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Elements of a Successful Informed Consent

Training for Investigators and Research Staff



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Our outline for today:

- Why informed consent matters?
- Why is informed consent important?
- Elements of a successful informed consent
- IRB: Informed Consent Process
- Know Your Forms!
- How to Fill Out Our TTUHSC El Paso Informed Consents
- Common Informed Consent Problems and Solutions
- Why Follow the Rules?

Questions? Comments? Concerns?

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[TTUHSC El Paso ORR](#)



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Why informed consent matters?



Why Informed Consent Matters... presented by
LifeSciSocValues



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Why is informed consent important?



University of Maryland IRB Manager discusses the importance of informed consent in research



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Elements of a Successful Informed Consent



Presented by the National Institute of Mental Health within the National Institute of Health



Elements of a Successful Informed Consent

During the video you learned how to conduct a proper informed consent, however it is important to note that some items are done differently at TTUHSC El Paso:

- The TTUHSC El Paso informed consent template can be obtained through [iRIS](#), and must be prepared at a 7th grade reading level
- In order to mail a consent document to a prospective subject, you must first obtain approval from the IRB
- If the eligibility of a prospective subject will be determined prior to consent, approval to do this must first be obtained from the IRB
- There is a separate TTUHSC El Paso blood and tissue consent available on [iRIS](#) that may be used in order to collect and retain samples taken from the subject
- Impartial witnesses are necessary if a subject is blind, illiterate, or speaks a language other than the language available on the consents and must be present throughout the informed consent discussion
- Research personnel must sign after the subject signs the informed consent, and before any research procedures occur
- The subject should receive a photocopy of the signed informed consent document after the informed consent discussion takes place



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IRB: Informed Consent Process



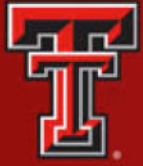
Presented by the Emory University



IRB: Informed Consent Process

During the video you learned about proper consenting procedures, however it is important to note the following:

- When a prospective subject is provided consent form, they must be given adequate time to review the consent document prior to the consent discussion. This means that a subject may choose to take a form home and review it further with their family or significant other in order to make a decision. If this occurs, then a clean consent should be provided to the prospective subject at their next visit for the informed consent discussion.
- If any changes to the informed consent have been approved and a new consent document is available after the subject has reviewed a previous version, then the subject must be allowed adequate time to review the consent with the new changes.
- If changes are approved and a new version of the informed consent is available, ongoing subjects must be re-consented with the new version of the consent if the changes are applicable to the subject's participation.



True or False

A subject does not need to be provided with a copy of their signed informed consent form.

False



According to HHS Regulations [45 CFR 46.117](#):
A copy of the informed consent document shall
be given to the person signing the form

According to the IRB TTUHSC EP [HRPP Manual](#)
The Principal Investigator shall maintain all
original consent documents



Multiple Choice

Exculpatory language is _____ on an informed consent form:

- a. Always allowed
- b. Only allowed when followed by a thorough explanation from the Principal Investigator or staff
- c. Never allowed



According to HHS Regulations [45 CFR 46.116](#):

- The inclusion of any exculpatory language in informed consent through which the subject is made to waive, or appear to waive, any of the subject's legal rights is prohibited



True or False

Any clinical staff member can obtain informed consent from a participant. This includes medical assistants, nurses, doctors, and residents.

False



According to the TTUHSC El Paso [HRPP Manual](#)

- Only authorized study personnel may obtain informed consent from a participant.
- Authorized study personnel consist of faculty and staff that have been delegated duties by the Principal Investigator and have been added to the research study on iRIS .



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Know Your Forms!



For full versions of each consent and assent template, please refer to [iRIS](#)



Types of Forms at TTUHSC El Paso

English and Spanish Biomedical Consent Forms:

Notice: Instructions for filling out the consent form are written in **BLUE**. DELETE the instructions before submitting your informed consent. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." Delete this notice.

This consent form is not valid without a TTUHSC EP IRB stamp in the lower left corner of each page.

CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family and friends if you wish.

STUDY TITLE: (This title must match in all documents)

INVESTIGATOR(s):

CONTACT TELEPHONE NUMBERS:

(You may contact the investigator(s) at the number(s) listed above (Choose one of the following: at any time OR during normal business hours) if you develop any of the conditions listed in Question # 8 of this form or if you have any unexpected complications.)

