

Informed Consent & Waivers

Human Subjects Protection Program (HSPP)



THE UNIVERSITY
OF ARIZONA

Fall 2022 HSPP Workshop Series

1. Ethical & Regulatory Foundation of Human Subjects Research & IRB Review
2. A Step-by-Step Guide to Successful IRB Submissions
3. Informed Consents & Waivers (October)
4. Let's Talk About Research Data (November)
5. Your Study is Approved, Now What? (December)

HSPP Training: <https://research.arizona.edu/compliance/human-subjects-protection-program/hspp-training/irb-training-opportunities>

Agenda

- **Overview**
- **Consent Types**
- **Required Elements**
- **Additional Requirements**
- **UA Templates**
- **Uploading ICFs to eIRB**
- **Waivers**
- **Resources**
- **Q&A**





1. Non-Written Consent Documentation
2. Exculpatory Language #1
3. Exculpatory Language #2
4. Waivers
5. Belmont Report Principles

Overview



Informed Consent Ethical Background

The Nuremberg Code

The voluntary consent of the human subject is absolutely essential.

Declaration Of Helsinki (Sections 25-32)

Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

The Belmont Report (Principle of Respect for Persons)

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what should or should not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.



Common Rule Requirements

45CFR46.111 Criteria for IRB approval of research.

- Informed consent will be sought from each prospective subject or the subject's LAR; for children Parental Permission/Assent is obtained.
- Informed consent will be appropriately documented or waived.

45CFR46.116 General Requirements for Informed Consent.

- Includes Waiver or alteration of consent.

45CFR46.117 Documentation of informed consent.

- Includes Waiver of signed informed consent.

The NEW Rule (2018) streamlined consents, but it also added more consent elements (i.e., future use, commercial profit, sharing of results, and whole genome sequencing).



Informed Consent Process

Informed	Consent	Process
<ul style="list-style-type: none">• Provide sufficient information to potential participants about study details so they can make an informed decision.• Use visual aids, information sheets, and/or videos to promote understanding.• Answer questions and assess understanding.• Always Required, regardless of method.	<ul style="list-style-type: none">• A document or an alternate method that confirms the agreement to participate in research.• Should be appropriate for the participant, and should consider the age, maturity, cognitive status, and language level of a potential participant.• Consent requirements can be waived in certain situations.	<ul style="list-style-type: none">• Starts with recruitment.• It's continuing and ongoing.• Provide participants new information that could affect participation.• Re-assess willingness to participate.• Reconsenting or an addendum might be required.

Considerations to Enhance Understanding

- Participants should have **ample time** to read the consent and adequate opportunity to ask questions.
- If the participant has **difficulty reading the consent**, it should be read to them.
- If enrolling participants with **impaired decision-making ability**, when possible, explain to the extent of their ability to understand, request some sort of affirmation, and document consent from their Legally Authorized Repetitive (LAR).
- **Translate documents** to the language the participant is most comfortable with to receive medical/research related information. **Short Forms** can be used for less than Five (5) participants, translated documents are needed beyond that number.
- For long/complex/online consents use attention checks or a short survey to assess understanding.



NO “Exculpatory Language”

No informed consent, whether oral or written, may include any exculpatory **language through which the subject is made to waive or appear to waive any of the subject's legal rights**, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. *[45 CFR 46.116]*

- **ICF Template Injury Section:** “This, however, does not waive your rights in the event of negligence. If you suffer an injury from participating in this study, you should seek treatment.”
- **ICF Signature Section:** “I am not giving up any legal rights by signing this form.”

HHSP Guidance on Exculpatory Language

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html>



Zoom Poll Question & Answer

Which of These Statements is Allowed in Consent? (Single Choice) *



- A: "This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research."
- B: "I waive any possibility of compensation for injuries that I may receive as a result of participation in this research."

UA/Banner Template Language: "The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study."



Zoom Poll Question & Answer

Which on of These Statements is Allowed in the Consent? (Single Choice) *

) A: "By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances."



) B: "Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur."

ICF Template Section: Will my specimens be sold for commercial profits? Describe whether subjects will or will not share in any commercial profit from the use of their biospecimens, even if identifiers are removed.

Sample Language: "The information/specimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or other compensation from products developed using the information/specimens."

UA Informed Consent Guidelines

- Use the **latest ICF Templates**.
- **Include all required elements** of informed consent, and if applicable, all the additional elements of informed consent.
- Written **in a language understandable to the participant**.
- Written at a **6th to 8th grade level**, or an appropriate reading level.
- **Add and update the version date** to ensure that the most recent IRB approved version is used.
- Submit as a **Microsoft Word document** (.doc or .docx) so it can be edited during pre-review and so that the approval stamp can be applied.
- Use **track-changes** when submitting revisions.

HSPP Informed Consent Guidance

<https://research.arizona.edu/sites/default/files/Informed%20Consent%20v2022-08.pdf>

Consent Types



Types of Informed Consent

- **Written Informed Consent**

- Participant signs and dates a consent form (usually in person, and a signed/dated copy is given to participant).
- The individual obtaining consent also signs and dates the consent document.
- The signature of a Legally Authorized Representative (LAR) is needed for participants with impaired decision-making capacity.

