ARROWHEAD
REGIONAL MEDICAL CENTER

The Heart of a
Healthy Community

How to write an Informed Consent

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Informed Consent

- The Informed consent process is a vital part of any research that will have any time of patient involvement
- The informed consent should clearly outline all the risks and benefits the participant may inquire
- Researchers conducting the study should note the language of the study should be clear and easy to understand for the participant

Introduction:
This section should include the study title and the reasons in which you are asking the participant to join the study (why they meet criteria).

Arrowhead Regional Medical Center
Informed Consent Form for Participation in a Research Project

Study Title: *Protocol Title*
Principal Investigator: *Principal Investigator*

Introduction:

You are being asked to join a research study. You are being asked to take part in this study because *qualifying condition/criteria.* You do not have to participate in this research study. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There is no penalty if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at Arrowhead Regional Medical Center.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to, before deciding about this research. You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

Purpose:

Description of your involvement: This is the researchers chance to inform and explain all purpose of the study and also what the involvement includes for the participant for the duration of the study.

Purpose:

You are invited to be part of a research study about *topic.*

The purpose of the study is to *state what the study is designed to discover or establish.* You are invited to be in this study because *reason why you are asking person to participate in study*.

The persons responsible for the research project are *name of the principal investigator and other persons, if appropriate.* Your doctor is interested in your health as well as conducting this research project. If you feel that your doctor can not represent your best interest, you can ask for another doctor to take care of you.

Description of Involvement:
This section is where the PI will include the details as it pertains to the participants involvement in the study.

Description of your Involvement:

If you are eligible and decide to participate in this study, your participation will last approximately *Your participation in this study may last up to __ days/weeks/months/years.* Your participation will involve *thoroughly describe the study activities. If there are multiple study visits, state the various procedures and time involved for each visit. Identify any procedures that are experimental. When appropriate, describe what will happen to the subject when the study is over, such as being transferred to standard medical care, accessing other resources, etc. If the study involves the ongoing collection of data from medical records, inform the subject what information will be collected from their records. If blood will be drawn*

Risks and Benefits:
This section is mostly self explanatory however the researchers must disclose any possible risks or discomforts that the participant may incur during the study.

Risks and Discomforts of Participation:

There may be some risk or discomfort from your participation in this research. This study *If less than minimal risk or minimal risk; "poses no greater risk to you than what you routinely encounter in day-to-day life" if greater than minimal risk; "may pose greater risk to you than what you routinely encounter in day-to-day life, however, those risks will be minimized."* Participating in this study will involve the following risks: *possible breach of confidentiality, discuss known risks/discomforts of study participation and how risks will be minimized.*

All records and research materials that identify you will be held confidential. Any published document resulting from this study will not disclose your identity without your permission. Information identifying you will only be available to the study personnel. *Include a brief description of how identity will be protected, if applicable.* Your rights regarding permission to use your health information are described on the attached "Authorization for Use of Protected Health Information" form.

There may be other risks of the study that are not yet known.

Benefits:

You may or may not directly benefit from this study. Although you may not directly benefit from being in this study, others may benefit because *provide details.*

Subject Rights:
The researcher should input all of the necessary details so the participant is informed and understands their rights in the study they will be participating in.

Subject Rights:

You do not give up any legal rights to privacy, confidentiality, or safety by participating in this study. Participating in this study is completely voluntary. Not participating in the study will not be held against you and will not affect your access to care or treatment unrelated to this research. Even if you decide to participate now, you may change your mind and stop at any time without affecting your medical care. Your study doctor or primary care doctor can discuss alternatives with you which may include, *details about alternative care (explain standard of care).* If you decide to withdraw before this study is completed, *details about use of data (will it be included in the analysis or removed).* You will be given a copy of the California Experimental Subject's Bill of Rights and a copy of this Informed Consent to keep.

Potential Costs/Compensation: The researcher must provide whether there will or will not be compensation or costs for this study. This section is custom for the study that will be conducted.

Potential Costs:

You and/or your health insurance must pay for those services, supplies, procedures, and care required for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance. If you participate in this study, there may be additional costs to you, such as travel for study visits.

Potential Compensation:

For your participation in this research project, *provide details, describe the compensation or incentive for individual activities, if applicable or enter 'there will be no compensation' Note the total compensation that could be earned. Describe how compensation will be determined if the subject withdraws from the research prior to its completion. Clearly describe, if applicable, what costs are the responsibility of the subject's to pay and what services they might receive that are gratis, such as parking.*

Injured during Study: Participant must understand that if they do become injured they will not be compensated in any way, however they may choose to withdrawal from the study

Storage & Future use of Data: This statement informs the participant of their privacy and the ways in which their data will be stored and protected. The researchers will input what there storage and future data use will be for this particular study.

Injured during Study:

If you feel you have been injured by taking part in this study, consult with a physician or call 911 if the situation is a medical emergency. No funds have been set aside nor any plans made to compensate you for time lost for work, disability, pain or other discomforts resulting from your participation in this research.

Storage and Future Use of Data:

Your privacy will be protected and your research records will be confidential. Your data/specimens (*will be or will not be) stripped of identifiers and used for future research purposes. Then, provide details where they will be stored, how, duration, who has access, and time reference for destruction of data or specimens.* It is possible that other people may need to see the information you give us as part of the study, such as organizations responsible for making sure the research is done safely and properly like the Arrowhead Regional Medical Center, government offices or the study sponsor, *full sponsor name(s), if any*

Contact Information for the Study Team:
This section should list the Principal Investigator's main contact information in any case that the participant may have additional questions about the study.

Contact Information for the Study Team:

If you have questions about this research, including questions about scheduling or your compensation for participating, you may contact *PI name, contact info for PI and faculty advisor, if PI is a student.*

Contact Information for Questions about Your Rights as a Research Participant:

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), the IRB Coordinator is an impartial third party who is not associated with the research. You may address complaints or questions about this protocol to this person, who may be contacted at (909) 580-6336

Participant's Statement of Consent:
This section of the consent form is where the participant acknowledges and understands all of the contents of the study and gives their consent to move forward with their participation.

Participant's Statement of Consent:

- I have read the contents of the consent form and have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

_____

Printed Name of Participant

_____ _____

Signature of Participant **Date**

Subject is unable to consent/sign because _____.

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Legally Authorized Representative **Date**

Investigator's Statement

I have discussed the research project with the participant; have explained all of the information contained in the Informed Consent to the participant including any adverse reactions; the participant was encouraged to ask questions; and that all questions were answered.

_____

Printed Name of Investigator

_____ _____

Signature of Investigator **Date**