INSTITUTION: (Include the campus and other approved sites that will be involved in the study)

1. Why is this study being done?
2. How many people will take part in this study?
3. Why am I being asked to take part in this research study?
4. What will happen during this study?
5. What will be done that is different from my usual care? (If all procedures are only for research purposes, please state this.)
6. How much of my time will this study take? How long will I be in the study? (Number of visits, time for each visit, time to complete procedure(s), total length of time, etc.)
7. Are there any benefits to me if I take part in this study? (If there are benefits, describe them; payment is not a benefit.)
8. What are the risks and/or discomforts to me if I join this study? (No study is without risk and all interventional studies must include the following statement after listing the anticipated risks). There may be other risks that are unknown.

This form should be an exact translation of the approved English consent form.

Notice: Instructions for filling out the consent form are written in **BLUE**. DELETE the instructions before submitting your informed consent. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." Delete this notice.

Esta forma de consentimiento es inválida sin el sello de aprobación de TTUHSC EP IRB en la esquina izquierda más baja de cada página.

CONSENTIMIENTO PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACION

Este es un estudio de investigación que incluye a sujetos que deciden participar voluntariamente. Por favor dedique el tiempo necesario para tomar una decisión y hablar de este estudio con su médico, los miembros de su familia y sus amigos, si así lo desea.

TITULO DEL ESTUDIO:

INVESTIGADOR(es):

NUMEROS TELEFONICOS DE CONTACTO:

(Puede ponerse en contacto con el investigador(es) en el número(s) indicado(s) arriba (Choose one of the following: en cualquier momento o durante las horas normales de negocio) si se produjera alguna de las condiciones mencionadas en la pregunta #8 de este formulario de consentimiento, o si se produjera alguna complicación inesperada.)

INSTITUCION:

1. ¿Por qué se realiza este estudio?
2. ¿Cuántas personas participarán en este estudio?
3. ¿Por qué se me pide que participe en este estudio de investigación?
4. ¿Qué ocurrirá durante este estudio?
5. ¿Qué se hará que pueda ser diferente de mi atención médica habitual?
6. ¿Cuánto tiempo tendré que dedicarle a este estudio? ¿Cuánto tiempo durará mi participación en este estudio?
7. ¿Existe algún beneficio para mi si participo en este estudio?
8. ¿Cuáles son los riesgos o molestias que puedo experimentar si participo en este estudio?



Types of Forms at TTUHSC El Paso

English and Spanish Biomedical Consent Forms are used for:

- Enrolling subjects onto biomedical studies that may require investigational procedures, devices, or drugs
- Enrolling subjects whose medical records will need to be accessed



Types of Forms at TTUHSC El Paso

English and Spanish SocioBehavioral Consent Forms:

Notice: Instructions for filling out the consent form are written in **BLUE**. DELETE the instructions before submitting your informed consent. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." Delete this notice.

This consent form is not valid without a TTUHSC EP IRB stamp in the lower left corner of each page.

CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family, and friends if you wish.

STUDY TITLE:

INVESTIGATOR(s):

CONTACT TELEPHONE NUMBERS:

(You may contact the investigator(s) at the number(s) listed above (Investigator choose one of the following: at any time **OR** during normal business hours) if you develop any of the conditions listed in Question # 5 of this form or if you have any unexpected complications.)

INSTITUTION: (Investigator: Include the campus and other approved sites that will be involved in the study)

1. Why is this study being done?
2. What will happen during this study?
3. How much time will this study take? (Number of visits, time for each visit, time to complete procedure(s), total length of time, etc.)
4. Are there any benefits to me if I take part in this study? (If there are benefits, describe them; payment is not a benefit.)
5. What are the risks or discomforts to me if I join this study? (No study is without risk. Possible loss of confidentiality is a common risk for socio-behavioral studies.)
6. What other choices do I have if I don't take part in the research study?
Taking part in this study is your choice. You do not have to take part in this study. If at any time you decide not to be in the study, it will not affect any benefits or rights to which you are entitled. (**If subject is an employee or student, please include the following statement:** If you are a student or employee, your participation in this study will have no effect on your grades or employment status.)

Notice: Instructions for filling out the consent form are written in **BLUE**. DELETE the instructions before submitting your informed consent. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." Delete this notice.

This should be an exact translation of the approved English Socio-behavioral consent form.

Esta forma de consentimiento es inválida sin el sello de aprobación de TTUHSC EP IRB en la esquina izquierda más baja de cada página.