- **Verbal Informed Consent "Disclosure"**

- An IRB approved Oral Script is used.
- Participant verbally agrees to participate.
- Signature is waived by the IRB.

- **Electronic Informed Consent**

- REDCap, Qualtrics (e-signature or checkbox)

OR

- **Waiver of Informed Consent**

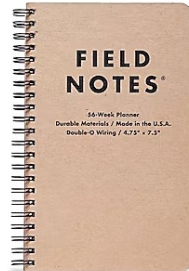
- If the regulatory criteria are met, the IRB can waive informed consent.

Non-Written Consent Documentation

Unwritten, Oral, or Electronic Informed Consent also require documentation.

Consider ways in which to verify human subject participants' oral consent if required to produce verification. This can be accomplished in a variety of ways, including:

- **Audio recording**
- **Video recording**
- **Photographs**
- **Drawings**
- **Witnesses**
- **Field Notes**



“Consenting” Children (<18 Years of Age)

Parental Permission, agreement of parent(s) or guardian(s) is required for all human subject's research involving minors unless waived by the IRB.

Minor Assent, a child's affirmative agreement to participate in research, must also be obtained unless waived by the IRB. Assent has to be affirmative, not objecting is not the same as agreeing.

When the minor reaches the **age of majority** (age 18), they should be Consented as an adult to continue participation.

HSPG Guidance Research Involving Children
<https://research.arizona.edu/sites/default/files/Research%20Involving%20Children%20v2021-09.pdf>



- Use age-appropriate language.
- The parent/guardian needs to be Consented first.
- The child needs to be Assented second.
- **IRB typically waives Assent for children 7 years old and younger.**
- The child can refuse participation.

Required Elements



Required Elements of the Informed Consent

(45 CFR 46.116)

(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 that are experimental.

UA Template Language

Summary of the research (or Intro)

This is a consent form for participation in a research study.

Why is this study being done?

Explain the purpose of the study and a statement that the study involves research.

What will happen if I take part in this study?

Explain the procedures to be done. Specifically identify any procedures that are for research only.

Include:

- The probability for random assignment to each treatment
- The subject's responsibilities

How long will I be in this study?

Explain the expected duration of the subject's participation.

Required Elements #2 & #3

(2) A description of any **reasonably foreseeable risks or discomforts** to the subject.

UA Template Language

What risks , side effects or discomforts can I expect from being in the study?

Explain any reasonably foreseeable risks or discomforts to the subjects because of participation or procedures from the research. Explain, if applicable, that a particular treatment or procedure may involve risks that are currently unknown or foreseeable.

Explain that if there are significant new findings that may impact a subject's participation they will be informed.

(3) A description of any **benefits to the subject or to others** that may reasonably be expected from the research.

UA Template Language

What benefits can I expect from being in this study?

Explain any reasonably expected benefits to subject or others.

- When there is no intended clinical benefit to the subject, a statement to this effect
- Do not include statements of unproven claims of effectiveness or certainty of benefit, either implicit or explicit

Required Element #4

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

UA Template Language

What **other** choices do I have if I do not take part in this study?

Explain 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.

Describe any appropriate alternative procedures or courses of treatment. For some studies, the only alternative would be to not participate.

Required Element #5

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

UA Template Language

Will my study-related information be shared, disclosed, and kept confidential?

Specify the extent, if any, to which confidentiality of identifiable records will be maintained.

Specify the entity(ies) which would potentially share or have access to research files and remove those that are not applicable.

If the study is associated with Banner Health, also add the Banner Gray Language in the UA/Banner Medical ICF.

Required Element #6

(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;

UA Template Language

What happens if I am injured because I took part in this study?

For research involving more than minimal risk, include the following elements:

- An explanation as to whether any compensation is available if injury occurs
- An explanation as to whether any medical treatments are available if injury occurs
- If compensation and/or treatment is available: what comprises that compensation and/or treatment, or where further information may be obtained

The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

Additional Sample Language is included in the sidebar of the ICF template, and UAHS/Banner might also edit the injury and compensation section.

Required Element #7

(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;

ICF Template:

Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact _____.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may **contact the Human Subjects Protection Program Director at 520-626-8630 or online at <https://research.arizona.edu/compliance/human-subjects-protection-program>**.

For studies involving greater than minimal risk include : If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact _____.

Required Element #8

(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.

ICF Template

Can I stop being in the study?

Explain 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.

If applicable, explain what may happen and what procedures are required for orderly withdrawal or termination if the subject leaves the study early, or is withdrawn from the study by the researcher.

Sample Language: " Your participation is voluntary. You do not need to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status."

Required Element #9



2018 New Common Rule Requirement:

(9) One of the following statements about any research that involves the collection of identifiable **private information** or **identifiable biospecimens**:

UA Template Language

Will my data or specimens be stored for future research ?

