OKLAHOMA STATE UNIVERSITY
Center of Health Sciences
PARTICIPANT INFORMATION AND CONSENT FORM

Title of Project**: BOLD**

Investigator(s): **BOLD**
(Give name(s), title(s), department(s), and telephone number(s)).

Sub-Investigator(s): **BOLD (optional)**
(Give name(s), title(s), department(s), and telephone number(s)).

"You" refers to the participant.

"We" refers to ….

You are being asked to participate in this research study because ….

What you should know about participating in a research study:
Participation in research is a voluntary choice, and this consent form will provide you with information about the risks, benefits or alternatives to participation in the study.

- Someone will explain this research study to you.
- You may volunteer to be in a research study.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

Who can you talk to?
Although this consent form provides detailed information about this study, a research team member is available to answer any questions you may have about this study and/or participation in it. If you have questions, concerns, or complaints, or think the research has hurt you, talk to the researcher or identified members of the research team at (insert contact information for the research team, e.g. phone number, email).

This research has been reviewed and approved by the Oklahoma State University Center for Health Sciences Institutional Review Board (IRB). You may contact the chairperson of this committee at 918-561-8325 for any of the following:

- Your questions, concerns, or complaints are not being answered by the researcher or research team.
- You cannot reach the researcher or a member of the research team.
- You want to talk to someone other than the researcher or the research team.
- You have questions about your rights as a research participant.

- You want to get information or provide input about this research or your experience in this research study.

Why are we doing this research?
The purpose of the research is ….

How long will the research last?
We expect that you will be in this research study for …..

How many people will be studied?
We expect about _____ people to be enrolled into this study. [*If applicable*: This research study intends to enroll __ people in the entire study nationally (or internationally).

What happens if you say yes, you want to be in this research?
The treatment you receive will be determined by chance, just like flipping a coin. *(If double blinded:)* Neither you nor the researcher will choose what treatment you get. You will have a _____ chance of being given each treatment. Neither you nor the researcher will know which treatment you are getting. *(If single blinded:)* You will not be told which treatment you are getting, however the researcher will know.

You will be asked to…(include a fair and understandable explanation of the nature of the activity and the procedures to be followed, including identification of any procedures which are experimental)

What happens if you say no, you do not want to be in this research?
You may decide not to take part in the research and it will not be held against you. A refusal to participate in this research study will involve no penalty or loss of benefits to which you are otherwise entitled.

Instead of being in this research study, you may choose to receive one of the following treatment choices:

The important risks and possible benefits of these alternatives are listed below

What happens if you say yes, but you change your mind later?
You can agree to take part in the research now and stop at any time. It will not be held against you. Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled.

If you decide to leave the research….

If you decide to leave the research, contact the researcher so that the researcher can ….

If you stop participating in the research study, data already collected may not be removed from the study database. You will be asked whether the researcher can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there a risk to being in this study?
You may expect the following (physical and/or mental) discomforts during the course of this research…

By participating in this research, you may be exposed to the following (physical, mental, and/or social) risks…

This drug may harm a pregnancy/unborn child or nursing infant in the following ways: _____. You should not become pregnant, nurse a baby, or father a child while on this study drug.

You may experience discomfort, pain, swelling and/or bruising where the blood is taken from your vein. Sometimes bleeding can occur at the place where blood is drawn. Fainting and infection can also occur, but they are rare.

In addition to these risks, this research may harm you in ways that are unknown and unforeseeable. If we learn of new risks that we think might affect your desire to stay in the research we will tell you. If major risks are discovered after the study is finished, it is possible that the sponsor may attempt to contact you.

If you are or become pregnant during this study, there may be additional risks to you, or to your baby. Some of these risks may be known, but some risks may not be known and may not be foreseeable. Because the risks to embryo/fetus/unborn babies and babies who are breast feeding may not be known or foreseeable, pregnant women and nursing mothers are not allowed to join this study. If you are a woman who can get pregnant, you should not become pregnant during this study.

If you think you are pregnant or if you become pregnant during the study, you must tell the researcher right away. It is important to tell the researcher because there may be risks to you or your baby if you continue in the study.