CONSENTIMIENTO PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Este es un estudio de investigación que incluye a sujetos que deciden participar voluntariamente. Por favor dedique el tiempo necesario para tomar una decisión y hablar de este estudio con su médico, los miembros de su familia y sus amigos, si así lo desea.

TÍTULO DEL ESTUDIO:

INVESTIGADOR(es) y NÚMEROS TELEFÓNICOS DE CONTACTO:

(Puede ponerse en contacto con el investigador(es) en el número(s) indicado(s) arriba (Choose one of the following: en cualquier momento o durante las horas normales de negocio) si se produjera alguna de las condiciones mencionadas en la pregunta #5 de este formulario de consentimiento, o si se produjera alguna complicación inesperada.)

INSTITUCIÓN:

1. ¿Por qué se realiza este estudio?
2. ¿Qué ocurrirá durante este estudio?
3. ¿Cuánto tiempo durará mi participación en este estudio?
4. ¿Existe algún beneficio para mí si participo en este estudio?
5. ¿Cuáles son los riesgos o molestias que puedo experimentar si participo en este estudio?
6. ¿Qué otras alternativas tengo si no participo en este estudio de investigación?
El participar en este estudio es su opción. Usted no tiene que participar en este estudio. Si usted decide en cualquier momento no estar en el estudio, no afectará a los beneficios o ventajas a las cuales tiene derecho. (**If subject is an employee or student, please include the following statement:** Si usted es un estudiante o empleado, su participación en este estudio no tendrá ningún efecto sobre sus calificaciones o estado de empleo.)



Types of Forms at TTUHSC El Paso

English and Spanish SocioBehavioral Consent Forms are used for:

- Enrolling subjects onto sociobehavioral studies that may analyze behavior by use of test and surveys
- If the subject's medical records will need to be accessed then a Biomedical consent form will be required instead of the SocioBehavioral consent form



Types of Forms at TTUHSC El Paso

English and Spanish Blood and Tissue Consent Forms:

Notice: Instructions for filling out the consent form are written in **BLUE**. DELETE the instructions before submitting your informed consent. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." Delete this notice.

This form is not valid without a TTUHSC EP IRB stamp on the bottom left hand corner of each page

INFORMED CONSENT FOR (fill in) BANK
Copy to be provided to subject signing

This consent is for research for volunteers who wish to take part. Please take your time to make a decision. If you wish, you may discuss this research with your personal doctor, family, and friends.

STUDY TITLE:

INVESTIGATOR(s):

CONTACT TELEPHONE NUMBERS:

You make contact the investigator(s) listed above if you have any questions.

INSTITUTION:

1. What is the purpose of this (fill in) bank?

We would like to keep some of your left over (investigator fill in) for future research. If you agree, your (fill in) will be kept by the principal investigator and will be used in research to learn more about your disease and other diseases. You will be asked specific questions about the use of your (fill in) at the end of this form.

2. Why am I being asked to donate to this (fill in) bank?

Your doctor has ordered laboratory tests to be performed on your (fill in) to provide for your routine medical care. There will probably be leftover (fill in). If there is, we would like to keep these leftover samples.

3. What is involved if I donate my (fill in) to this bank?

- a) **Investigator: choose one:** Your name or information linking you to the sample(s) will be removed **OR** your identity will be linked through your sample by your name or a code.
- b) The sample(s) will be stored indefinitely.
- c) The sample(s) may be examined to learn more about what causes various diseases.

[This form should be an exact translation of the approved English consent form.]

Notice: Instructions for filling out the consent form are written in **BLUE**. DELETE the instructions before submitting your informed consent. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." Delete this notice.

Esta forma de consentimiento es inválida sin el sello de aprobación de TTUHSC EP IRB en la esquina izquierda más baja de cada página.

CONSENTIMIENTO INFORMADO PARA EL BANCO DE (fill in)
Se entregará una copia firmada al sujeto

Este es un estudio de investigación que incluye a sujetos que deciden participar voluntariamente. Por favor dedique el tiempo necesario para tomar una decisión y hablar de este estudio con su médico, los miembros de su familia y sus amigos, si así lo desea.

TITULO DEL ESTUDIO:

INVESTIGADOR(es):

NUMEROS TELEFONICOS DE CONTACTO:

Puede ponerse en contacto con el investigador(es) en el número(s) indicado(s) arriba si tiene alguna pregunta.