The consent must include either:

- A statement that identifiers will or will not [choose one] be removed from the private information or biospecimens, and that after such removal, the information or biospecimens **may be used for future research studies without additional informed consent** [Include a description of what information/specimens will be stored and whom they will be shared with (both internal and outside the institution). Explain what research may be conducted with these data/specimens - including unspecified future research, genetics, disease specific, etc.]; or
- A statement that the identifiable information or biospecimen, even if identifiers are removed, **will not be used, or distributed for future research.**

Additional Requirements



Additional Elements #1- #6

- (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) **that are currently unforeseeable** (legal, financial, social, physical, or cultural harm).
- (2)** Anticipated circumstances under which the subject's **participation may be terminated** by the investigator without regard to the subject's or the legally authorized representative'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 that may relate to the subject's willingness to continue participation will be provided to the subject.
- (6)** The approximate number of subjects involved in the study.

Additional Elements #7- #9

2018 New Common Rule Requirements:



- (7) For research involving **biospecimens**, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- (8) A statement regarding whether **clinically relevant research results**, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- (9) For research involving **biospecimens**, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

UA Templates



UA Informed Consent Templates

Use the Correct Consent Template(s):

- **Internally funded/non-funded Social Behavioral** ICF/Parental permission (v. Sept 2021)
- **Externally funded Social Behavioral** ICF/Parental permission (v.2022_10)
- **UA/Banner Medical** ICF/Parental permission (required for Banner; also includes Banner PHI) (v.2022_10)
- **Enforcement of New Templates Starts November 7th**



HSPP ICF Templates <https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates>



Instructions

*This consent form is only for research that does not collect any biospecimens or will access HIPAA protected information. Delete the **RED** text prior to submitting this form to the IRB. Required language is in regular text. Additional language, as appropriate, are in comments.*

University of Arizona

Consent **and/or Parental Permission** to Participate in Research

Study Title:

Principal Investigator:

Sponsor (delete if not sponsored)

Conflict of Interest Statement (If applicable per COI management plan, delete if no COI management plan exists for researchers on this protocol)

Summary of the research

This is a consent form for participation in a research project. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

If your consent is more than 4 pages, provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. This summary should include:

- The purpose and expected duration
- Major requirements of the study
- The most important risks and/or benefits
- Other alternatives to participating, if appropriate
- Time commitment



Melton-Lopez, Christine Marie - (melton1)
If the study is sponsored by NIH, the following items need to be reflected in the consent:

1. COC language



Melton-Lopez, Christine Marie - (melton1)
If this consent form will be used as an adult consent form AND parental permission form, include this blurb:

Externally Funded Social Behavioral ICF template

Required Parts:

- UA Logo
- Version Date
- Regular text
- Summary of the Research (>4pg ICF)

Customizable Parts:

- This form can be used as an adult consent or parental permission.
- Red text can be removed/replaced
- Insert side bar comments as applicable.

Instructions

*This consent form is for medical research, including collection of biospecimens or research that will access HIPAA protected information. Delete the RED text prior to submitting this form to the IRB. Required language is in regular text. Additional language, as appropriate, are in comments. **Grey language is required by Banner if conducting research at B-UMC.***

Consent and/or Parental Permission to Participate in Research

Study Title:

Principal Investigator:

Sponsor and/or Funder (delete if not sponsored):

Conflict of Interest Statement (if applicable per COI review, Delete if no COI)

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

Provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. This summary may be a page or more, depending on the study. This summary should include:

- The purpose and expected duration
- Major requirements of the study
- The most important risks and/or benefits
- Other alternatives to participating, if appropriate
- Time commitment

[if applicable]: The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.



139 Research Partic

Approved by University of Arizona
Date Approved: 7/25/2022

HSPF Use Only:
Consent form Medical v2022-09

Melton-Lopez, Christine Marie -
(melton1)
If the study is sponsored by NIH, the following items need to be reflected in the consent:

Melton-Lopez, Christine Marie -
(melton1)
If this consent form will be used as an adult consent form AND parental permission form, include this blur:

If you are a parent of a child that is participating in this study, references to "you" and "your" throughout this document refer to both you and your child(ren).

Each section of the consent form should clearly include information for BOTH the adult participant and their child(ren). For example, the procedures section should address what the adult will be asked to do AND what their child(ren) will be asked to do.

If your study includes children 12 years of age and younger for online research, include a link to the online survey or data collection tool in this section. This requirement is to comply with the Children's Online Privacy Protection Rule (COPPA).

September 02, 2022, 10:22 AM

UA Medical ICF/Parental Permission Template

Use this template for:

- Medical Research
- B-UMC Research
- When Biospecimens are involved
- When PHI is accessed

BH Required Parts:

- Banner Logo
- Barcode on pg1
- Banner Gray Language

Customizable Parts:

- Red text can be removed/replaced
- Insert side bar comments as applicable

Helpful Hints:

- Submit the ICF as a MSWord document.
- Keep the version date on top updated.
- After approval, the consent will be PDFd and the approval date will appear on the bottom of the page.



