## [Instructions are in brackets and are highlighted in gray. Be sure to address each highlighted item and to remove all bracketed/highlighted template instructions before submission. If a section does not apply to your study, please remove the section.]

## Title of research study: [insert title of research study here with protocol number, if applicable]

## Investigator: [insert name of principal investigator]

## Supported By: [List all monetary and non-monetary support for this research. If not externally funded, state your department] This research is supported by \_\_\_\_\_\_\_\_\_\_\_\_\_.

## Financial Interest Disclosure:

[Include if there is a financial interest to disclose. Otherwise, delete.] The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: [specify the conflict of interest and actions to be taken to reduce the effect.]

## Taking part in this study is voluntary.

You may choose not to take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not be held against you in any way. You can ask all the questions you want before you decide.

|  |
| --- |
| Key Information: The first few pages of this document include a summary of this study to help you decide whether to participate. Detailed information is provided after the summary |

## Why is this study being done?

[Include a short, 1-2 sentence summary of the purpose of the research.]

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition (ie, status, age 18-25, disease or diagnosis) that makes subjects eligible for the research.]

## What will happen to me during the study?

You will be asked to \_\_\_\_\_\_\_\_\_ [include a high level summary of the research activities and procedures, if any, that will be done. For example: You will be asked to complete a survey and a follow-up interview.] We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

More detailed information about the study procedures can be found under **“What happens if I say yes, I want to be in this research?”**

## Is there any way being in this study could be bad for me?

[This beginning section of the consent form should identify the most important risks, e.g., loss of privacy/confidentiality; emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study]

More detailed information about the risks of this study can be found under **“Is there any way being in this study could be bad for me? (Detailed Risks)”**

## Will being in this study help me any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include for a study with no benefits to participation. Otherwise delete.] We do not expect you to receive any benefit from taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]

## What happens if I do not want to be in this research (Alternatives to Participation)?

Participation in research is completely voluntary. You can decide to participate or not to participate.

[Include if there are alternatives other than participating.] Instead of being in this research study, your choices may include:

* [List alternatives procedures. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]

[Include if there are no alternatives other than participating.] Your alternative to participating in this research study is to not participate.

|  |
| --- |
| Detailed Information: The rest of this document includes detailed information about this study (in addition to the information listed above). |

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team. Include a telephone number]

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (260) 266-8195, or irbcoordinators@parkview.com if:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research subject.
5. You want to get information or provide input about this research.

## Why is this study being done?

The purpose of this study is to [Insert explanation for why the research is being completed using language understandable to the subject (i.e., eighth grade level).

## How many people will be studied?

We expect about \_\_\_\_\_ people here will be in this research study [out of \_\_\_\_\_ people in the entire study nationally [or internationally]].

## What happens if I say yes, I want to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

* A time-line description of the research activities and procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* The drugs or biologics that will be given to the subject
* All devices that will be used
* All hospitalizations, outpatient visits and telephone or written follow-up
* The length and duration of visits, activities, and procedures
* If blood will be drawn, indicate the amount [in English units] and frequency
* With whom will the subject interact
* Where and when the research will be done
* List experimental procedures and therapies and identify them as such
* How often activities and procedures will be performed
* What is being performed as part of the research study
* What is being performed as part of standard or customary practice (i.e., if the study involves any type of clinical care, (e.g. mental health care) describe what is standard care and what is part of the research
* When applicable describe if audio or video recording any research activities. Include if agreement to be recorded is required for participation or if it is optional.
* 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
* When applicable indicate that the subject will be contacted for future research.

[Include for a trial that involves randomization. Otherwise delete.] The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being given each treatment. [For double-blinded research add] Neither you nor the study doctor will know which treatment you are getting. [For single blinded research add] You will not be told which treatment you are getting; however your study doctor will know.

## What are my responsibilities if I take part in this research?

[Delete this section if no responsibilities.]

If you take part in this research, you will be responsible for: [Describe any responsibilities of the subject.]

## What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research, [Describe the adverse consequences.] If you decide to leave the research, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the subject, if any.]

[Include for FDA-regulated research. Otherwise delete.] If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. [Note: The consent document cannot give the subject the option of having data removed.] If you agree, this data will be handled the same as research data. [Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.]

[For research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information.]

## Is there any way being in this study could be bad for me? (Detailed Risks)

[Delete this section if there are no risks or discomforts. Do not delete if loss of confidentiality/privacy is the only risk.]

[The risks of procedures may be presented in a table form.]

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.]

* [Physical risks
* Psychological risks
* Privacy and confidentiality risks
* Legal risks
* Social risks
* Economic risks]

[Include for research that may result in additional costs to the subjects. Otherwise delete.] Taking part in this research study may lead to added costs to you. [Describe what these costs are.]

