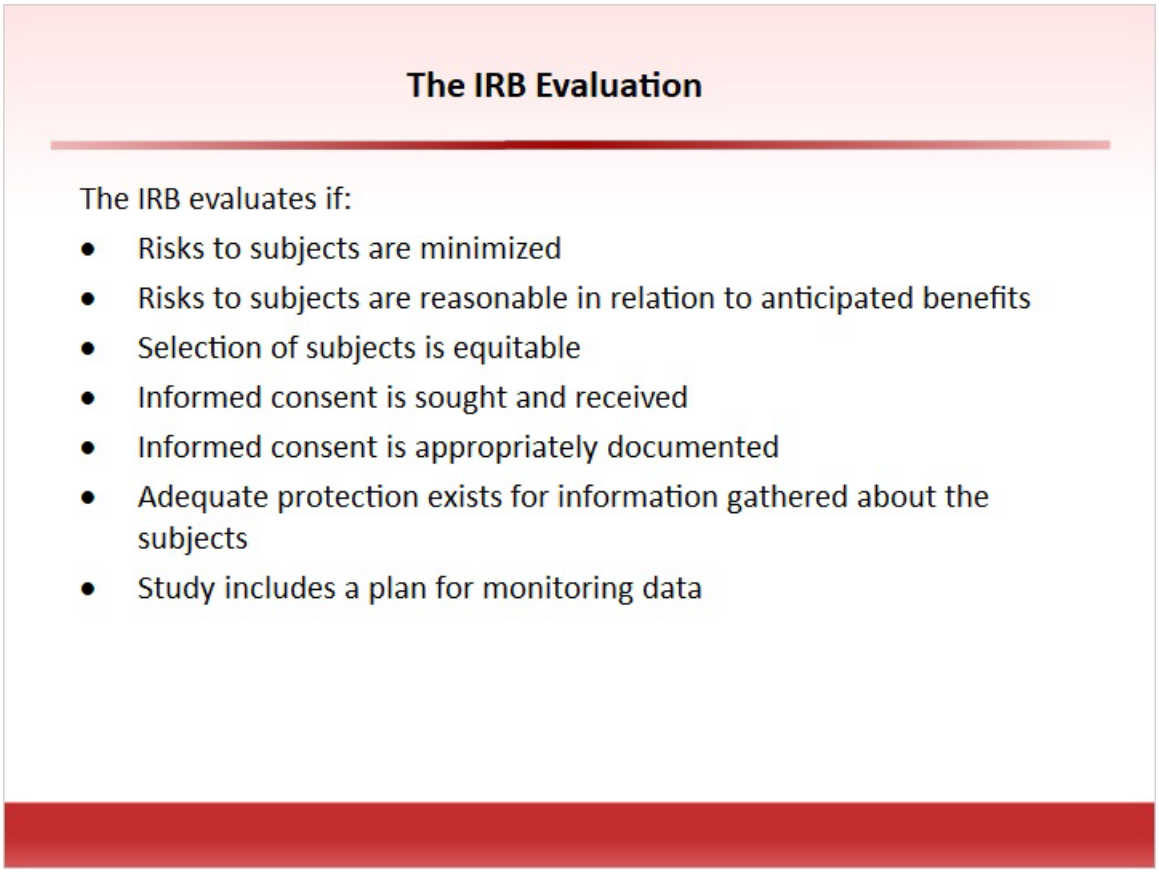
1.23 Decision Tree for Exempt vs. Expedited Studies



Notes:

Again, a decision tree may be helpful to determine if a study is exempt or expedited. Many IRBs allow the chairperson, or a smaller subcommittee to review such proposals rather than being reviewed by the entire board. All board members should be updated as to the status of the research.

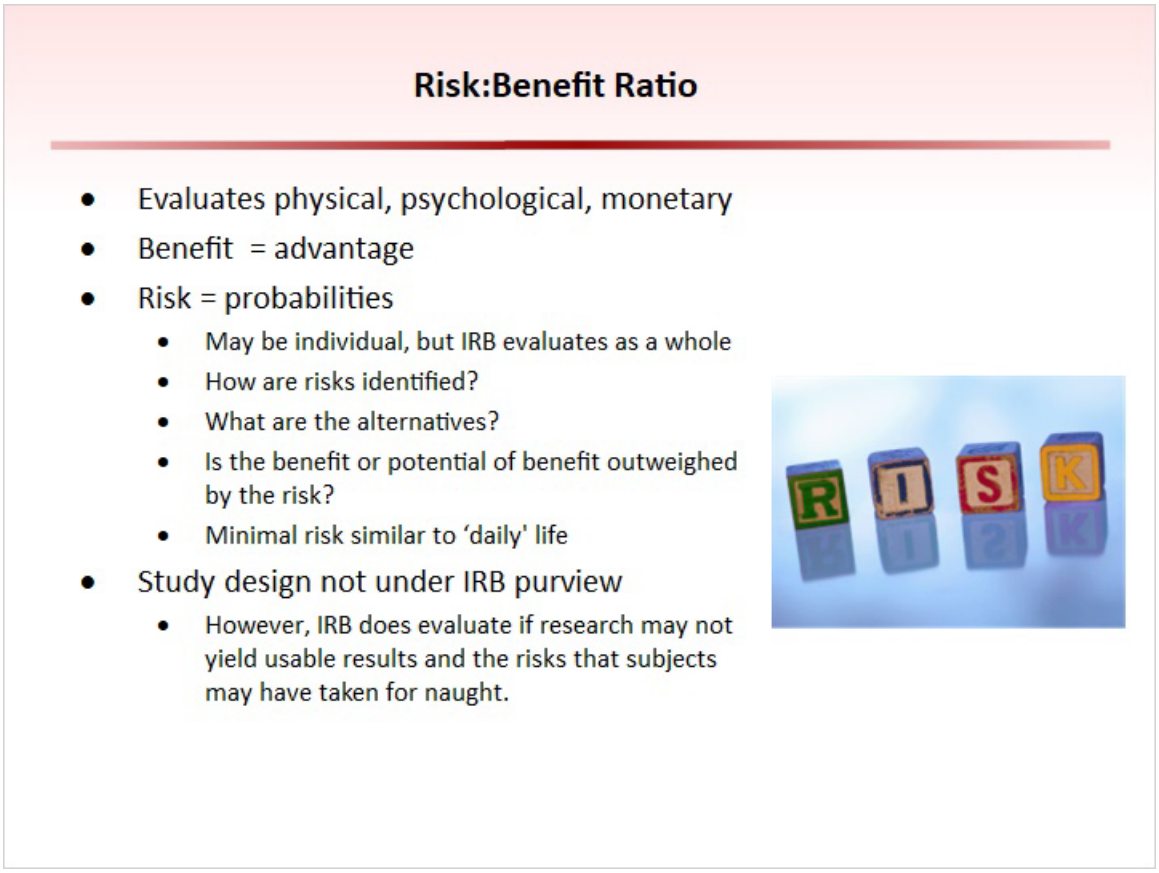
1.24 The IRB Evaluation



Notes:

Several key pieces of information are evaluated by the IRB during the approval process as listed here.

1.25 Risk:Benefit Ratio



Notes:

The IRB evaluates the risk:benefit ratio of the study. This includes risks that are physical, psychological, and even monetary. A benefit is deemed as a real advantage or the prospect of advantage, a fact. On the other hand, a risk is defined as a probability. Certain individuals may be more willing to take risks that others will not. The IRB's responsibility is to determine if *anyone* should be allowed to take that risk. Then individuals are free to decide if that is an acceptable risk for them. In making this determination, the IRB will evaluate how the risks are identified and presented to the subject. Are there alternatives to avoid those risks? Does the benefit or potential for benefit outweigh those risks?

Minimal risk is defined as a risk that is no greater than what might occur in a person's daily life. This includes routine physical or psychological exams. For example, having blood drawn is not always part of 'daily' life. But drawing a small amount of blood is considered minimal risk in that it can be part of a routine physical exam.