The University of Arizona Consent to Participate in Research Addendum

Study Title:

Principal Investigator:

Sponsor:

- This is a consent addendum for research participation. It contains important additional information about this study and what to expect if you participate (or continue to participate). Please consider the information carefully. Feel free to discuss the information with your friends and family and to ask questions before making your decision about whether or not to participate.
- Your participation is voluntary. You may refuse to participate (or to continue to participate) in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at The University of Arizona, your decision will not affect your grades or employment status.
- This consent addendum provides information in addition to the main consent for the research study in which you are participating. If you decide to participate (or to continue to participate), you will be asked to sign this form and will receive a copy of the signed form. All other information in the original consent form not addressed in this addendum still applies. Please refer to it for any questions you might have.
- Throughout this consent addendum, “you” refers to the study participant.

Insert description of the new or additional information.

For questions, concerns, or complaints about the study you may contact _____.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or <https://research.arizona.edu/compliance/human-subjects-protection-program>.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact _____.

UA ICF Addendum Template

- The consent addendum template should be used when there is a new portion of a research project that requires a participants’ signature.
- The ICF Addendum should include the following language: “This is a consent addendum for research participation. It contains important additional information about this study and what to expect if you participate (or continue to participate). Please consider the information carefully. Feel free to discuss the information with your friends and family and to ask questions before making your decision about whether or not to participate.”
- The ICF Addendum template is recommended, but it is not required.



Instructions

This assent form/disclosure form is for research that does not collect any biospecimens or will access HIPAA protected information. Delete the RED text before submitting this form to the IRB.

University of Arizona
Assent to Participate in Research: Ages 8-12 years old

Study Title:

Principal Investigator:

Researchers at the University of Arizona want to tell you about a research study they are doing about **[insert topic and describe the goals in simple language]**. A research study is done to find a better way to treat people or to understand how things work. You are being asked to participate in a research study because **[insert reason(s) for inclusion]**.

Your parents know about this study and have given permission for you to participate. If you agree, we will ask you to **[describe what the child will be asked to do in simple language that is appropriate for the child's age and maturity level. If the child will be asked to do several things, describe each one in the order they will occur. Explain how long each activity will take. If you are audio or video recording or photographing, address it here]**.

There is nothing bad that will happen to you, but **[describe possible risks in simple language]**.

The information you give us will be kept private. The researchers will not use your name or other private information in their study reports.

You do not have to be in this research study. If you want to participate and change your mind later, all you have to do is tell the researchers you want to stop. No one will be upset that you don't want to be in the research study anymore.

Before you say yes or no, the researchers will answer any questions you have. You can ask the researchers questions at any time.

Signatures are required as determined by the IRB. For many studies involving focus groups, observations, and online surveys, it may not be necessary to obtain a signature from participants. Use this signature line when you will be obtaining written assent.

Signing the assent form

If you want to be in this research study, please write your name below.

Name: _____ Date: _____

Name of Person Obtaining Assent: _____ Date: _____

UA Assent Templates

Assent Form 8-12yrs

Assent Form 13-17yrs

- Use for non-medical UA research with minors.
- The assent template is recommended, but not required.
- Assent is typically waived for children age 7 and younger.

The Waiver of Assent is included in the [Appendix for Children.](#)

Uploading to eIRB



Uploading the ICF in eIRB

Basic Study Information

Study Funding Sources

Local Study Team Members



Study Scope

Local Research Locations

Local Site Documents


Local Site Documents

1. Consent forms: (include an HHS-approved sample consent document, if applicable)


					
	Document	Category	Date Modified	Document History	
	 ICF - SBS non-funded or internally-funded consent form_v2021-09-02_0 (10).doc(0.01)	Consent Form	10/15/2022	History	
	 ICF - SBS externally-funded consent_form_v2022-09(6).doc(0.01)	Consent Form	10/15/2022	History	
	 ICF - Medical consent form v2022-09.docx(0.01)	Consent Form	10/15/2022	History	
	 t502b_-_consent_addendum_effective_2021-05-04 (5).doc(0.01)	Consent Form	10/15/2022	History	
	 assent_form_8-12yrs_v2020-02_0 (2).doc(0.01)	Consent Form	10/15/2022	History	
	 assent_form_13-17yrs_v2020-02 (1).doc(0.01)	Consent Form	10/15/2022	History	

Also upload the Oral Script & Translated Consent Documents to this section.

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

			
Document	Category	Date Modified	Document History
There are no items to display			

3. Other attachments:

			
Document	Category	Date Modified	Document History

The Appendix for Waiver or Alteration of Consent or PHI is uploaded here.

Use the Approved/Stamped ICF for Consenting



Approval Letter Language:
 “To document consent, use the consent documents that were approved and stamped by the IRB. Go to the Documents tab to download them.”