INSTITUCION:

1. ¿Cuál es el propósito de este banco de (fill in)?

Nos gustaría guardar algo de su (fill in) sobrante para la investigación futura. Si usted está de acuerdo, su (fill in) será guardada por el investigador principal y será utilizada en la investigación para aprender más sobre su enfermedad y otras enfermedades. Le interrogarán específicas acerca del uso de su (fill in) en el extremo de esta forma.

2. ¿Por qué se me pide donar (fill in) a este banco?

Su doctor ha pedido que pruebas de laboratorio sean realizados en su (fill in) como parte de su cuidado médico rutinario. Probablemente habrá (fill in) sobrante. Si hay, nos gustaría guardar estas muestras de sobra.

3. ¿Qué está implicado si dono mi (fill in) a este banco?

- a) **Choose one:** Su nombre o información que le liga a las muestras será quitado **O** su identidad será ligada a través de su muestra por su nombre o un código.
- b) Las muestras serán almacenadas indefinidamente.
- c) Las muestras se pueden examinar para aprender más sobre qué causa varias enfermedades.
- d) Las muestras se pueden examinar para aprender cómo son afectadas por diversos tratamientos aplicados fuera del cuerpo.



Types of Forms at TTUHSC El Paso

English and Spanish Blood and Tissue Consent Forms are used for:

- Enrolling subjects onto a study that involves the collection of blood, tissues, saliva, or anything else to store in a tissue bank.
- If the subject's medical records will need to be accessed then a Biomedical consent form will be required instead of the Blood and Tissue consent form



Types of Forms at TTUHSC El Paso

English and Spanish Parental Consent Forms:

Notice: Instructions for filling out the parental permission form are written in **BLUE**. **DELETE the instructions before submitting your form**. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." **Delete this notice**.

This parental consent form is not valid without a TTUHSC EP IRB stamp in the lower left corner of each page.

PARENTAL CONSENT FORM FOR CHILD'S RESEARCH PARTICIPATION

This form provides important information about participating in research. If you are a parent or legal guardian of a child who may take part in this study, permission from one or both parents is required. The assent (agreement) of your child may also be required. If you have more than one child who will take part in this study this consent form will cover them as well.

This research study is optional and participation is completely voluntary. Please read this form carefully. You and your child have the right to take your time in making decisions about your child's participation in this research. You and your child may discuss the decision with family, friends and/or your child's doctor. If you or your child has any questions about the research or any portion of this form, please ask us. If you decide your child can participate in this research you will be asked to sign this form.

STUDY TITLE: (This title must match in all documents)

INVESTIGATOR(s):

CONTACT TELEPHONE NUMBERS:

(You may contact the investigator(s) at the number(s) listed above (Choose one of the following: at any time OR during normal business hours) if your child develops any of the conditions listed in Question # 8 of this form or if your child has any unexpected complications.)

INSTITUTION: (Include the campus and other TTUHSC EP IRB approved sites that will be involved in the study)

1. Why is this study being done?
2. How many children will take part in this study?
3. Why is my child being asked to take part in this research study?
4. What will happen during this study?
5. What will be done that is different from my child's usual care? (If all procedures are only for research purposes, please state this.)

This form should be an exact translation of the approved English version

Notice: Instructions for filling out the consent form are written in **BLUE**. **DELETE the instructions before submitting your informed consent**. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." **Delete this notice**.

Esta forma de consentimiento paternal es inválida sin el sello de aprobación de TTUHSC EP IRB en la esquina izquierda más baja de cada página.

FORMA DE CONSENTIMIENTO PATERNAL PARA LA PARTICIPACION DEL NINO EN UN ESTUDIO DE INVESTIGACION

Esta forma contiene información importante sobre la participación en un estudio de investigación. Si es un padre o tutor legal de un niño que puede tomar parte en este estudio, el permiso de uno o ambos padres se requiere. El consentimiento (acuerdo) de su niño también puede ser necesario. Si tiene más de un niño que tomará parte en este estudio esta forma de consentimiento los cubrirá también.

Este estudio de investigación es opcional y la participación es totalmente voluntaria. Por favor lea esta forma cuidadosamente. Usted y su niño tienen el derecho a tomar su tiempo en la toma de decisiones sobre la participación del niño en esta investigación. Usted y su niño pueden discutir la decisión con la familia, amigos y/o el médico de su hijo. Si usted o su hijo tiene alguna pregunta acerca de la investigación o cualquier parte de esta forma, por favor pregúntenos. Si usted decide que su niño puede participar en esta investigación, se le pedirá firmar esta forma.