The IRB is not responsible for the study design. The board may make suggestions to the study design to minimize harm or so a subject is not potentially part of a research study that will not have usable data or could cause unnecessary harm. For example, a study is conducted and there are not adequate subject numbers to draw valid conclusions. Or, a

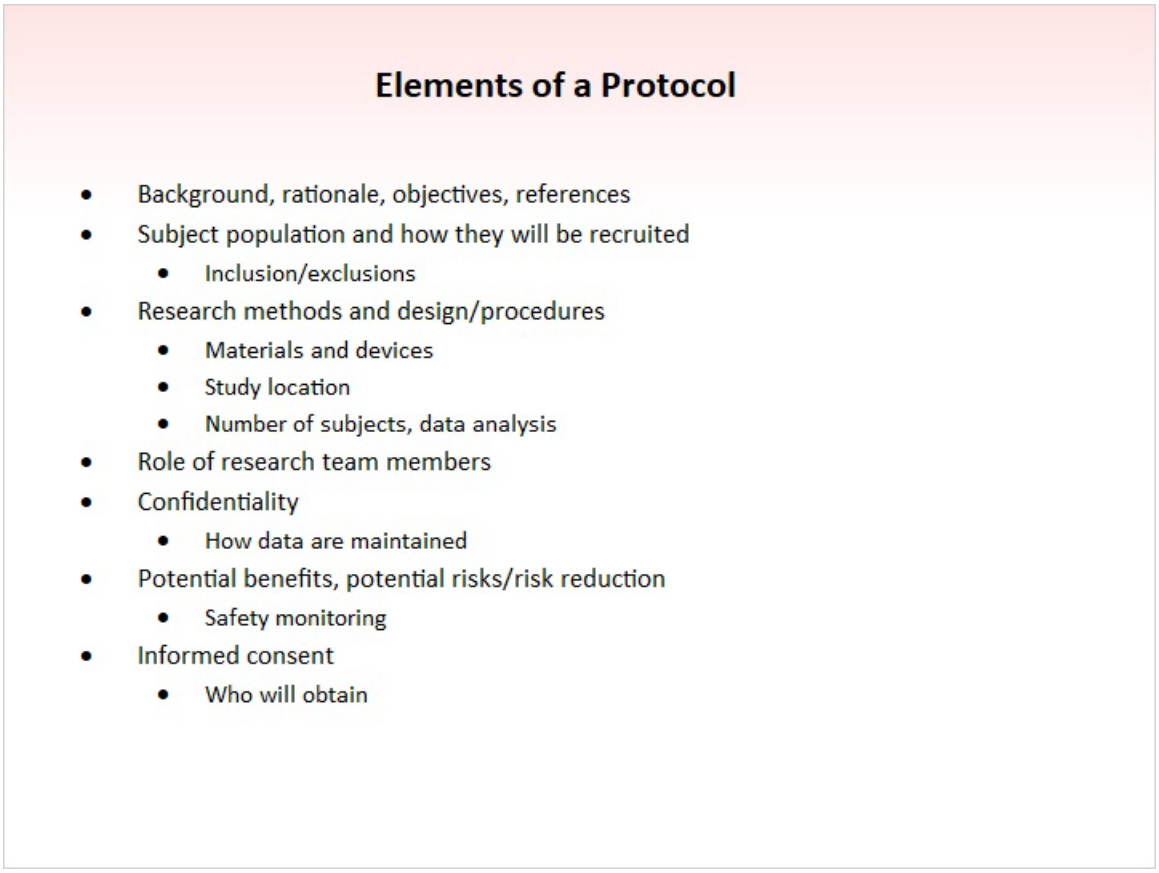
study is conducted without having a proper control. The participant may have been subjected to a study where adequate conclusions cannot be made under a current study design so it may be part of the IRB review to recommend changes to the study design to minimize the subjects' harm.

1.26 IRB Submissions

Notes:

Several documents are listed here that should be presented to the IRB for evaluation so the board has the information to determine if approval should be granted.

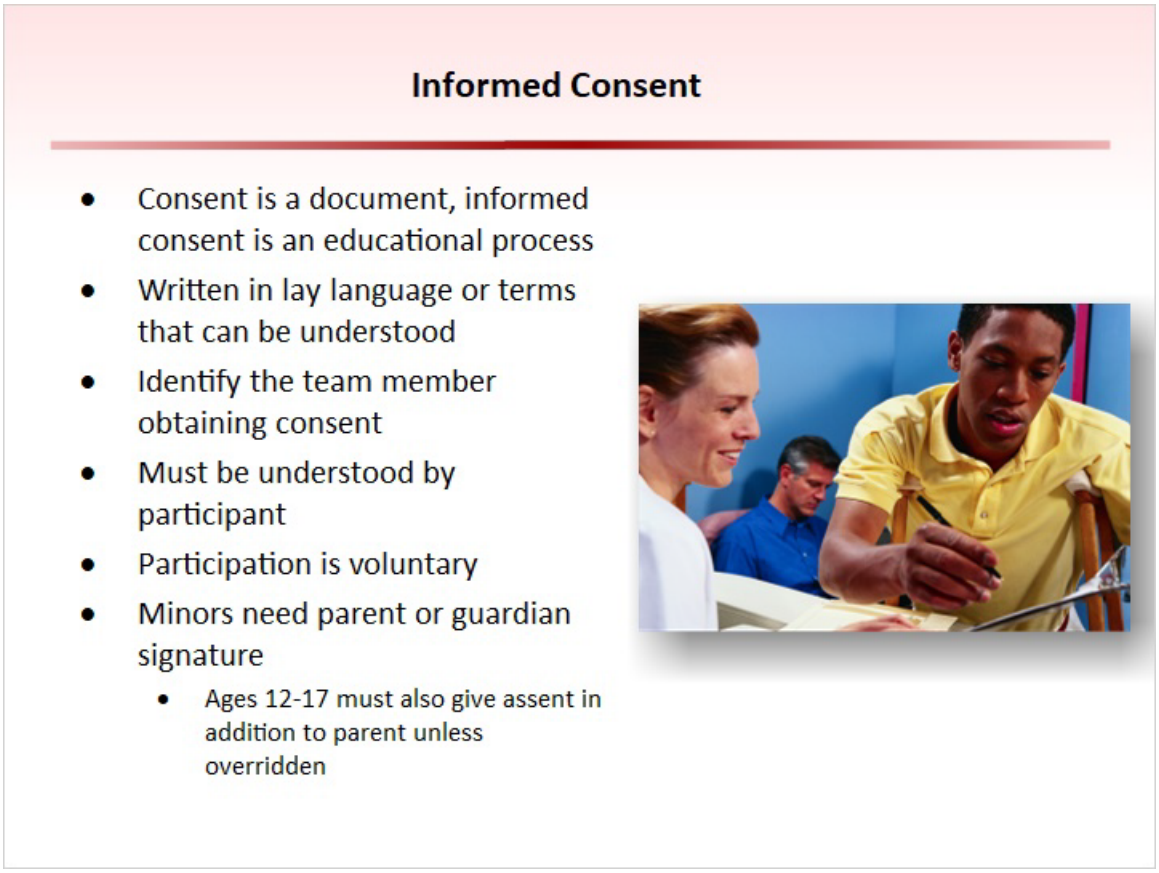
1.27 Elements of a Protocol



Notes:

The protocol submitted to the IRB should address the elements listed here.