History	Funding	Contacts	Documents	Reviews	Snapshots
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Study Related Documents

Draft	Category	Final	Last Finalized	Document History
IRB Protocol for Human Subjects Research v2022-09 (4).docx	IRB Protocol	IRB Protocol for Human Subjects Research v2022-09 (4).docx	10/15/2022 1:55 PM	History

Site Related Documents

Draft	Category	Final	Last Finalized	Document History
ICF - SBS non-funded or internally-funded consent form_v2021-09-02_0 (10).doc	Consent Form	ICF - SBS non-funded or internally-funded consent form_v2021-09-02_0 (10).pdf	10/15/2022 1:55 PM	History
ICF - SBS externally-funded consent_form_v2022-09 (6).doc	Consent Form	ICF - SBS externally-funded consent_form_v2022-09 (6).pdf	10/15/2022 1:55 PM	History
ICF - Medical consent form v2022-09.docx	Consent Form	ICF - Medical consent form v2022-09.pdf	10/15/2022 1:55 PM	History
t502b_-_consent_addendum_effective_2021-05-04 (5).doc	Consent Form	t502b_-_consent_addendum_effective_2021-05-04 (5).pdf	10/15/2022 1:55 PM	History
assent_form_8-12yrs_v2020-02_0 (2).doc	Consent Form	assent_form_8-12yrs_v2020-02_0 (2).pdf	10/15/2022 1:55 PM	History
assent_form_13-17yrs_v2020-02 (1).doc	Consent Form	assent_form_13-17yrs_v2020-02 (1).pdf	10/15/2022 1:55 PM	History

Waivers



Consent Waivers & Alterations

In some cases, it may not be appropriate or possible to consent subjects. The federal regulations have provisions for when consent can be waived.

An IRB may also approve a consent procedure that omits some, or alters some or all, of the elements of informed consent; this is called a consent alteration.

Types of Waivers

- Waiver of Consent
- Alteration of Consent
- Waiver of Documentation of Consent (applies to the signature requirement)



FDA Requirements & Waivers

The FDA does not have a Consent Waiver, but the Agency does allow for an **Exemption from Informed Consent for** FDA-regulated planned emergency research.

Use the [Appendix for Exception from Informed Consent \(EFIC\)](#) when an exception from informed consent is needed (21 CFR 50.24)

Planned Emergency Research is a systematic investigation of a condition experienced by individuals in a setting where the emergency circumstances require prompt action and generally provide insufficient time and opportunity to locate and obtain consent from each subject's legally authorized representative (LAR). Planned emergency research involves the prospective identification and enrollment of participants into a study.

[Also see FDA General Requirements for Informed Consent \(21 CFR 50.20.\)](#)

Regulatory Criteria for Waivers

In order for the IRB to waive or alter consent, the IRB must find and document that:

- (i) The research involves no more than minimal risk to the subjects;
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Waiver of Informed Consent Documentation

45CFR46.117(c)

(1) The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

The IRB also needs to review/approve the oral script and all participant facing materials.



Appendix for Alteration/Waiver of Consent or PHI

This form should be used when a Waiver of Consent, Waiver of Documentation of Informed Consent, Alteration of Consent, or Alteration/Waiver of Protected Health Information (PHI) Authorization is needed. Only fill out the section(s) that apply to your study.

Instructions: Red text is included as a guide on how to properly fill out this form.

Basic Information	
Title of Study:	<input type="text"/>
Short Title:	<input type="text"/>
Principal Investigator Name:	<input type="text"/>
Section 1: Waiver or Alteration of Consent	
A. Waiver of Informed Consent (45 CFR 46.116(f)(3) and 21 CFR 50.55(d) Complete this section if you are requesting a Waiver of Consent, otherwise leave blank.	
Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject: <input type="text"/>	
Explain why the waiver/alteration will not adversely affect the rights and welfare of the subjects: <input type="text"/>	
Explain why it is impracticable to conduct this research when informed consent is required: <input type="text"/>	
Explain, if appropriate, how the subjects will be provided with additional pertinent information about the research after participation. If not appropriate, explain why: <input type="text"/>	
If the research involves using identifiable private information or identifiable biospecimens, the research could not practically be carried out without using such information or biospecimens in an identifiable format: <input type="text"/>	

Use this forms to request:

- **Waiver of informed consent** (Section 1 A)
- **Waiver of documentation** (Section 1B)

OR

- **Alteration or waiver of protected health information (PHI)** (Section 2 A-C/Section 3).

Answer all questions in each section that you are requesting.

Waiver of ICF Documentation Section 1B

B. Waiver of Documentation of Informed Consent Complete this section if you are requesting to omit the signature requirement during the consenting process, otherwise leave blank. Complete only one: Subpart 1, Subpart 2, or Subpart 3.

Subpart 1: Waiver of Documentation of Informed Consent (45 CFR 46.117(c)(1))

Explain how the consent document is the only record linking the subject and the research:

■

Explain how the principal risk would be the potential harm resulting from a breach of confidentiality:

■

Subpart 2: Waiver of Documentation of Informed Consent (45 CFR 46.117(c)(2))

Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject

■

Describe how the research involves no procedures for which written consent is normally required outside the research context:

■

Subpart 3: Waiver of Documentation of Informed Consent (45 CFR 46.117(c)(3))

Explain how subjects or legally authorized representatives are members of a distinct cultural group or community in which signing a form is not the norm:

■

Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject:

■

Section 2: Waiver or Alteration of PHI (45 CFR 164.512(i)) Complete this section if you are requesting a Waiver of PHI authorization to access the electronic medical record for recruitment or research purposes, otherwise leave blank.

