A glossary is included in the Resources section on the Home Page of this course. Those terms will be included in the quiz.

**Informed consent** is an ongoing process between research staff members and research participants. The IRB reviews all aspects of the consent process, including:

- Seeking and contacting people to participate,
- Explaining details about the research,
- Answering questions about the research, and
- Providing additional information when necessary.

The informed consent process is regulated and can affect research that does not deal directly with living people.

The IRB determines the requirements for the informed consent process on the basis of federal regulations, state law, and institutional policies. Based on those regulations, the IRB has policies for the review of projects that involve:

- Living people,
- Cell lines,
- Medical records,
- Data sets, and
- Other sources of information that cannot provide informed consent.

Contact the Office of the IRB if you have questions about:

- Whether your project requires IRB review or
- How to address the informed consent requirements.

**“Participant’s Rights” and Researchers’ Responsibilities**

Participants have the right to know about the research and be informed at all times. This is the Principal Investigator’s (PI’s) responsibility.

Failure to adhere to the procedures of the consent process may result in a determination of serious non-compliance by the IRB.

Although the principal investigator can delegate activities within the consent process, the principal investigator cannot delegate responsibility for the process itself.

Whether you are a principal investigator or a research staff member, this information will describe how you can help to ensure that all responsibilities are fulfilled

**Informed consent is NOT a form...**

Informed consent is an ongoing “process” that can begin before a participant contacts the investigator – as when someone sees a recruitment flyer and considers enrolling or when someone sees an advertisement on TV, in the newspaper, or hears it on the radio.
The informed consent process can even happen when a person discusses the research with someone who knows about the protocol.

_Note: The IRB must review and approve all advertisements, flyers, videotapes, web sites, or other materials that will be used to inform participants about research studies before they are used._

**Informed consent can continue after the study has ended.**

The informed consent process can continue after the participant has completed all research-related activities — as when new information is discovered and must be given to people who participated in a study that has ended.

Participants always have the choice **not** to participate and to withdraw at any time.

**Informed consent must be legally effective so...**

The PI must obtain consent from a person with the legal right to provide consent.

To provide consent for research in Alabama, a person must:

- Be 19 years of age or older
- Be 18 years of age and emancipated (i.e., married or widowed)
- Have parental permission (unless the IRB waives that requirement)

_Note: Alabama law allows people to consent to standard medical treatment at 14 years of age but research is not standard treatment. The IRB can consider altering the above age-requirements for certain types of research._

**Parental permission**

In cases where parental/guardian permission is required, both parents must sign **unless**

- The IRB has approved a waiver of parental permission.
- The IRB has determined that the signature of one parent/guardian is sufficient.
- One parent/guardian is deceased, unknown, incompetent, or not reasonably available, OR when only one parent has legal responsibility for the care and custody of the child.

_In some studies, the IRB can alter the age requirement, but the alteration must be requested, reviewed, and approved by the IRB._

**Each participant must be given a copy of the consent form unless the IRB has waived the requirement:**

- To obtain informed consent,
- To use a form in the consent process, or
- To provide participants with a copy of the form.
Informed consent is about making choices.

Your taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care.

You may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

Copied from the UAB Sample Informed Consent
8th-grade reading level

Participants always have the choice not to participate. This must be stated in the form. However, there are times that the participant may be removed without his/her permission. This should always be stated in the form as well.

Making choices takes time.

Before enrolling in research, people need time to think about the risks, benefits, costs, and other aspects of being a participant. They may also want to discuss their choices with family members, clergy, or others before they make a final decision.

Federal regulations require that people be given “sufficient opportunity to consider whether or not to participate.” (45 CFR 46.116)

The UAB IRB has determined that 24 hours is sufficient and that participants must be given that much time to decide.

Can the 24-hour “think it over” period be waived?

The PI can request a waiver of the 24-hour “think it over” period if the delay might negatively affect a person’s ability to enroll in the study.

For example, an individual may be approached about participating in a study, but returning to the doctor’s office from their home might be inconvenient for him/her.