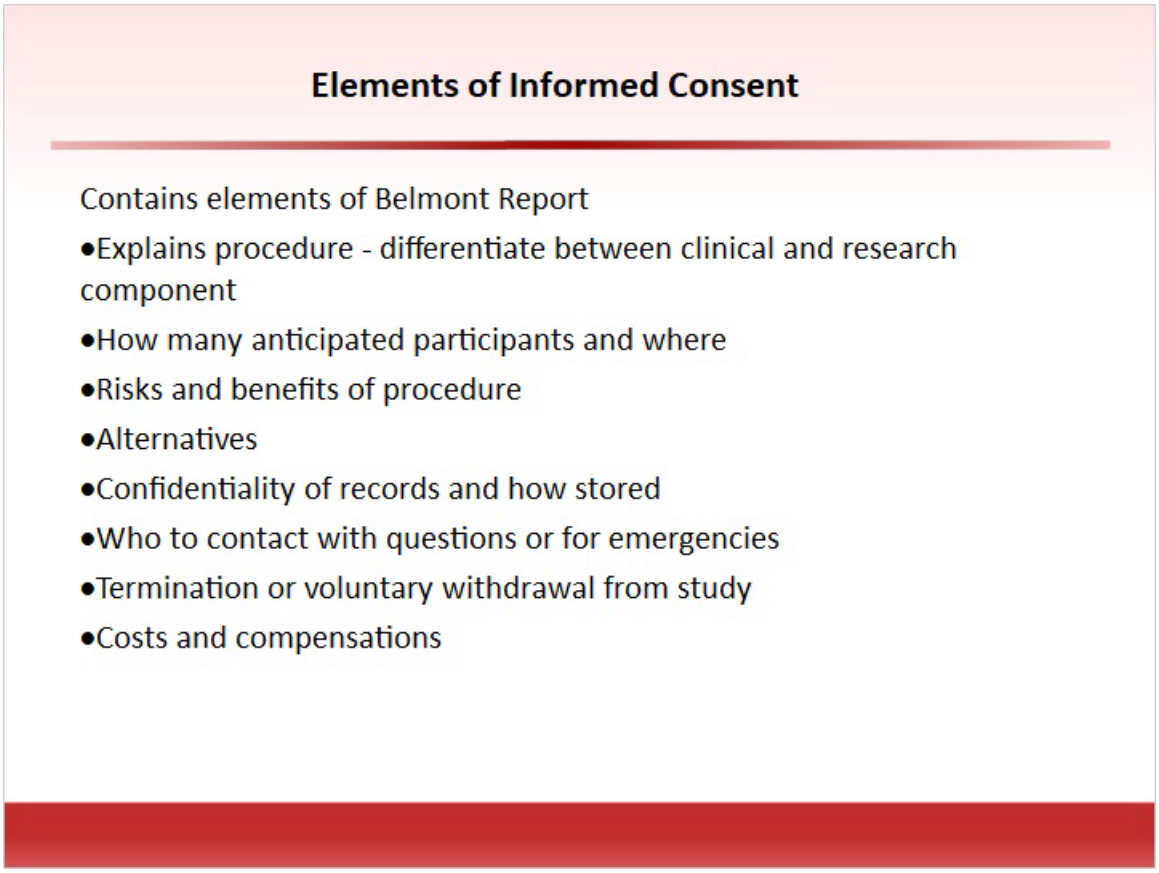
1.28 Informed Consent



Notes:

The consent form itself is just a document, but obtaining informed consent is part of the educational process. A research participant needs to be given the time and opportunity to read through the document. Although one cannot guarantee that the document is actually understood, the consent form consists of elements that will enhance that understanding as explained next. The person or persons obtaining the informed consent are identified to the IRB in the submission so adequate training is ensured. Consents for participants less than 18 years of age must be signed by the parent or legal guardian. State laws vary as to whose signature is required for emancipated minors. If a minor is ages 12-17, the parent must sign, but the minor must also be given the opportunity to agree to the research, and their signature is required unless an override of the child is approved by the IRB.

1.29 Elements of Informed Consent

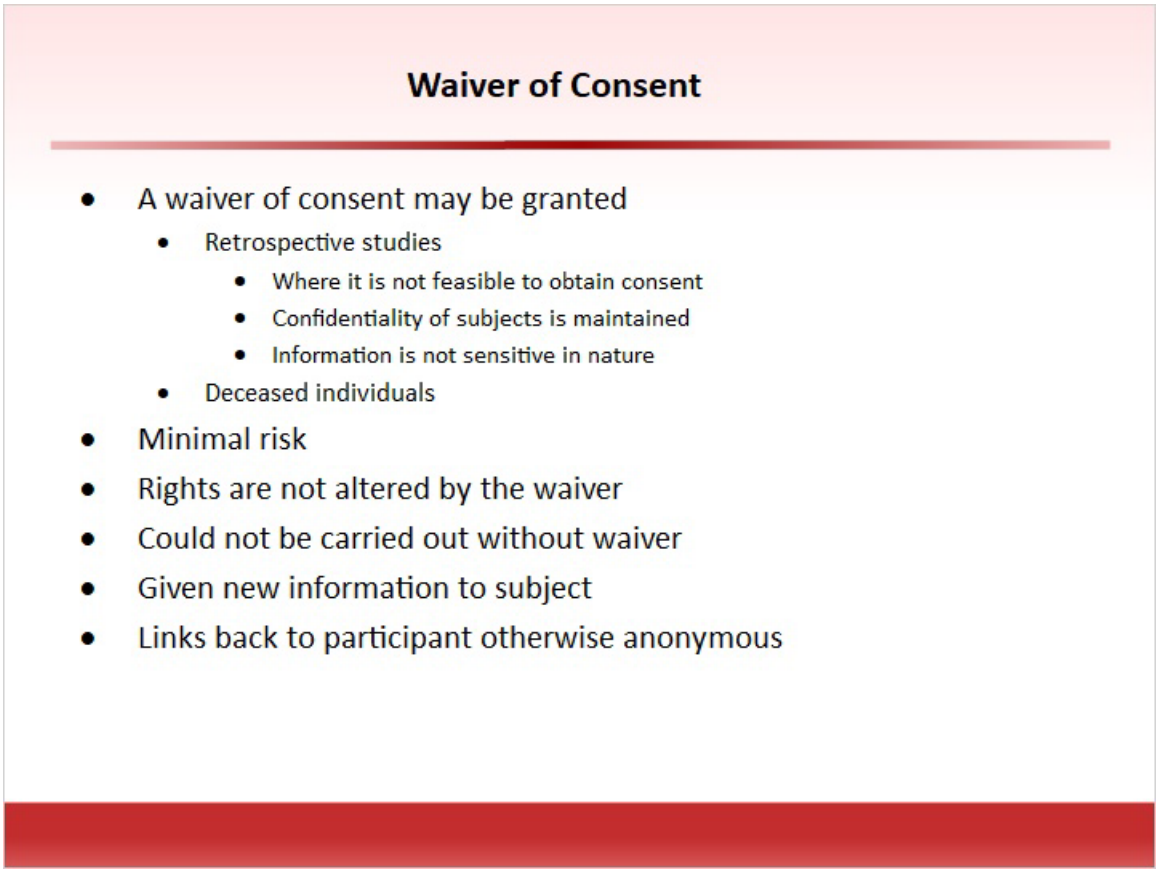


Notes:

The elements of a consent relate to the principles of autonomy, beneficence and justice. The procedure and the time involved are clearly explained. Some of the procedures may be routine clinical care while others are considered research. It is important to know how many other participants are expected and where the study will be conducted; is this part of a multi-center study or just at that clinic? The risks and benefits should be explained as well as alternative treatments should a potential subject decide not to participate. The subject should understand how the confidentiality of their records will be maintained, generally in a password-protected database or locked file cabinet with limited access. It must be disclosed to the participant if any of their protected health information is released to a person or an entity outside of those named as study team members. For example, will protected health information be released to the sponsor of the study or to another investigator? The participant must know who and how to contact someone in the event of questions of an emergency. The participant should understand how they may withdraw from the study or how the investigators may terminate their place in the study without any additional harm or prejudice affecting their medical care.
Lastly, the consent form states if there are any additional costs involved with this study

or if the participant will be compensated as a result of participation.