A. Protected Health Information - Describe the PHI being used or disclosed in your study

- Patient/subject name
- Address street location
- Address town or city
- Address state
- Address zip code
- Elements of dates (except year) related to an individual (i.e., DOB, admission/discharge dates, date of death)
- Telephone number
- Fax number
- Electronic mail (email) address
- Social security number
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identification numbers and serial numbers including license plates
- Medical device identifiers and serial numbers
- Web URLs
- Internet protocol (IP) address
- Biometric identifiers (finger and voice prints); specify:
- Full face or comparable photographic images
- Any unique identifying number, characteristic or code (a rare disease can be considered a unique id)
- Link to identifier (code)

- Complete Section 2 for a Waiver of PHI to access electronic medical records for recruitment or research purposes.
- Check all that apply.
- Make sure this matches the PHI information in the protocol.

B. Record/Specimen Use - Indicate your source(s) of health information

- Physician/clinic records
- Interviews/questionnaires
- Mental health records
- Billing records
- Lab, pathology and/or radiology results
- Biological samples obtained from the subjects
- Hospital/medical records (in- and out-patient)
- Data previously collected for research purposes
- Other; specify:

C. Request for Waiver or Alteration of Authorization (45 CFR 164.512(i))

List every investigator, research staff member, or other staff member who will have access to this data (anyone listed here must also be listed in *Local Study Team Members* in the eIRB system):
[REDACTED]

Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:
[REDACTED]

Describe investigator's plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time:
[REDACTED]

Explain why research could not practicably be conducted without the waiver or alteration:
[REDACTED]

Explain why research could not practicably be conducted without access to and use of the protected health information:
[REDACTED]

Section 3: Attestation: **Required only when requesting Waiver or Alteration of PHI**

Principal Investigator

I assure the IRB that the protected health information which I have detailed in this Waiver of Authorization and/or Consent application will not be reused (i.e.: used other than as described in this application) or disclosed to any person or entity other than those listed above, except as required by law, for authorized oversight of this research protocol, or as specifically approved for use in another protocol by the UA IRB.

I also assure the UA IRB that the information that I provide in this application is accurate and complete, and that the PHI that I request is the minimum amount of identifiable health information necessary for my research protocol.

Attestation of Principal Investigator:

Print Name: [REDACTED]

Date: [REDACTED]

Section 2 C

- Provide details about why a waiver or alteration is needed.
- For the list of individuals, you can add a general statement, i.e., "only study personal listed on the delegation log will have access to this data after all required training and approvals are completed."

Section 3

- Signature is only needed if a PHI waiver or alteration is requested.

Section 3: Parental Permission

Answer the question by selecting the most appropriate box below

What parental permission will be obtained?

- Obtained from both parents or Legally Authorized Representative (LAR)
- Obtained from only one parent (45 CFR 46.408(b) and 21 CFR 50.55(e)(1)) or LAR
- Research involving not greater than minimal risk as defined in 45 CFR 46.404 or 45 CFR 46.405 up above
- Waiver of Parental Permission (45 CFR 46.116(f)(3) and 21 CFR 50.55(d))
- Research involves no more than minimal risk to subjects
 - The waiver or alteration will not adversely affect the rights and welfare of the subjects
 - The research could not practicably be carried out without the waiver or alteration
 - If the research involves using identifiable private information or identifiable biospecimens, the research could not be carried out without using such information or biospecimens in an identifiable format
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- Waiver of Parental Permission (45 CFR 46.116(e)(3))
- The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law
- Waiver of Parental Permission (45 CFR 46.408(c))
- The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study evaluate, or otherwise examine (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration

If a Waiver of Parental Permission is being requested, provide justification for the waiver:

If permission is going to be obtained from someone other than the parent, how will the Legally Authorized Representative (LAR) be determined? Explain:

Complete the Appendix for Children/Wards to request:

Section 3

- A waiver of one parent signature.
- Waiver of Parental Permission.

AND/OR

Section 4

- A Waiver of Child Assent

Section 4: Child Assent

If obtaining assent, explain how it will be obtained:

If requesting a Waiver of Assent, **select the most appropriate box below:**

<input type="checkbox"/>	<p>Waiver of Assent (45 CFR 46.408(a) and 21 CFR 50.55(c)(1))*</p> <ul style="list-style-type: none">The IRB has <u>taken into account</u> the ages, maturity, and psychological state of the children involved and determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted; therefore, the assent of the children is not a necessary condition for proceeding with the research. <p><i>*Note that if your age range is between 0-7 years, this box may be checked</i></p>
<input type="checkbox"/>	<p>Waiver of Assent (45 CFR 46.408(a) and 21 CFR 50.55(c)(2))*</p> <ul style="list-style-type: none">The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and that the intervention is only available in the context of the research.Therefore, the assent of the children is not a necessary condition for proceeding with the research. <p><i>*Note that this request may only be used when 45 CFR 46.405 has been checked in the section above</i></p>
<input type="checkbox"/>	<p>Waiver of Assent (45 CFR 46.116(f)(3)) and 21 CFR 50.55(d))</p> <ul style="list-style-type: none">The research involves no more than minimal risk to subjects.The waiver or alteration will not adversely affect the rights and welfare of the subjects.The research could not practicably be carried out without the waiver or alteration.
	<ul style="list-style-type: none">If the research involves using identifiable private information or identifiable biospecimens, the research could not be carried out without using such information or biospecimens in an identifiable format.Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Assent