TITULO DEL ESTUDIO:

INVESTIGADOR(es):

NUMEROS TELEFONICOS DE CONTACTO:

(Puede ponerse en contacto con el investigador(es) en el número(s) indicado(s) arriba (Choose one of the following: en cualquier momento o durante las horas normales de negocio) si se produjera alguna de las condiciones mencionadas en la pregunta #8 de esta forma de consentimiento, o si se produjera alguna complicación inesperada.)

INSTITUCION:

1. ¿Por qué se realiza este estudio?
2. ¿Cuántos niños participarán en este estudio?
3. ¿Por qué se le pide a mi hijo/a que participe en este estudio de investigación?
4. ¿Qué ocurrirá durante este estudio?



Types of Forms at TTUHSC El Paso

English and Spanish Parental Consent Forms are used for:

- Enrolling child subjects onto a research study
- The parent(s) is(are) the ones that fill out this consent, not the children
- This consent is a Biomedical consent and contains a HIPAA in case a child subject's medical records need to be accessed
- An assent still needs to be used for subjects under the age of 18



Types of Forms at TTUHSC El Paso

English Assent Forms:

Notice: Instructions for filling out the assent form are written in **BLUE**. DELETE the instructions before submitting your informed consent. Delete this notice.

Notice: If a large blank space is found on any page of the form, the IRB staff may insert the following text, "Space left intentionally blank." Delete this notice.

This assent form is not valid without a TTUHSC EP IRB stamp in the lower left corner of each page.

ASSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who choose to take part.

STUDY TITLE: (this may be simplified if necessary to allow a minor to understand)

We are trying to learn about [insert topic of study in simple language] because [explain research purpose in age-appropriate language]. If you would like, you can be in our study.

If you decide you want to be in our study, you will [explain all tasks and procedures clearly and simply].

[Explain the benefits and risks in clear, simple child-friendly language.

Other people will not know if you are in our study. We will put things we learn about you together with things we learn about other [children, teens], so no one can tell what things came from you. When we tell other people about our research, we will not use your name, so no one can tell who we are talking about.

Your parent(s) or guardian have to say it's OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don't want to be in the study, no one will be mad at you. If you want to be in the study now and change your mind later, that's OK too. You can stop being in the study at any time.

Our telephone number is [study contact telephone number]. You can call me if you have questions about the study or if you decide you don't want to be in the study any more.

We will give you a copy of this form in case you want to ask questions later.

Your Agreement

I have decided to be in the study. I know that I don't have to do it. My questions have been answered.

Printed Name of Child

Age of Child



Types of Forms at TTUHSC El Paso

English Assent Forms are used for:

- Enrolling child subjects onto a research study
- A parental consent must be filled out by one or both parents as well in order to obtain proper consent
- The assent is not necessary for children under the age of 7, unless the investigator feels that the child understands the information well enough to provide consent (per our [HRPP Manual](#))



How to Fill Out Our TTUHSC El Paso Informed Consents

Your signature indicates that:

- this
- you
- ans
- you
- rese
- med
- you

You will be

Printed Name _____

Signature of _____

A signature this study requires a p consent form

If applicable _____

I have discussed _____ using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

Printed name of authorized research personnel who conducted the informed consent discussion _____

Signature of authorized research personnel who conducted the informed consent discussion _____

Date _____

Time AM/PM _____

(Investigator: If population includes subjects who are unable to read the written consent form [English/Spanish] and lack an authorized representative, contact your IRB administrator for additional instructions and language.)

Texas Tech University Health Sciences Center
IRB NUMBER: E16500
IRB APPROVAL DATE: 5/10/16
IRB EXPIRATION DATE: 5/15/17

Page 5 of 8 Version date:

This is the signature page for the Biomedical Consent form. This line may or may not be on your consent form, depending on how Always ensure that there is an IRB stamp on the lower left hand corner of the consent. If the stamp is missing, then the consent has not been approved by the IRB for use.

It is recommended that both the research subject and the research personnel use the same clock or watch to add time to the consent so that the time recorded by the research personnel is not before the time added by the subject.

The subject or the research personnel must observe the subject signing the form and should print their name, sign, date and add time to the form promptly after the subject signs the form, but prior to any research procedures required but are required by our IRB. Be sure that either AM or PM are circled.