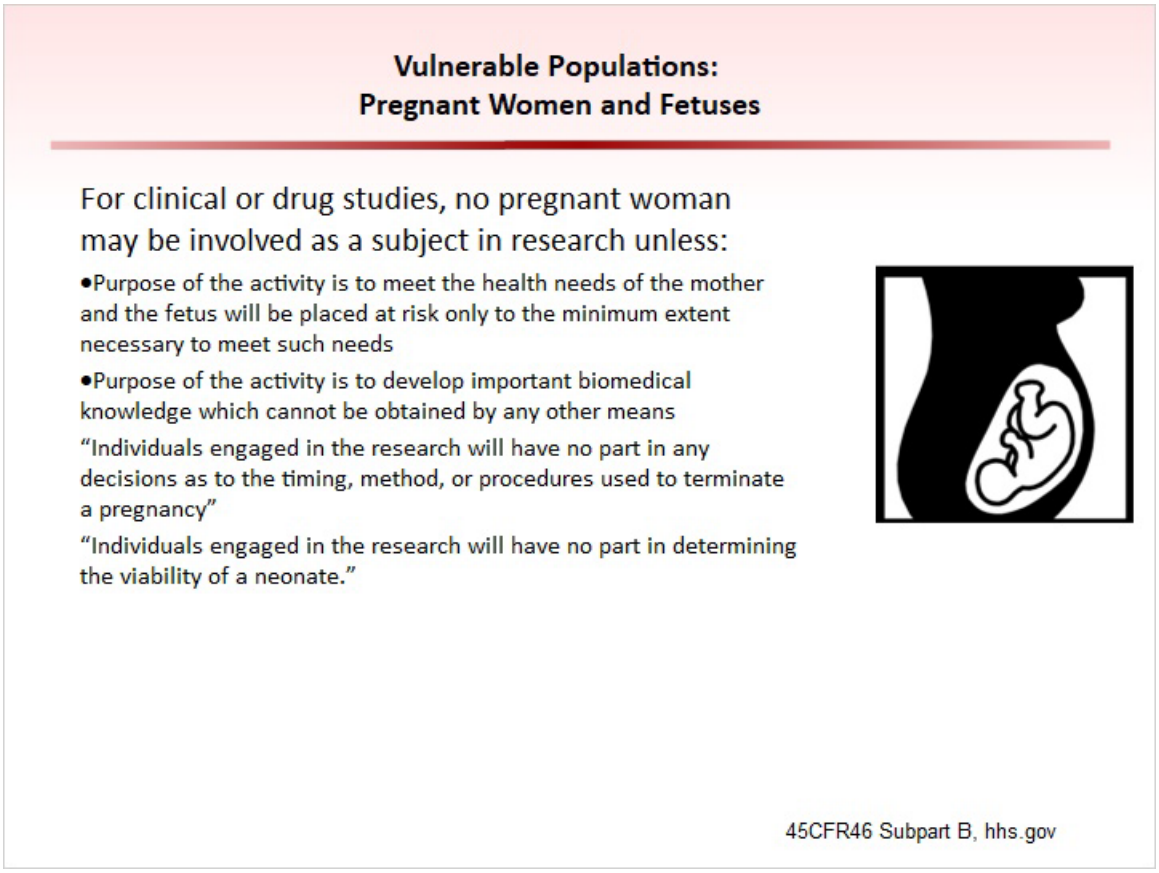
1.30 Waiver of Consent



Notes:

A waiver of consent may be granted by the IRB for certain types of studies such as those under expedited review. In those circumstances, a consent may be waived since it may not be feasible to contact the study participants, as in the case of a retrospective chart review. Consent is not needed from ‘deceased' individuals since the regulations are concerned only with living human subjects. Still, the deceased must be treated with respect and the Health Insurance Portability and Accountability Act protects their confidential information.

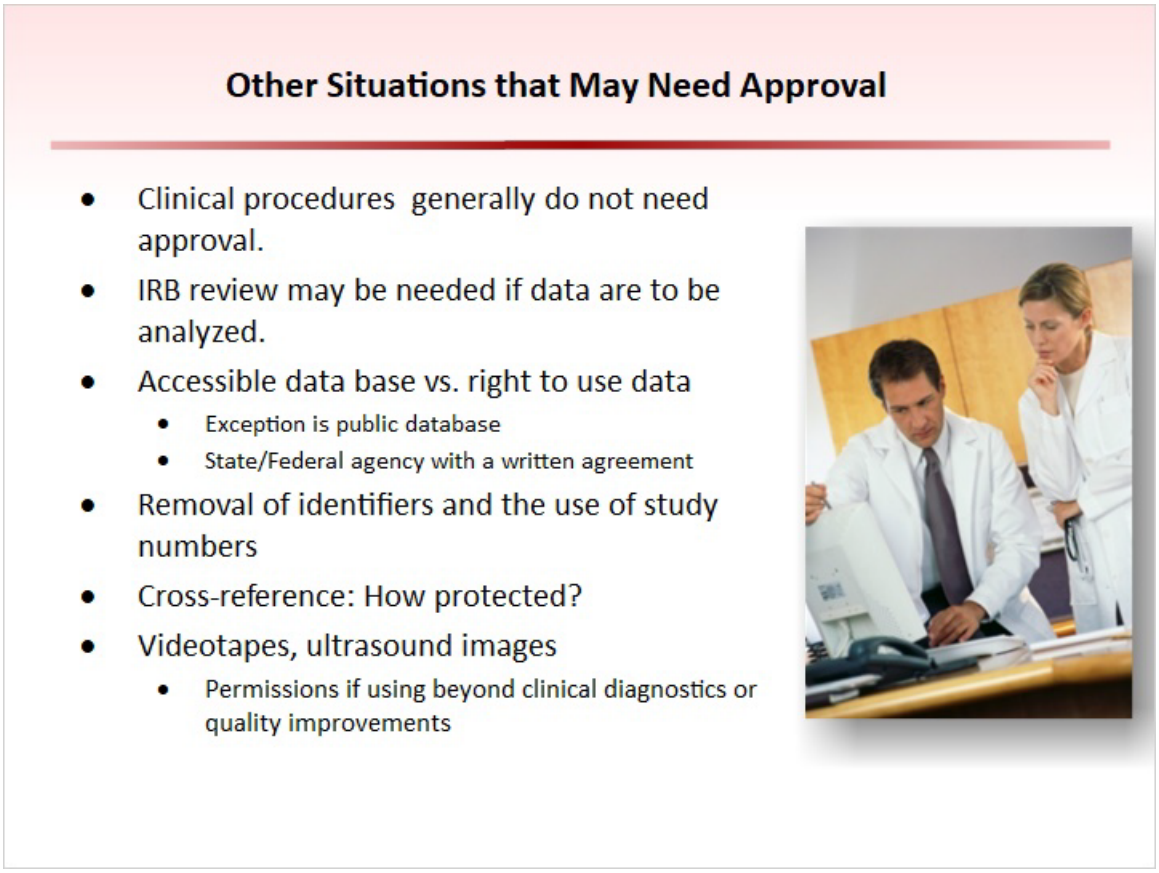
1.31 Vulnerable Populations:



Notes:

Many IVF studies also obtain information after the patient or subject becomes pregnant. Pregnant women and fetuses are a protected population according to 45CFR46 subpart B at www.hhs.gov and information regarding the regulations is listed there. The last two points are directly from the federal regulation and must be emphasized that individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and individuals engaged in the research will have no part in determining the viability of a neonate. This means for example that if a pregnancy must be terminated, the researcher must refer that participant to medical personnel not affiliated with the study. Or if the researcher is present at the delivery of the baby, someone other than the research team determines if the newborn is viable.

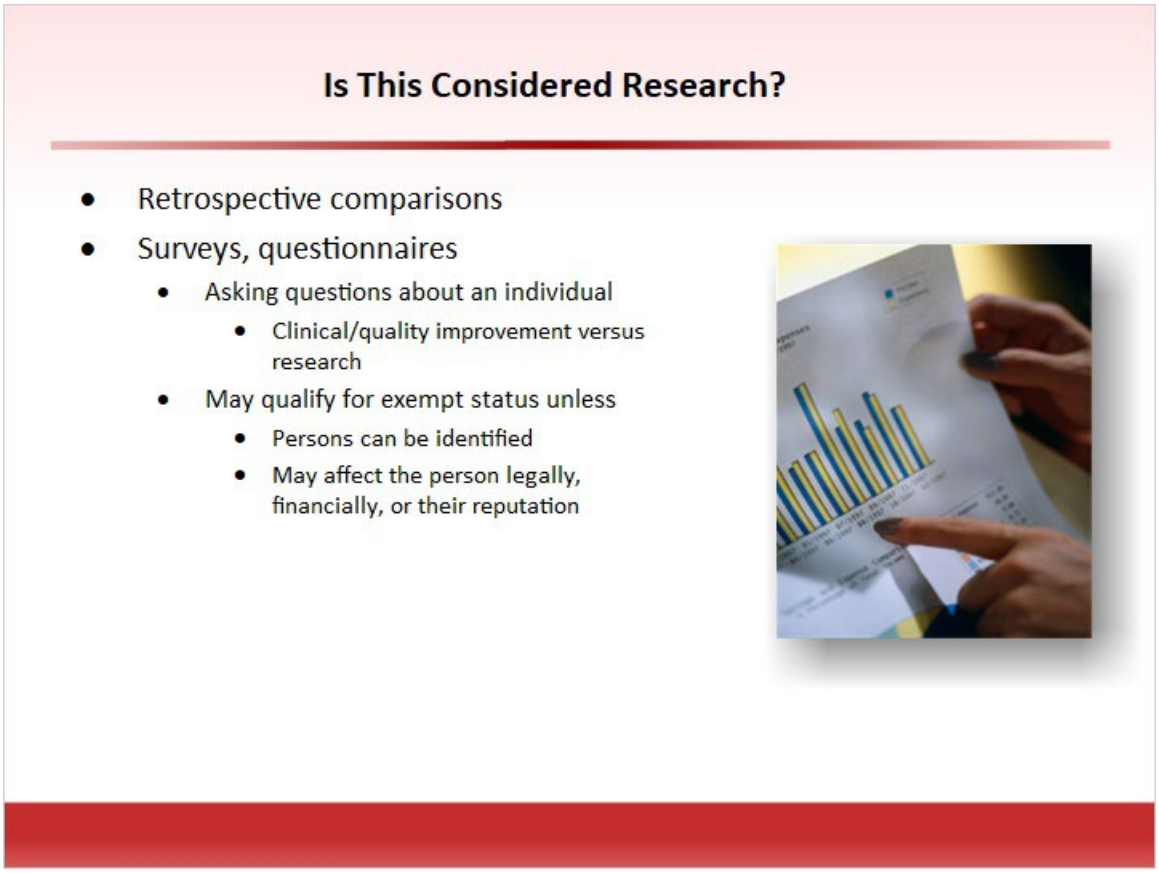
1.32 Other Situations that May Need Approval