Women who can get pregnant must have a negative pregnancy test before being allowed to join in this study.

Will it cost you anything to be in this study?
Taking part in this research study may lead to added costs to you (list possible costs).

You or your health insurance will be billed for this procedure. If your insurance company requires any co-payment or deductible, you will be responsible for making that payment.

What are your responsibilities?
Tell the researcher or research study staff about any medications you are taking. Tell researcher or research study staff about any side effects, doctor visits, or hospitalization that you may have whether or not you think they are related to the study therapy.

Will being in this study help you in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits may include …

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others may include …

What happens to the information we collect?
Efforts will be made to limit your personal information, including study data and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information for quality assurance and data analysis include [*only include those that are applicable to your study*]:

- The Researcher and his/her research staff
- Oklahoma State University staff or its agents
- The IRB and staff
- Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS)
- National Institutes of Health (NIH)
- The Sponsor(s) of the research or its agents (monitors, auditors)
- Other collaborating institutions

Some of these organizations may be given direct access to your medical records for verification of the research procedures/date involved. By signing this document you are authorizing this access.

We may publish the results of this research. However, we will keep your name and other identifying information confidential and anonymous.

Federal law provides additional protections of your personal information. These are described in a later section (HIPAA Authorization for Release of Health Information for Research Purposes).

Can you be removed from the research without your OK?
The investigators (or the sponsor) can remove you from the research study without your approval. Possible reasons for removal include:

- If you have adverse or serious side effects from the study drugs
- If you need a treatment not allowed in this study
- If you do not keep appointments…, etc
- The investigator (or sponsor) can also end the research study early.

What if you are injured or made sick from the research?
If you are injured as a result of your participation in this study, Oklahoma State University will assist you in obtaining emergency care, if necessary, for your research related injury(s). If you have insurance for medical care, your insurance carrier will be billed in the usual manner. As with any medical insurance, any costs that are not covered or are in excess of what are paid by your insurance, including deductibles, will be your responsibility. Oklahoma State University does not provide compensation for lost wages, disability, pain or discomfort unless required by law to do so. However, this does not mean that you are giving up any legal rights that you may have. You may contact the researcher for more information.

What else do you need to know?
If you agree to take part in this research study, we will pay you _____ for your time and effort.

If any significant new findings develop during the course of the research which may relate to your willingness to continue participation, we will provide that information to you.

(*If your study falls under FDA regulations, use this language*: A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HIPAA Authorization for Release of Health Information for Research Purposes
The Health Insurance Portability and Accountability Act (HIPAA) allows a hospital or doctor's office to use or release protected health information (PHI) for the purposes of treatment, payment or health care operations. Health care operations activities include such things as audits, quality assurance initiatives, audits from insurance companies, treating physicians, legal advisors, insurers and data storage companies.

This HIPAA authorization gives permission from you to use or release your PHI for research purposes. A HIPAA authorization is in addition to your consent to participate in this research study.

What will be done with your protected health information?
Your protected health information (PHI) will be collected and entered in a database along with the information from other people taking part in this study.

Why are you being asked to release it?
Your protected health information (PHI) will be used to ….

What will be released?
To complete this research study, we will need to collect and release (disclose) information about you. This information may include [*Be very specific*]:

- Your date of birth, name, contact information, social security number, medical record number, and insurance information.
- Existing medical records and medical history.
- New health information collected for purposes of this study.
- Full-face photographic images and any comparable images.
- Biometric identifiers, such as fingerprints and voiceprints.

Who will use it or share it? [*only include those that are applicable to your study*]

- The researcher and his/her research study staff
- Oklahoma State University staff or its agents
- The IRB and staff
- Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS)

- National Institutes of Health (NIH)
- The Sponsor(s) of the research or its agents (monitors, auditors)
- Other collaborating institutions

Once your protected health information (PHI) has been disclosed it is possible that anyone who receives that information may re-disclose it. Because some of these individuals who receive your PHI may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party once it leaves Oklahoma State University. Therefore, we share your information only if necessary and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

How long will this authorization last?
This authorization has no expiration date.