The stamp should look similar to this one



The signature page for all other consents is similar to what we just reviewed, thus the same rules should be followed. The HIPAA on both the Biomedical Consent and the Parental Consent are very similar as well. Since the child is the subject on studies that involve a parental consent, the child's name must be added to the HIPAA.



How to Fill Out Our TTUHSC El Paso Parental Form

This is the signature page for the Parental Consent form and it is a bit more complicated than the signature page for the Biomedical Consent form. It is important to note that the IRB may require an approved study to obtain permission from both parents for the recruitment of child subjects. The appropriate checkbox must be checked according to the requirements set forth by the IRB for the study at hand

You will be given a signed copy of this form.

Printed Name of Child/Children: BAILEY DOE, BOBBY DOE

Age of Child/Children: 5, 8

Printed Name of (First) Parent/Guardian/Authorized Representative: _____

Relationship to the Child/Children: _____

Signature of (First) Parent/Guardian/Authorized Representative: _____

Date: _____ Time: _____ AM/PM

Printed Name of (Second) Parent/Guardian/Authorized Representative (when required): _____

Relationship to the Child/Children: _____

Signature of (Second) Parent/Guardian/Authorized Representative (when required): _____

Date: _____ Time: _____ AM/PM

If signature of second parent not obtained, indicate why by selecting one:

- IRB determined that the permission of one parent is sufficient
- Second parent is deceased
- Second parent is unknown
- Second parent is incompetent
- Second parent is not reasonably available
- Only one parent has legal responsibility for the care and custody of the child

I have discussed this research study with the child and his or her parent/guardian/authorized representative, using language that is understandable and appropriate. I believe I have fully informed the child and his or her parent/guardian/authorized representative of the possible risks and benefits, and I believe they understand this explanation. I have given a copy of this form to the parent/guardian/authorized representative.

Printed name of authorized research personnel who conducted the discussion and obtained consent: _____

Signature of authorized research personnel who conducted the discussion and obtained consent: _____

Date: _____ Time: _____ AM/PM

Texas Tech University Health Sciences Center
IRB NUMBER: E16500
IRB APPROVAL DATE: 5/10/16
IRB EXPIRATION DATE: 5/15/17

who are unable to read the written permission form alternative, contact your IRB administrator for additional assistance.

For studies that require enrollment of multiple children in one family, it is encouraged that only one or authorized representative, signature, date and time must be used. To do this, the child's names and ages should be entered on these lines respectively. (Note: each child representative cannot sign, add time or date for the other parent. Be sure that either AM or PM are circled.)

This should be filled out the same way as with the Biomedical Consent form. (Remember to circle AM or PM)

Remember to look for that stamp!



How to Fill Out Our TTUHSC El Paso Blood and Tissue Consent

This is the question page that comes before the signature page on the Blood and Tissue consent. The signature page for this consent is very similar to the signature page on the Biomedical Consent

This section should be filled out the same way as was reviewed in previous slides

WHETHER OR NOT YOU DECIDE TO PARTICIPATE IN THIS (fill in) BANKING STUDY HAS NO EFFECT ON YOUR CARE.

By signing this form, you are agreeing that:

1. My (fill in) may be kept for use in research to learn about, prevent, treat, or cure my disease.

YES	NO	Initial _____
-----	----	---------------
2. My (fill in) may be kept for research about other health problems (for example: causes of diabetes, Alzheimer's disease, and heart disease). Sometimes tissue is used for genetic research (about diseases that are passed on in families).

YES	NO	Initial _____
-----	----	---------------
3. The principal investigator for this study may contact me in the future to ask me to take part in more research.

YES	NO	Initial _____
-----	----	---------------

These questions must be filled out by the subject and initialed in order to be valid. If they are not filled out, the subject may need to be re-consented or even withdrawn from this study

Printed Name of Subject

Signature of Subject

Date

AM/PM
Time

I have discussed this research study with the subject using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

Printed name of authorized research personnel who conducted the informed consent discussion

Signature of authorized research personnel who conducted the informed consent discussion

Date

AM/PM
Time

Remember to look for that stamp!!





How to Fill Out Our TTUHSC El Paso Assent

Have the child print their name, add their age and the date. You can tell guide them in writing the date by dictating the date to them and instructing them on how it should be written. The child can then sign or print again on the signature line depending on what is easier for them.