Notes:

Performing a retrospective chart review may appear to be low risk to the human subject and many clinics have databases to make that task easier. However, just because the database is accessible, it does not automatically mean that the investigator has the right to mine data without IRB approval. For example, a clinic wishes to review their IVF data to compare the use of two different types of media. A clinical decision was made to culture clinical IVF embryos in Medium 'A' and in Medium 'B'. Is that considered research? The clinical decision to treat patients with an acceptable medium is not in itself research. The laboratory can freely choose to use Medium 'A' or Medium 'B' or both as it sees fit. The research component comes into play when the laboratory wishes to collect the data and analyze the results. Do these data only pertain to the clinic (quality control) or will the results be generalizable - i.e., might another clinic review the results from this study and decide to also do their own comparison or switch to that medium? If the difference can't be determined, it is better to have an IRB do that for you!

1.33 Is This Considered Research?

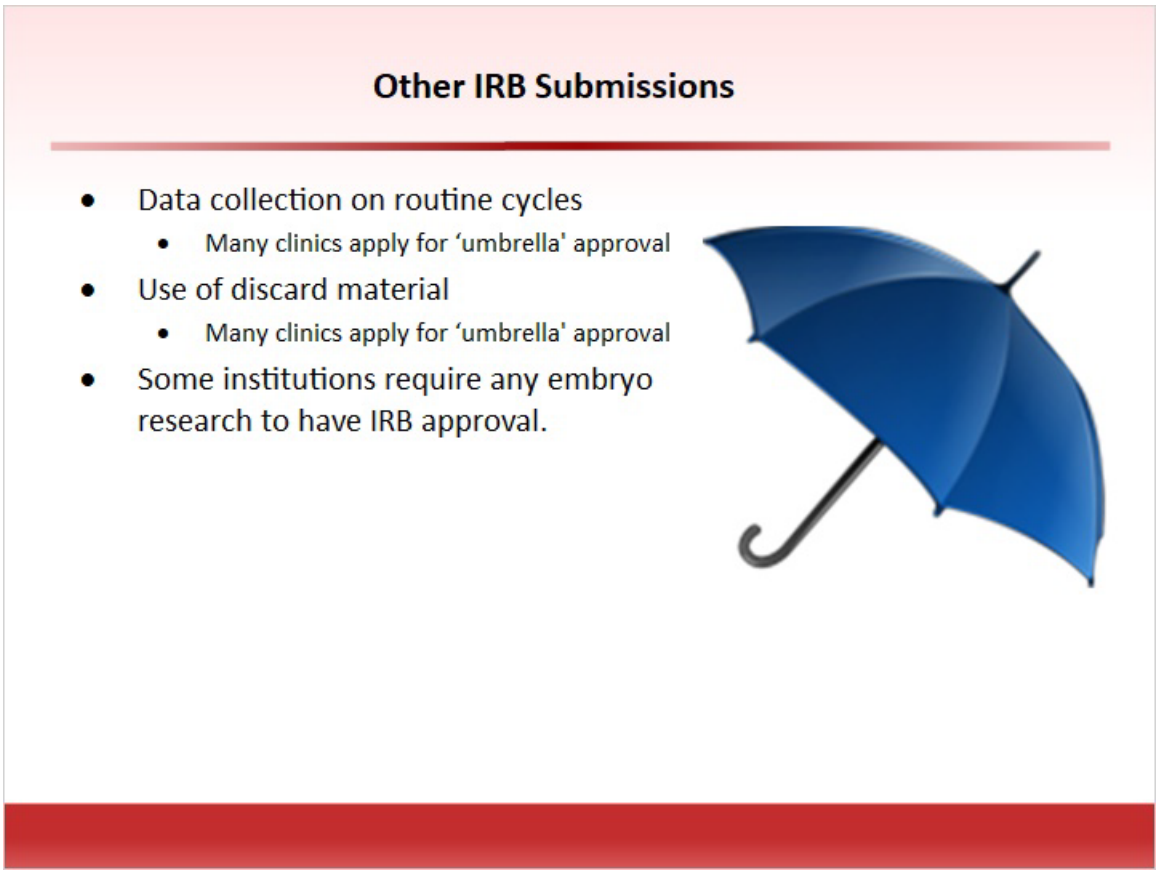


Notes:

Another example to consider: An IVF laboratory performed cryopreservation using a 'slow-freeze' protocol. The staff is trained and they have now switched to vitrification. The switch did not require IRB approval because that was a clinical decision. The lab director now wishes to compare the survival rate from the 'slow-freeze' thaw to the survival rate in the vitrification warming. This will require going through the database, electronic record, or patient charts. Is this research? More than likely, yes. Even though the population comes from the clinic's own patients, it is a retrospective record review. How will the patients' privacy be maintained? Who will perform the data collection? Where will those new data sheets be stored?
What if a lab director wishes to compare the survival rates between embryologist A and embryologist B. This probably does not need IRB approval as that appears to be quality improvement.

Surveys and questionnaires may fall under IRB review if outside part of the clinical practice or quality improvement. For example, surveying patients to ask questions about the service they received is quality improvement. Surveying patients to ask them about their attitudes toward infertility treatment in general is probably considered research.