[Include for a clinical trial. Otherwise delete.] You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. [Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration, when the research if FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:

* If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

**OR**

* Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include for research where the sponsor may pay for medical expenses of the subject.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] The sponsor, monitors, auditors, and the IRB will be granted direct access to your medical records to conduct and oversee the research. 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.

## Can I be removed from the research without my OK?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the subject may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What else do I need to know?

[Include for sponsored research. Otherwise delete.] This research is being funded by [Insert name of sponsor].

[Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

[Include for a clinical trial. Otherwise delete.] Instead of being in this research study, your choices may include: [include alternatives.] The important risks and possible benefits of these alternatives include: [Describe the important risks and potential benefits of the alternatives.]

[Include when applicable. Otherwise delete.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans [or replace with plans when using identifiable information/samples] to tell you, or to pay you, or to give any compensation to you or your family.

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens. Otherwise delete.] Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will/will not contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

**HIPAA Authorization**

Federal law provides additional protections of your medical records and related health information.

I agree to permit the Principal Investigator [name] and research staff (“Researchers”) [and study sponsor, the sponsor of this study,] may use and disclose health information that identifies me for the purposes described below. I also agree to permit Parkview Health and its affiliates, [name of any other institutions,] my doctors, and my other health care providers may disclose health information in my medical records to the Researchers [and to study sponsor] for the purposes described below.

1. The health information that may be used and disclosed includes:

* all information collected during the research described in the Informed Consent Form; and
* health information in your medical records that is relevant to the research described in the Informed Consent Form.

2. The Researchers may:

* use and share my health information to conduct the research;
* [disclose my health information to the sponsor of the research, [study sponsor]and its agents;]
* disclose my health information to Parkview Health and its affiliates;
* disclose my health information as required by law;
* disclose my health information to representatives of government organizations and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research; and
* remove from my health information my name and other information that could be used to identify you.

3. [Study Sponsor may:

* use and share my health information to conduct the research;
* use my health information as described in the Informed Consent;
* disclose my health information as required by law;
* disclose my health information to representatives of government organizations and other persons who are required to watch over the safety and effectiveness of medical products and therapies, and the conduct of research; and
* remove from my health information my name and other information that could be used to identify me.]

4. Once information that could be used to identify you has been removed, the information that remains is no longer subject to this Authorization and may be used and disclosed by the Researchers [and Study Sponsor] as permitted by law.

5. Once your health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure. However, the Researchers [and study sponsor] agree to protect your health information by using and disclosing it only as permitted by me in this Authorization and the Informed Consent. Also, no publication about the research will reveal my identity without my specific written permission. These limitations continue even if I revoke (take back) this Authorization.

6. Please note that:

* You do not have to agree to this Authorization, but if you do not, you may not be allowed to participate in the research.
* You may change your mind and revoke this authorization at any time. To revoke this Authorization, you must write to [Principal Investigator at address]. However, if you revoke this Authorization, you may no longer be allowed to participate in the research. Also, even if you revoke this Authorization, the information already obtained by the Researchers [and study sponsor] may be used and disclosed as permitted by this Authorization and the Informed Consent.
* While the research is in progress, you will not be allowed to see your health information that is created or collected in the course of the research. After the research is finished, however, you may see this information as described in Parkview’s Notice of Privacy Practices.

7. This Authorization will expire 50 years from the date of signature.

[Omit the following signature page if there is no written documentation of consent.]

**Signature**

I have been given a copy of all [number of pages] pages of this form. I have read it or it has been read to me. I have had the opportunity to ask questions, and have had my questions answered. I understand the information and I willingly agree to take part in this study.

By signing this consent form, I have not waived any of the legal rights that I otherwise would have.

 \_\_\_\_

**Signature** of Study Subject Date

**Printed** Name of Study Subject

Study Subject’s Address

**Authorized Representative (If Applicable)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature** of Authorized Representative, (If Applicable)

**Printed** Name of Authorized Representative (If Applicable)

Relationship to Study Subject (in order of priority, left to right):

\_\_Healthcare POA/Representative \_\_Guardian \_\_\_Spouse \_\_\_Adult Child \_\_\_Parent

\_\_Adult Sibling \_\_Grandparent \_\_Adult grandchildren \_\_Nearest other next of kin

\_\_Adult friend with regular contact and familiar with individual’s activities, health, and beliefs

\_\_Religious superior if individual is in a religious order

Authorized Representative’s Address (If Applicable)

**Signature** of Investigator/Designee **Printed** Name Date

Obtaining Informed Consent

---------------------------------- Use the following only if applicable ---------------------------------

*If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:*

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in this [name of procedure, test, medication, or test article].

### Signature of Impartial Witness Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Impartial Witness

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Impartial Witness Address

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.