<input type="checkbox"/>	<p>Waiver of Assent (45 CFR 46.116(e)(3))</p> <ul style="list-style-type: none">The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study evaluate, or otherwise examine (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration.
	<p>If requesting a Waiver of Assent, provide justification for the request:</p>

Appendix for Cognitively Impaired Individuals

Complete this form to request inclusion of adult participants with decisional impairments (i.e., with diminished decision-making capacity) or those that may lack the ability to provide valid informed consent to participate in research (e.g., as a result of trauma, intellectual disability, certain mental illnesses, cognitive impairment, or dementia).

Note: Decisional impairment/diminished decision-making capacity may be temporary, permanent, progressive, or fluctuating during research participation.

For research involving GREATER than minimal risk, an independent assessment of the potential participant's capacity to consent (e.g., subjective assessment by a qualified professional independent of the research team, use of a valid objective instrument designed to evaluate capacity, etc.) should be performed, except in unusual circumstances.

Basic Information	
Title of Study:	<input type="text"/>
Short Title:	<input type="text"/>
Principal Investigator Name:	<input type="text"/>
Section 1: Cognitively Impaired Individuals	
Describe the expected range of participant impairment.	<input type="text"/>
Explain how, and by whom, the capacity to consent/assent will be determined. Specify the qualifications of person(s) making the capacity determination.	<input type="text"/>
If capacity is expected to fluctuate during research participation, describe the process for ensuring ongoing capacity assessment and consent.	<input type="text"/>
Describe how assent/consent will be obtained. (If a Waiver of Consent is being requested, please indicate that here and complete the Appendix for Waiver or Alteration of Consent or PHI.)	<input type="text"/>
Describe the steps that will be taken to identify, locate, and obtain informed consent from the legally authorized representative (LAR). (Reference HSPG guidance on Cognitively Impaired Adults)	<input type="text"/>

Cognitively Impaired Appendix

- Complete the **Appendix for Cognitively Impaired Individuals** to Request a Waiver of Consent for Cognitively Impaired Participants.
- This form needs to be filled out in addition to the Appendix for Waiver or Alteration of Consent/PHI.
- For more information see the **HSPG Guidance on Research Involving Cognitively Impaired Adults** <https://research.arizona.edu/sites/default/files/Research%20Involving%20Cognitively%20Impaired%20Adults%20v2021-09.pdf>

Resources

An aerial photograph of a city during the golden hour of sunset. The sky is a clear, vibrant blue, transitioning to a warm orange glow near the horizon. The city below is densely packed with buildings of various heights and colors, including prominent orange and brown structures. In the foreground, a large parking lot with several cars and a white semi-truck is visible. The background features a range of low mountains under the soft light of the setting sun.



Resources



- **HSPP Forms:** <https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms>
- **HSPP Informed Consent Guidance**
<https://research.arizona.edu/sites/default/files/Informed%20Consent%20v2022-08.pdf>
- **HHS Informed Consent** <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html>
- **45 CFR 46 Requirements** <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html>
- **HHS Informed Consent Resources** <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111>

Contact Information



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HSPD Webpage:



<https://research.arizona.edu/compliance/human-subjects-protection-program>

HSPP Office Hours

HSPP Virtual Office Hours
are held every other Thursday
from 10 am – 11 am.

No registration is required



Use this link to join :

<https://arizona.zoom.us/j/86232995912>



Remaining 2022 Dates

- October 27
- November 10
- November 24
- December 8
- December 22



Stay in the Loop



Subscribe to the HSPP listserv:

- Send a blank email to: list@list.arizona.edu
- In the subject line, enter: subscribe UA-IRB Firstname Lastname
- Delete any signature line and/or confidentiality statement that you may have in your e-mail.

Subscription Instructions: <https://it.arizona.edu/documentation/how-subscribe-and-unsubscribe-list>.



- Non-Written Consent Documentation
- Exculpatory Language #1
- Exculpatory Language #2
- Waivers
- Belmont Report Principles

Q & A

Q1: What Kind of Consent or e-Signature is Required for Online Minimum-Risk Studies?

- For certain activities, such as online surveys, a written or authenticated electronic signature is not necessary.
- No names or other identifying information need to be collected.
- The regulations allow IRBs to waive the requirement to obtain a signature on the consent form. This is called a waiver of documentation of informed consent.
- One of three categories must apply to your study:

Best Practices for Online/Unsigned Consent

- **First, have a clear plan for the consent process.**

How will subjects access the consent document? How will subjects indicate consent? Discuss on the IRB Protocol form.

- **Ensure the consent form submitted to the IRB reflects the chosen method for obtaining consent.**

Instead of a signature block, include a prompt: "I have read this consent form and agree to participate in this research study: _____"

- **If an electronic signature is not possible, consider which of the three categories for the waiver of documentation are most applicable.**

You'll need to choose one and provide a rationale on HSPP Appendix for Waiver/Alteration of Consent or PHI form.