1.34 Other IRB Submissions

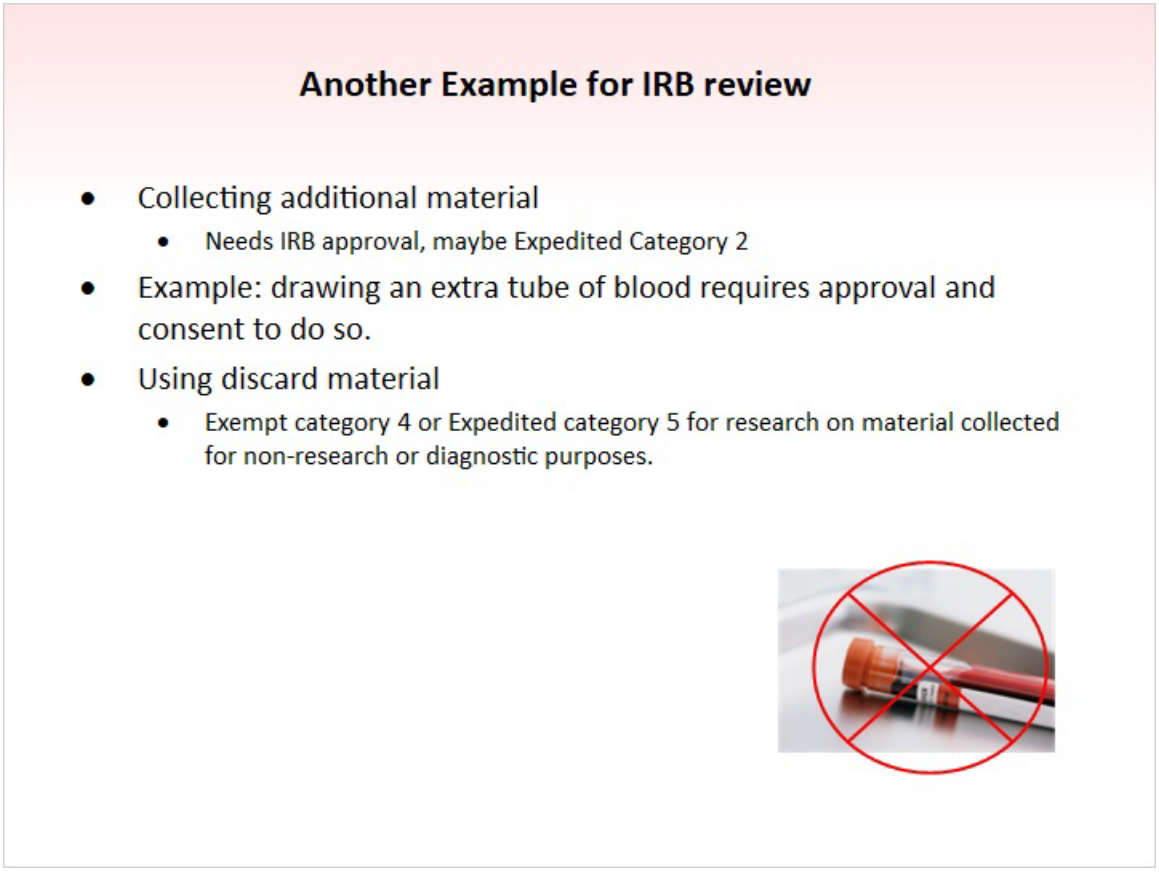


Notes:

Clinics that are affiliated with federally funded entities should have IRB approval for many instances of data collection, but it can be cumbersome to submit to the IRB and wait for approval each time a clinic wants to review its statistics. As an example: a clinic would like to compile the statistics for the past two years of vitrifying oocytes. The data collection itself can be quality control-what are the clinic's success rates and how might they determine their practices based on that? That may be exempt from IRB approval. Many institutions will ask the IRB for a letter stating their intent. However, if the clinic would like to submit an abstract or publically discuss those data, that will likely become a research study since the knowledge could be considered generalizable. In that case, IRB approval is needed. Many clinics will seek an 'umbrella' approval to cover collection of the routine data from their clinic, such as the number of cycles, patient ages, particular types of treatment, etc. These data are collected in aggregate and do not contain protected health information, but rather are a summation of routine clinic data that could be part of a formalized study. An IRB still needs to approve this as such, but it is very helpful for the clinic to be able to analyze their data.

Another area where the clinic may apply for an ‘umbrella' approval is the use of discard material. The patient must consent to the use of their leftover gametes, or embryos. Many clinics may use this for training purposes. For example, if the laboratory acquires a new incubator and wishes to culture a donated embryo to determine if cleavage can occur prior to routine patient use. The use of that donated embryo is quality control, but the patient should consent to this generic type of research. This may be covered under a different ‘umbrella' policy for use of discard or donated material. However, if that same donated material is used instead for a specific study that poses a hypothesis and procedure to test, an IRB approval is probably needed.

1.35 Another Example for IRB review

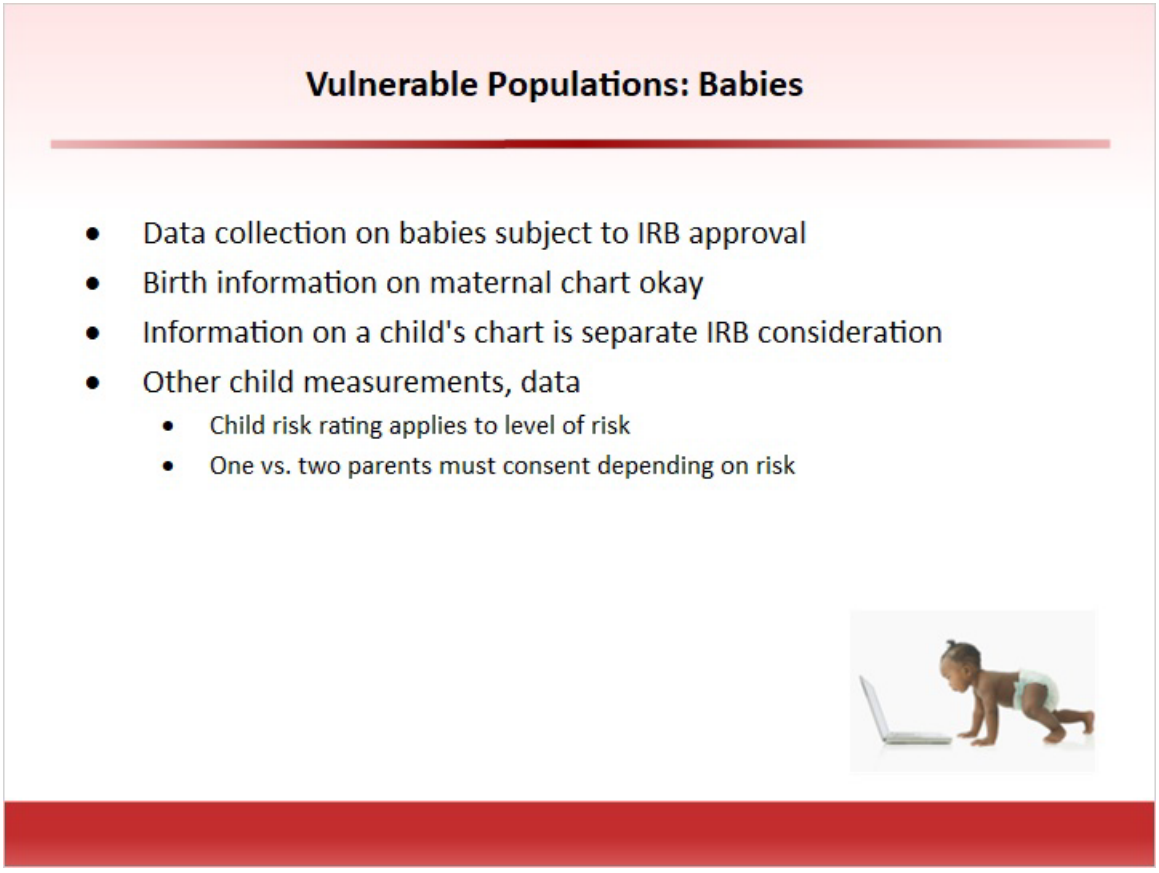


Notes:

Another example is if a patient comes in for ovulation induction monitoring and has her blood drawn to determine her estradiol levels. This is standard clinical practice. The lab director asks the phlebotomist for an extra tube of blood because they are doing a pilot study trying to identify markers in the blood that may predict the success of subsequent implantation. Is IRB approval needed? Yes. Even though drawing blood carries minimal

risk, it is not part of the standard of care to collect an extra blood sample and is probably submitted under expedited review.
Is IRB approval needed if the remainder of sample is used after the endocrine evaluation? Yes. Even though the blood is discard material, it falls under the exempt category of research involving specimens collected for diagnostic purposes. This latter scenario may fall under the umbrella approval as previously discussed if so included in the protocol/consent.