Can you stop your protected health information (PHI) from being used?
You can tell us to stop collecting health information that can be traced to you at any time. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this please ask.

If you want us to stop, you must tell us in writing. Write or email……

What happens if you do not want us to collect and release your information?
If you decide not to authorize release of your protected health information (PHI) as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use or release of your PHI.

When will it be destroyed?
We do not know when your information will no longer be used therefore the information will be kept for an indefinite length of time.

Signature Block for Capable Adult: Long Form

Your signature below documents your consent to take part in this research and to the use and disclosure of your protected health information. You will receive a signed copy of this complete form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[The following signature block is to be used when an impartial witness is needed for non-readers or visually impaired participants]

I witnessed the entire consent discussion and attest that the information in the consent document and any other written information were accurately read to the participant. I witnessed that all of the participant's questions were addressed. I witnessed the subject freely giving consent to participate in this study.

Signature of Impartial Witness	Date
Printed name of Impartial Witness	

Signature Block for Adult Unable to Consent

Your signature below documents your consent for the participant named below to take part in this research and to the use and disclosure of this person's protected health information. You will receive a signed copy of this complete form.

Printed name of participant

Signature of legally authorized representative | Date

Printed name of legally authorized representative

Signature of person obtaining consent and assent | Date
[remove latter section if assent will not be obtained]

Printed name of person obtaining consent and assent
[remove latter section if assent will not be obtained]

[Add the following block if you will document verbal assent of the participant on this consent form. If you will be documenting written assent add an assent "printed name of participant" line, "signature of participant" line, and "date" line to the consent form or have a separate assent form.]

Assent

- ❑ Verbal Assent Obtained
- ❑ Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.

[The following signature block will be completed if an impartial witness is required for LAR that is a non-reader]

I witnessed the entire consent discussion and attest that the information in the consent document and any other written information were accurately read to the participant. I witnessed that all of the participant's questions were addressed. I witnessed the subject freely giving consent to participate in this study.

Signature of Impartial Witness | Date

Printed name of Impartial Witness

Signature Block for Children

Your signature below documents your permission for the child named below to take part in this research and to the use and disclosure of this child's protected health information. You will receive a signed copy of this complete form.

_____
Printed name of child

_____ _____
Signature of parent or guardian Date

❑ Parent
❑ Legal Guardian (See note below)

_____
Printed name of parent or guardian

Note on permission by legal guardians: An individual may provide permission for a child only if that individual can provide a written document indicating that he or she is legally authorized to consent to the child's general medical care. Attach the documentation to the signed consent.

[The following second parent or guardian block is required if your study is greater than minimal risk with no prospect of direct benefit but likely to yield generalizable knowledge about the child's disorder or condition 45 CFR 46.406 & 21 CFR 50.53.]

_____ _____
Signature of second parent or guardian Date

❑ Second Parent
❑ Guardian (See note above)

_____
Printed name of second parent or legal guardian

If signature of second parent not obtained, indicate why: (select one)

❑ Second parent/LG is deceased
❑ Second parent/LG is unknown
❑ Second parent/LG is incompetent
❑ Second parent is not reasonably available
❑ Only one parent has legal responsibility for the care and custody of the child

[Add the following block if you will document verbal assent of children on this form. If you will be documenting written assent add an assent "printed name of child" line, "signature of child" line, and "date" line to the consent form or have a separate assent form.]

Assent

❑ Verbal Assent Obtained
❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

_____ _____
Signature of person obtaining consent and assent Date
[remove latter section if assent will not be obtained]

_____
Printed name of person obtaining consent and assent
[remove latter section if assent will not be obtained]

Signature Block for Non-English Speaking: Short Form

Your signature below documents your consent to take part in this research and to the use and disclosure of your protected health information. You will receive a signed copy of this complete form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[Add the following statement of Interpreter]

I certify, to the best of my ability, that the an oral presentation was interpreted fully and accurately by the appointed medical interpreter in the participant's stated primary language, and that I was present for the entire informed consent discussion.

Signature of Witness to Informed Consent Presentation	Date
Printed name of Witness to Informed Consent Presentation	