Waiting until his/her next visit might be too much of a delay to make him/her eligible.
A person must not feel coerced to enroll.
A participant must be able to withdraw without fear.

When teachers conduct studies, their students can feel coerced to enroll. Students may fear getting a low grade if they don’t enroll or if they withdraw.

It is never a good idea to approach or enroll subordinate employees. Employees may fear losing their job if they don’t enroll or if they withdraw.

Generally, a personal physician should not obtain informed consent from his or her patients, who may enroll to “please the doctor.” Patients may fear they won’t get the same care if they don’t enroll or if they withdraw.

Note: If withdrawing from the study could carry special risks, the consent process should include information about how to withdraw and minimize those risks.

A consent signature requires a witness signature.

When a written consent form is used, it is used to document the basis for consent and for the participant’s future reference.

The UAB IRB requires that a witness’s signature be obtained on the form to help ensure that the participant:

• Knows this consent is for research,
• Signs the consent form voluntarily, and
• Is given a copy of the signed form.

When appropriate, the IRB can waive the requirement—for example, if the consent form is mailed out, signed, and mailed back.
Information given to participants must be in understandable language.

The written informed consent should be written on an 8th grade level – no matter what the education level of the participants may be.

When medical terms or highly technical phrases cannot be avoided, provide an explanation in simpler language.

We are asking you to take part in a research study. This research study will test how well a new drug lowers blood pressure. The new drug, Trimycin, is investigational and not yet approved by the U.S. Food and Drug Administration (FDA). Wise Drug Company, the company that makes Trimycin, is paying for the study. People who enter into the study will take either the new drug, Trimycin, or Hydrochlorothiazide (water pill). Hydrochlorothiazide is the FDA approved drug that most people take now to lower blood pressure. Trimycin is approved in Europe, but has not been approved in the United States. More than 200 people in other research studies in the United States have safely used Trimycin. This is a Phase III study. A Phase III study is a research study that looks at a large number of patients receiving a common or routine treatment. This study will enroll 200 participants nationwide, and 20 of them will come from UAB.

If English will not be the primary language of some or all of the participants, describe for the IRB

- How consent will be discussed in the person’s native language;
- Whether or not an interpreter will be used; or
- Whether or not a translated consent form will be used

Explain the risks and benefits.

In general, research involves risks to individuals and benefits to society.

The consent process should:

- Describe in detail the risks to participants, and
- Clearly state whether any direct benefit to the participant may occur.
An example to explain the risks...

• You may have some side effects from taking these drugs.
• Hydrochlorothiazide can cause the following side effects: low blood potassium; a rise in blood uric acid and blood sugar; and a lowering of red and white blood cells.
• About eighty percent (80%) of people who take Hydrochlorothiazide have these problems.
• There may also be risks that are unknown at this time. You will be given more information if other risks are found.

Taken from the UAB IRB Sample Informed Consent Form
6th-grade reading level

Minimal risk...

Minimal risk means that 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.

Minimal risk **for prisoners** means that the risk is not greater than the risk of daily life or medical care for healthy persons.

*Note: For consent purposes, the term prisoners includes not only persons in jail or prison, but also persons in alternative sentencing programs, and persons awaiting arraignment, trial, or sentencing (45 CFR 46.303(c)).*

Changes and findings...

The IRB-approved informed consent document may NEVER be changed without prior IRB approval.

If the information in the process or form is changed, then it may be necessary to “re-consent” enrolled participants.

Usually, participants should be re-consented when the change may affect their willingness to stay in the study:

• Procedures will be changed (Explanation of Procedures, Confidentiality)
• Additional risks have been identified (Significant New Findings)
• When a person who was a minor at the time of enrollment attains the age of majority, and could now provide legally effective informed consent.

Explain any costs...

There may be costs involved in the study – such as medicines, tests, parking, transportation, time, etc.

These costs should be explained during the consent process. If a consent form is used, the costs should be described in detail.
An example of costs explained...