1.36 Vulnerable Populations: Babies

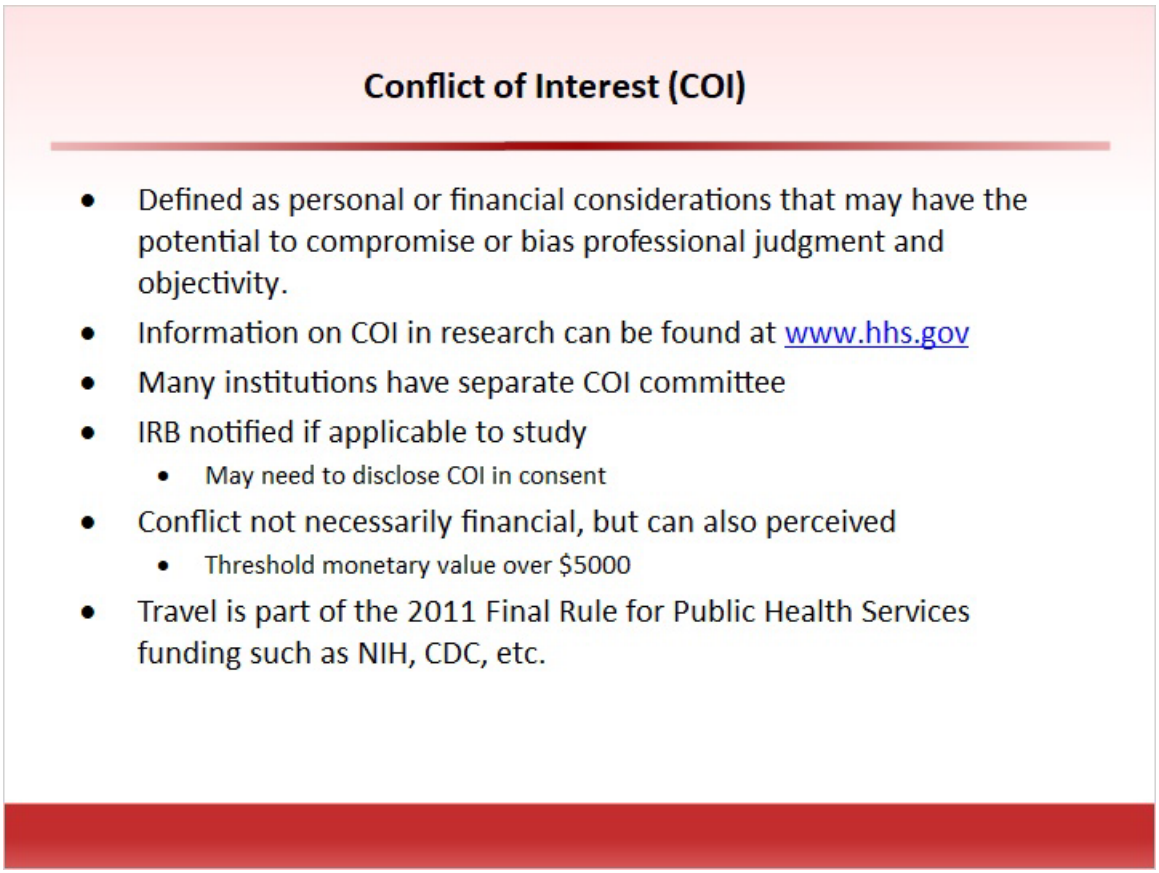


Notes:

Minors are a vulnerable population and a child risk rating needs to be included in the IRB's oversight.
For example: a study is being conducted reviewing the success of preimplantation genetic screening. If the only data collected concerns the live birth of a baby, that does not necessarily need a child risk rating. What if the study goes further than the birth and would like to collect data on development of the baby from the baby's chart and not the maternal record? Even if the data are retrospective, the IRB needs to know and be able

to assign a risk rating. In this case, it is minimal risk, but the IRB has to be informed. Those ratings determine if one or two parents are required to sign the informed consent.

1.37 Conflict of Interest (COI)

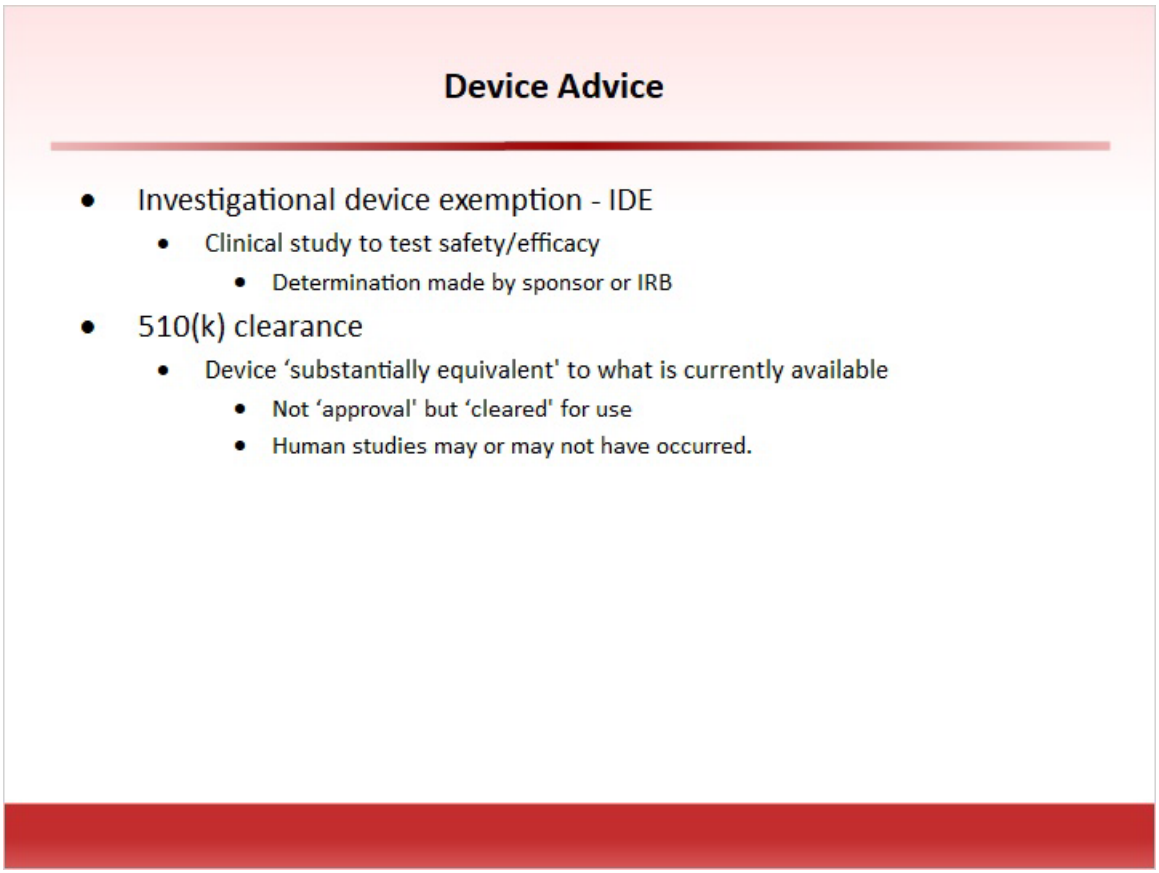


Notes:

The final Rule of the Federal Register at www.hhs.gov details what constitutes a conflict of interest in research. Briefly, it is defined as personal or financial considerations that may have the potential to compromise or bias professional judgment and objectivity. The conflict can be real or perceived.
For example, the laboratory is performing a study comparing Medium A versus Medium B sponsored by Company A. In addition, the laboratory director travels to give lectures and is paid an honorarium by Company A. That appears to be a conflict of interest that needs review. It could even be a conflict if the director is paid from Company B even though Company A is the sponsor. A plan to manage this apparent conflict may be decided by a Conflict of Interest committee or the IRB. Although the director may be able to participate in the research, there are some institutions that will require the recusal of the conflicted party.

Since the implementation of the Final rule, those receiving federal funds must also disclose travel reimbursement.