This should be filled out the same as what has been reviewed on previous slides

Your Agreement

I have decided to be in the study. I know that I don't have to do it. My questions have been answered.

Printed Name of Child	Age of Child
Signature of Child	Date

I have discussed this research study with the child and his or her parent/guardian/authorized representative, using language that is understandable and appropriate. I have given a copy of this form to the parent/guardian/authorized representative.

Printed name of authorized research personnel who conducted the discussion and obtained assent	
Signature of authorized research personnel who conducted the discussion and obtained assent	Date

Remember to look for that stamp!!



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Common Informed Consent Problems and Solutions





Common Informed Consent Form (ICF) Mistakes

There are many mistakes that can often occur in regards to the use of the informed consent form. The following mistakes are ones that occur more regularly than others:

- The incorrect version of the informed consent form is used to consent a subject
- An expired version of the informed consent is used to consent a subject
- A name or phone number changes and instead of submitting the change for the IRB's review and approval, the name or phone number will be scratched out resulting in an altered and unapproved form
- An informed consent form will be missing an IRB stamp, indicating that the form has not been approved by the IRB



This consent form is not valid without a TTUHSC EP IRB stamp in the lower left corner of each page.

CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family and friends if you wish.

This form has been altered

STUDY TITLE: WBC Function, Infection, and Inflammation in Subjects with Celiac's Disease
INVESTIGATOR(S): ~~John Smith, M.D.~~ ^{JANE ROBERTS, MD} ~~545-6626~~ ^{545-2262 JM 6/10/16}

CONTACT TELEPHONE NUMBERS: ~~(915) 545-6626~~ ^{545-2262 JM 6/10/16}
 (You may contact the investigator at the number listed above during normal business hours if you develop any of the conditions listed in Question # 7 of this form or if you have any unexpected complications.)

INSTITUTION: Texas Tech University Health Sciences Center El Paso

Can You Spot
What's Wrong?

- Why is this study being done?**
We are doing a study to investigate possible changes in white blood cell (WBC) function which might lead to infections and different diseases in persons with Celiac's disease.
- How many people will take part in this study?**
~~About 200~~ people will be participating in this study.
^{300 JM 6/10/16}
- Why am I being asked to take part in this research study?**
You are being asked to participate in this study because you have been diagnosed with Celiac's Disease and are between the ages of 18 - 35.
- What will happen during this study? What will be done that is different from my usual care?**
All the procedures in this study are research related and not part of typical standard of care. The procedures consist of answering a questionnaire about your Celiac's Disease and a blood draw. Approximately 40 to 50 ml (about 2-3 tablespoons) of blood will be drawn from a vein in your arm. Your demographics, medical history, and diagnosis will also be reviewed by the investigator after you have given consent.
- How much of my time will this study take? How long will I be in the study?**
The consent process may take anywhere from 15 minutes to an hour. After obtaining consent, answering the questions on the questionnaire and collecting the blood may take anywhere from 30 minutes to an hour.
- Are there any benefits to me if I take part in this study?**
There will be no direct benefit to you, but the information we collect from your participation may help someone in the future with the same disease you have.

There's no IRB stamp



Common ICF Process Mistakes

There are also many mistakes that can often occur during the informed consent process as well. The following mistakes are ones that occur more regularly than others:

- Missing or incorrect research personnel or subject signatures on the ICF
- Unauthorized signatures, from faculty or staff that have not been approved to work on a study, on the line designated for research personnel on the ICF
- Incorrect or missing dates and times on the ICF
- The subject is not provided with a signed copy of the ICF
- The subject is inadvertently given the original ICF
- AM or PM is not circled
- An impartial witnesses signs the consent when there is no need for a witness to sign



Common ICF Process Mistakes

- Initials missing from places on the informed consent that require the subject to initial
- Either the subject or the research personnel sign on the wrong line
- Scribbling out errors instead of putting one line through them, initialing, and dated them and then adding the correct entry above the error
- The research personnel pre-signing the ICF before the subject signs the form or is even allowed to review the form
- Parents adding their name in place of their child's name on parental ICFs
- Not adding the legally authorized representative's relationship to the subject on the HIPAA when it is required



Can You Spot What's Wrong?

We can't be sure if this is a scribble or a signature. If this is a mistake then it should have been lined through, initialed, and dated. (Note: Once the informed consent process is completed, a mistake cannot be corrected, and will have to be documented on a note-to-file)

You will be given a signed copy of this form.