There will be no cost to you from taking part in this study. All drugs, exams, and medical care related to this study will be provided to you at no cost during the 6-month study period. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Copied from the UAB IRB Sample Informed Consent Form
8th-grade reading level

Explain any payments...

Whether or not participants will be paid should be clearly stated.

If payment reimbursement or other compensation is offered, explain:

- Amount(s) to be paid, including the total possible amount,
- Timing of payment(s), and
- Effects of withdrawal on payment

An example when there is compensation involved:

- You will be paid $10 for each study visit, including the placebo phase of the study.
- If you quit the study, you will be paid $10 for each study visit made to the clinic.
- Payments will be made after 3 months and 6 months if you complete the entire study.
- If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study.
- If you complete the entire study, you will receive a total of $290.

Copied from the UAB IRB Sample Informed Consent Form
7th-grade reading level

Explain any injury compensation...

If the research involves greater than minimal risk,

- Explain whether medical treatment is available for research-related injuries.
- Explain whether injury compensation is available. If it is, also explain:
  - What it consists of, and
  - Who to contact for more information.
An example in which case the sponsor will not pay for research-related injuries or medical treatment related to such injuries:

UAB has not provided for any payment if you are harmed as a result of taking part in this study.

If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Copied from the UAB IRB Sample Informed Consent Form
6th-grade reading level

Exculpatory language must be avoided. For example, a statement that says that “UAB is not liable for any harm caused by the research study” is exculpatory and will be rejected by the IRB.

Confidentiality and privacy...

Confidentiality refers to the treatment of information about people.

- Keeping medical records secure by putting them in a locked area with limited access
- Protecting patient information that may be on a computer with secure passwords and limiting access
- Refusing to discuss medical conditions and/or treatments except as described in the consent process

Privacy refers to interactions among people.

- Having the interview about the study with the participant where it cannot be overheard
- Discussing participants with people not involved in the study

A consent form is not always necessary.

If your research is not subject to FDA regulations, you can request a waiver of the requirement to use a written consent form.

However, the IRB can approve the waiver only if specific regulatory requirements are met.

To read about the specific regulatory requirements, click on the link below or copy it and visit the website:

45 CFR 46.117(c)(1) and 45 CFR 46.117 (c)(2)
Consent cannot be implied.

Let's say that a researcher wants to conduct an anonymous online survey as a part of her study. No information will be collected that could be used to identify the participants.

Is a consent form needed?

Agreeing to answer survey questions is not necessarily agreeing to the use of those answers in research. The researcher could add the following statement at the top of the website:

“By completing this survey and submitting your responses, you are agreeing to allow us to use your answers for our research study.”

If the survey includes a clear statement that the answers are for research, the IRB may be able to waive the use of a separate consent form.

If you have questions, please contact the Office of the IRB.

Informed consent must include specific “basic” elements.

8 basic elements must be addressed for all research.

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
Informed consent may include specific “additional” elements

The IRB determines whether 6 additional elements must be addressed:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6. The approximate number of subjects involved in the study.

What parts of the process can the IRB waive or alter?

The IRB can consider requests to waive or alter:
- The entire consent process
- Elements of the process
- Participant's signature
- Use of a consent form

The Waiver of Consent form

The Waiver of Consent form addresses the federal criteria that must be met:
- Why the research involves no more than minimal risk;
- Why the waiver will not adversely affect participants’ rights and welfare;
- Why the research could not practicably be carried out without the waiver; and
- Whether more information will become available during the research.
Certain elements of consent may not apply.

Depending on the type of research and procedures, some of the elements may not apply:

- For minimal risk research, injury compensation (Basic Element 6)
- Risks to a fetus (Additional Element 1) if
  1. women will be tested for pregnancy and
  2. pregnant women will be excluded and
  3. women who become pregnant will be withdrawn

For research completed in one sitting, significant new findings (Additional Element 5) may not apply.

The participant signature can be waived.

Participants may not have to sign a consent form.

If the signed form would be the only record of participation and a breach of confidentiality would be the primary risk.