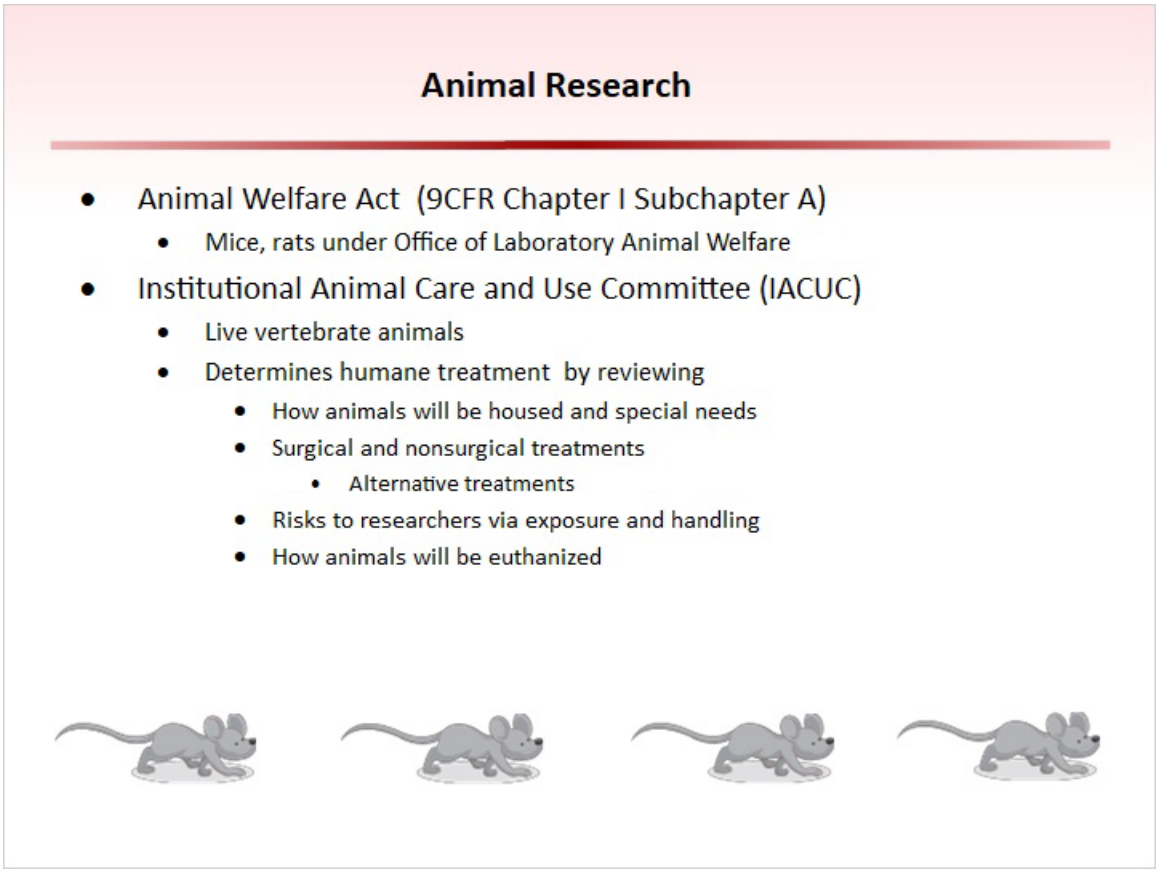
1.38 Device Advice



Notes:

To test new devices in humans in the United States, a sponsor could apply to the Food and Drug Administration for an investigational device exemption (IDE), to allow clinical studies to be performed using the device to test its safety and efficacy.
Section 510K of the Federal Food, Drug, and Cosmetic Act requires that manufacturers of new devices to be used in the United States must notify the FDA of the intent to market new devices. Premarket approval of new devices requires human studies on the device's safety. The FDA could determine that the device is 'substantially equivalent' to a device already available in the market place. In that case, the FDA does not approve these new devices per se, but rather can 'clear' the device for use. This does mean that human studies do not have to have occurred for that particular device prior to the routine use in humans.

1.39 Animal Research



Notes:

The humane treatment of animals used in research is covered by the 1966 Animal Welfare Act, under the United States Department of Agriculture. However, the act does not pertain to mice or rats bred specifically for research purposes. Those species are covered under the NIH Office of Laboratory Animal Welfare. Since the IRB only covers human subjects, the Institutional Animal Care and Use Committee (IACUC) reviews protocols that involve the use of live vertebrate animals for teaching, testing, or research. The IACUC reviews how the animals are housed and cared for, if they need a special diet, medical care, the treatment plan, and if there are alternative treatments. The IACUC also is concerned with protection of investigators and if they are exposed to hazards, toxins, or disease while interacting with the animals. Lastly, the euthanization of animals, if applicable, should be handled in a humane manner.

1.40 ASRM Ethics Committee Opinion

Notes:

The ASRM Ethics Committee issued an opinion paper in 2014 concerning gamete and embryo research. Several key points are listed here, including the need to obtain IRB approval for any gamete or embryo research, including patient consent as appropriate. Persons who donate gametes specifically for research and not for clinical purposes must also have the appropriate informed consent that includes information regarding that there is no commercial value to the biological material. Genetic information obtained through research methods may be linked back to the individual.
It is the clinic's responsibility to ensure that consent and IRB approval are obtained prior to sending or receiving embryos from outside sources for research purposes.

1.41 Summary of Research Determination

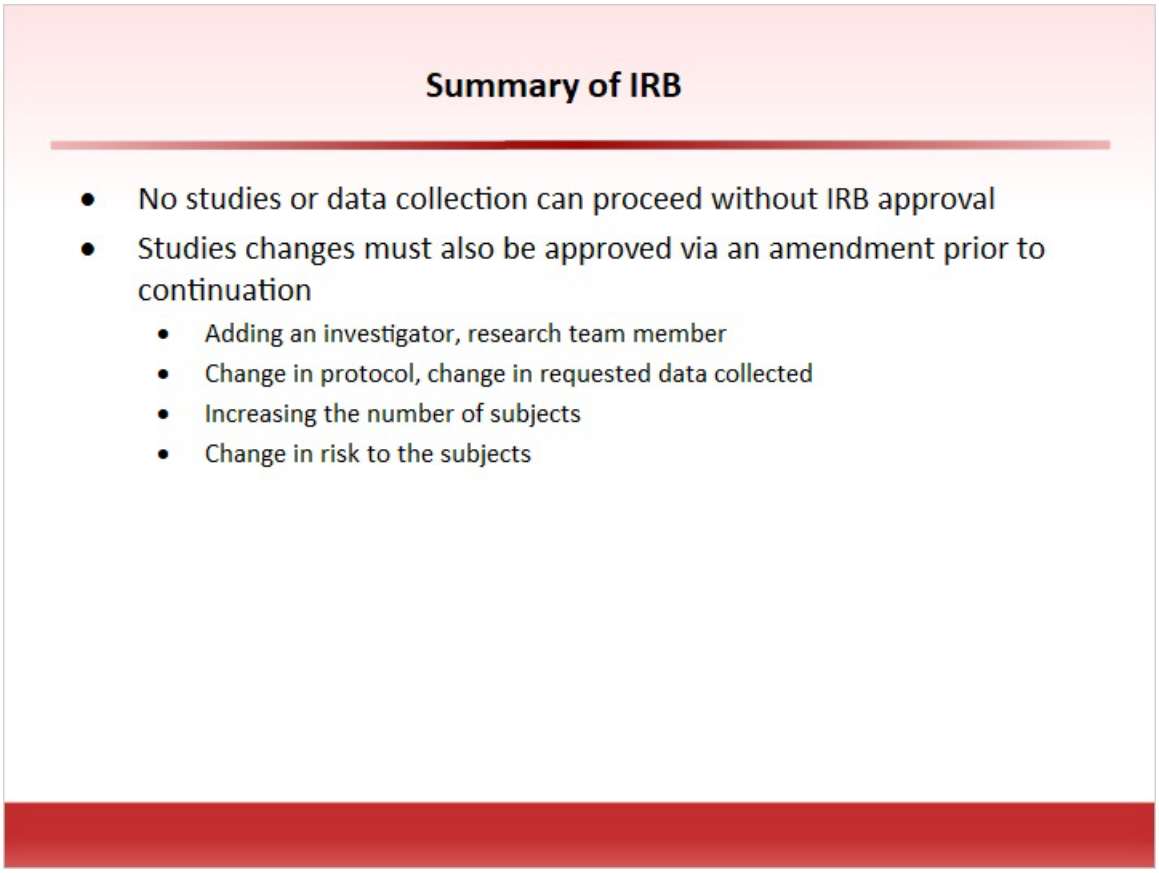
Summary of Research Determination

	Research	Quality Improvement	Program Evaluation
Generalizable knowledge	Yes	No	No
Part of professional goals and development (tenure, funding, recognition)	Yes	No	No
Operational procedures?	No	Yes	Yes
Impact on practice	No	Yes	Yes
Benefit to participant?	May or may not	Yes	No
Presumption to publish	Yes	No	No
Includes procedures outside of standard practice	Yes	No	No

Notes:

In summary, this table may help in determining if a study is considered research or considered quality improvement or program evaluation.

1.42 Summary of IRB



Notes:

It is important to remember that no studies or data collection can proceed without IRB approval if the institution receives federal funding. The IRB and not the investigator decides the level of review and whether or not the project involves human subjects or is quality improvement. The IRB must be notified and the approval amended when there are changes in team members, protocols, requesting new subjects, and risk to the subjects.

1.43 Thank you!

Notes:

Thank you for participating in this educational activity.