Waiver of ICF Documentation Criteria

1. Is a signed consent form the only record that would link the subject to the research?
Is a loss of confidentiality the principal risk to subjects?
2. Does the study carry no more than minimal risk? Do study activities normally require written consent outside the research context?
3. Does the study carry no more than minimal risk? Is the study population part of a distinct cultural group or community in which written signatures are not the norm?

Best Practices Cont'd

- Remember that waiving the signature requirement is not the same as waiving informed consent altogether. You will still need to present subjects with a document containing the basic elements of informed consent.
- If your study involves deception or incomplete disclosure of the aims of the research, the IRB will require you to provide a debriefing as well. The Informed Consent section of the IRB Protocol form should explain how the debriefing will be presented to subjects.
- The HSPP Guidance page now includes information on deception in research: <https://research.arizona.edu/sites/default/files/Deception%20Research%20v2022-05%20NEW.pdf>

Q2: What's the best way to incorporate information about data sharing and future use into the consent?

The Consent language should reflect the information in the protocol, and vice versa. Specifically,

14.2 Will data be kept for future research, including unspecified future research and genetics? Yes No

***If your funder requires a Data Management Plan, additional information will be collected below.**

14.3 If yes to the above question, describe future use plans here including any storage in a repository (if applicable), and what data will be retained/reused.

Future Use Language for De-Identified Data

When a protocol includes future research use, the IRB requires the following:

- The anticipated sharing or future use should be described on in the consent document.
- The consent should explain the potential uses in layman's terms.

For example, if you plan to store **de-identified data for future research**, we recommend adding something like:

“Your de-identified samples and data will be stored for future unspecified research. This data may be shared with researchers both inside and outside of the institution.”

If the data sharing is optional, use an opt-in or opt-out checkbox or initial line.

Sharing Identifiable Data

If you plan to share **identifiable data**, including audio or video recordings, the consent should explain this as well. HSPP consent templates contain standard language that can be adapted as appropriate:

- "Information that may identify you may be used for future research or shared with another researcher for future research studies *without additional consent*. [Explain]"
- "Information that identifies you will only be used for future research or shared with another researcher *after obtaining your consent*. [Explain]"
- Also consider adding an opt-in prompt. For example: "The research team may use or share my information for other studies in the future: _____"

Future Use Language for NIH/Federal Funding

Will my data or specimens be stored for future research ?

The consent must include either:

- A statement that identifiers will or will not [**choose one**] be removed from the private information or biospecimens, and that after such removal, the information or biospecimens may be used for future research studies without additional informed consent [Include a description of what information/specimens will be stored and whom they will be shared with (both internal and outside the institution). Explain what research may be conducted with these data/specimens - including unspecified future research, genetics, disease specific, etc.]; or
- A statement that the identifiable information or biospecimen, even if identifiers are removed, will not be used, or distributed for future research.

If your study is funded by the NIH or another agency that requires a Data Management Plan, relevant information from your Data Management Plan will need to be included in this section.

NIH sample consent language can be found here: <https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf>.

Optional/NOT-Optional Future Use of PHI Language

Use this language when future research is NOT optional

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document.

Use this language when there is additional optional research

Optional Research Activity

Optional research activity is part of this project. If you choose to participate in this optional activity your PHI shall be included for this optional activity.

By initialing the line below, you agree to allow your PHI to be used and/or disclosed for the optional research activity referenced above. _____ Initials

Use this language when future research is optional

Future Use of PHI

Future research activity is part of this project. If you choose to participate in the future research activity your PHI will be included in this future research activity.

By initialing the line below, you agree to allow your information to be used and/or disclosed for the optional future research referenced above. _____ Initials

Q3: What consent template is needed when conducting research in collaboration with Banner Health ?

The **University of Arizona-Banner Health Consent Form** is required when conducting research at any of the Banner-University of Arizona Medical Center sites (e.g., Banner-University Medical Center Tucson, South and Phoenix campuses) or using Banner Health patients.

“This consent form is for medical research, including collection of biospecimens or research that will access HIPAA protected information. Delete the RED text prior to submitting this form to the IRB. Required language is in regular text. Additional language, as appropriate, are in comments.

Grey language is required by Banner if conducting research at B-UMC.”

Banner ICF Question Continued

If recruiting Banner staff for participation in research, include the required [Banner employee addendum](#) *in addition to* the normal research consent.

If you are using a **consent disclosure**, you may insert the following language into your disclosure form in place of the Banner employee addendum consent.

"Completion of the survey and participation in this research project is voluntary. If you complete the survey you are confirming that you voluntarily consent to participate in this research project and you understand that participation in this project is not a condition of employment at Banner Health. You may complete this survey at work. If you elect to complete the survey on your own time, you will not be paid for your time spent on completing the survey. "

Collaborative Activities with Banner Health HSPP Webpage

<https://research.arizona.edu/compliance/human-subjects-protection-program/collaborative-activities-banner-health>

Questions?