Example: Research on sensitive information such as abuse or HIV

If the research does not involve greater than minimal risk and consent would not be required outside of the research context.

Example: Anonymous surveys on academic practices

Can the witness signature be waived?

The purpose of the witness and his/her signature is to ensure that the participant received a full and accurate description of the information and voluntarily signed the consent form.

So in order to avoid all appearances of wrongdoing, the person obtaining the informed consent should never sign as the witness.

The witness signature can be waived when...

the consent process will be conducted by phone, and the form will be mailed to the participant to sign, and the participant will return the signed form by mail, then the witness signature can be waived.

What if changes need to be made?

The informed consent document itself must not be changed without prior review and approval by the IRB—not even to eliminate apparent immediate hazards to one or more subjects.

For example, if new risks have been identified with one of the drugs used in the study and the sponsor plans to continue, the informed consent should be revised for use with future participants.

An addendum informed consent document should be prepared for currently enrolled participants, and they should be re-consented as soon as the PI receives the IRB-approved addendum.
Some changes may require a Project Revision/Amendment form and revised consent form. For small changes – such as “from” instead of “form” – the person obtaining consent can verbally inform the participant that the word is wrong. The wrong word should not be marked out or have the right word written in. Re-consenting for minor errors is not necessary.

**NEVER make changes while obtaining the informed consent!**

**Does HIPAA always apply?**

Biomedical studies conducted in hospitals or by other health care providers almost always require HIPAA authorization.

HIPAA regulations apply to research when a UAB researcher seeks to obtain protected health information from a participant in a research study. Regardless of who collected the information, when hospitals or other health care providers store protected health information, HIPAA regulations apply.

HIPAA regulations do not prevent a doctor from reviewing his/her own patient’s records to determine eligibility. **However**, if doctors want to review protected health information of persons who are not their patients, the investigator may need to apply for a Partial Waiver of Authorization for Recruitment/Screening.

**The form must almost always have the correct date.**

When a form is used to document the consent of adult participants or the assent of minors, the form must almost always have the UAB IRB or Western IRB (WIRB®) stamp on page 1.

The UAB IRB stamp shows the date on which the IRB approved the consent form for use with participants. It also shows the expiration date – the date the consent form will expire.
Participants should **NEVER** sign:

- Before the approval date,
- On the expiration date, or
- After the expiration date on any consent form.

WIRB is an external IRB that reviews some UAB human subjects proposals.
Their approval date is printed on the page on the upper-right corner and shows the approval date (only).
The UAB IRB does not place its stamp of approval on consent forms reviewed by the WIRB.

**Who can obtain informed consent?**

Not everyone who works with a researcher can obtain consent from participants. The procedure and staff for obtaining consent must be described in the Human Subjects Protocol form.

Each person who obtains informed consent must:

- Be listed in the Human Subject Protocol and
- Have up-to-date IRB training.

The principal investigator may or may not be directly involved in the consent process, depending on the IRB-approved procedure.

**List the entities that can access identifiable information.**

*Privacy* refers to interactions among people.

*Confidentiality* refers to treatment of information about people.

The Human Subjects Protocol form must describe how both will be assured.

The Confidentiality section should **always include**:

- The UAB IRB and
- The U.S. Office for Human Research Protections (OHRP).

It **may** also include:

- The sponsor, for sponsored research,
- The data coordinating center, for multicenter research, and
- The FDA, for research on drugs or devices.
The informed consent process is an integral part of research that involves human subjects. This course has covered the general guidelines and basic requirements regarding the informed consent process.

For further information, please see:

• The additional course materials located under the Resources section and on the IRB home page,
• The IRB Guidebook for Investigators, and
• The UAB sample consent form.

This concludes the IRB Informed Consent Course.

You may now return to the course and access the quiz by clicking on the quiz icon. Please remember to save each answer, and click on the Finish button when you are through.

80% or higher is considered passing. If you fail the quiz three times, you must e-mail or call the course administrator to reset the quiz. Good luck!