Jane Smith
Printed Name of Subject

Jane Smith
Signature of Subject

[Scribble]
Signature of
or Authorized

I have discussed
using language
subject of the
explanation.

[Scribble]
Signature of a
conducted the

Notice that according to the times recorded on the form, it looks like the subject signed this form after the research personnel signed. This brings up questions of whether or not the research personnel really observed as the subject signed the consent. AM or PM were also not added to the time, making it difficult to determine if informed consent happened before or after study procedures for that day.

It is important to
Some sponsors re
consent, like requiring subject initials on the lower right hand
corner of each page. In this case, the subject initials are missing.

5/12/16 8:37
Date Time

Date Time

his or her authorized representative,
believe I have fully informed the
e subject understands this
ct.

5/12/16 8:35
Date Time

This is an expired form, and it was used to consent the subject after it expired





Strategies to Improve Informed Consent Compliance

Mistakes

- Ensure that you know what items must be signed or filled out on a consent document before beginning the consent process
- Show or point to where subjects need to print, sign, date and add time when they are ready to do so
- Explain to subjects how to date and/or add time to a consent by dictating the date and/or time to them
- Observe as the subjects prints, signs, dates and adds time
- Know when a witness is needed vs. when they are not needed
- Review the consent a second time after completion for accuracy and completeness. If you notice a mistake have the subject line through, initial and date their mistake and then have them add in the correct entry if applicable. If you made a mistake, then go ahead and line through, initial and date the mistake and then add in the correct entry if applicable.
- Make sure you have the original informed consent form before the subject leaves
- Provide a full copy of the signed document to subject



Strategies to Improve Informed Consent Compliance

Mistakes

- NEVER use white-out to correct mistakes
- Don't pre-sign the ICF before you consent a subject
- Don't sign the ICF before you allow the subject to sign
- Make sure to sign the ICF soon after the subject. It may look suspicious if too much time goes by before the research personnel signs the ICF after the subject
- Use the same watch to tell time for the subject and yourself
- Review the consent again before photocopying it
- File the original ICFs in a consistent and safe place



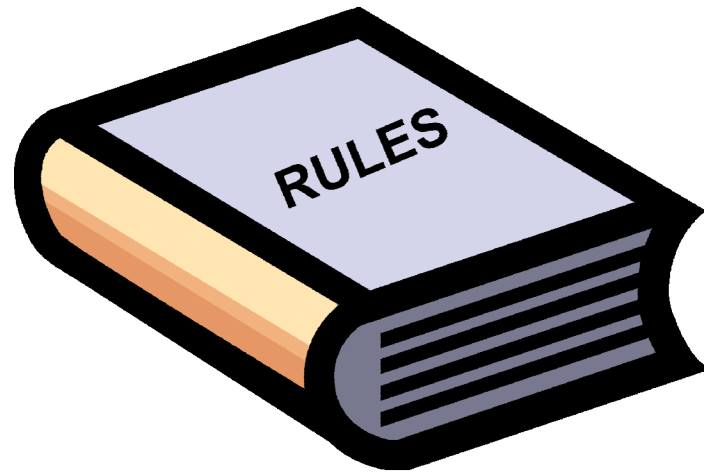
Strategies to Improve Informed Consent Compliance Process

- Don't save different approved versions of the ICF to your computer
- Don't print a version of the ICF that you have saved on your computer
- Always print the ICFs directly from iRIS to make sure you are getting the most up-to-date version
- Check your consent document to ensure it is the correct one and that it is not expired before you use it
- Submit any changes regardless of how small they might be to the IRB
- Obtain IRB approval prior to using a newly altered ICF. If the form has already been submitted to the IRB for approval, but has not been approved yet then you will have to use the currently approved ICF to consent a subject. If there are a lot of changes on the consent, then you will have to wait on enrolling subjects until the consent form is approved.



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Why Follow the Rules?





We Follow the Rules to...

- Be in compliance with federal and institutional policy and regulations
- Maximize the safety of the research subject
- Demonstrate study integrity and prevent research misconduct from occurring



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Test Time!

Complete the test following this presentation.
(Note that you must score an 80% or above to pass the test, and you will only have 3 chances to take the test)

For Questions Contact:
Jacqueline Roberts
Research Compliance Officer
915-215-4814
Jackie.Roberts@ttuhsc.edu



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