**Health & Biological/Medical Research Informed Consent template – Updated January 2019**

**Delete this instruction box by selecting text within box and hitting “delete” twice.**

**Instructions for BIOMEDICAL RESEARCH template:**

1. Text in [ ] and in red is to be replaced with specific information about your research study, including the footer. Some red text may need to be deleted.
2. ***Italicized*** text in [ ] are directions. Delete the directions and corresponding text as applicable.
3. 🡪 and *italics* indicate guidelines. Delete guidelines, arrows, and italicized text before finalizing the document.
4. Suggested text is often included in the guidelines. Suggested text is preceded by **\**Suggested Text\**** tag. Delete **\**Suggested Text\**** and text not being included in the consent before finalizing the document.
5. Plain or bolded text is required. Plain text separated by ***OR*** indicates that there are several options. Pick one and delete the others.
6. **Please be concise and use plain language understandable by non-medical individuals reading at an 7th grade level!**

**Research Information and Consent for Participation in Biomedical Research**

**[Insert Study Title]**

**[Insert Study #]**

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1. **Overview:** You are being asked to take part in a research study. The information in this document should help you to decide whether you want to participate in this study. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

**Study Staff:** This study is being led by enter name of PI, who is a enter title/position of PI at/in enter department or institution. This person is called the Principal Investigator. Other approved research staff may act on behalf of the Principal Investigator. Enter emergency contact name & information

**Study Details:** This study is being conducted at name of institution and is supported by Enter funding information if applicable. The purpose of the study is to describe the purpose of the research*.* The study procedures include: list the study procedures.

* *Briefly explain in a few sentences, in lay language (understandable at a 7th grade reading level), the purpose of the study and the expected duration of the prospective subject’s participation.*
* *Example: The purpose of this study is to find out....*
* *Tell the person, in lay terms, how the research will be carried out and whether the research includes an experimental drug, intervention, or procedure; if applicable, state whether or not the investigational product has been tested in humans before.*
* *Identify what funding agencies (such as NIH, NIMH, etc.) or companies are involved in the study through funding, cooperative research, by providing supplies or equipment, and/or the provision of administrative costs.*
* *Optional: Indicate the form of support from the sponsor.*

**Participants:** You are being asked to take part because you click here to enter text. You will be asked to participate state the expected duration of the subject’s participation.

**Voluntary Participation:** Your participation in this research is voluntary. You do not have to participate and may stop your participation at any time. Your decision whether or not to participate will not affect your current or future dealings with [insert involved provider organizations, e.g. name of independent physician clinic, Vail Health and its affiliates]. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.** Alternatives to participating in the study include: If there are alternatives, describe the procedures/treatments/interventions that the participant could receive such as taking a different course of treatment, etc.

**Benefits, Compensation, and Risks:** We do not know if you will receive any benefit from your participation. ***OR*** State the benefits, see guidance arrow below There is no cost to participate. ***OR*** State the costs to participation You will or will not be compensated Enter amount if compensated for your participation. **\**Suggested Text\****This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life. ***OR*** The most common and most serious risks that may be related to taking part in this research include: insert risks here [For example most common (occurring in >10% or 20 of the time) and most serious (those that lead to hospitalization, disability or death, etc.)]

* *Note: Risks described here do not have to be listed below.*

**Confidentiality:** Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

* *Benefits Guidance: Consider: one can benefit from being a participant if they are able to: learn more about their condition; obtain better information about their pathology – imaging, exam, history; or to obtain treatment for your condition…..etc.)*

**\*Suggested Text\*** You may not directly benefit from participation in the research. ***OR***

Based on experience with this [Insert drug, procedure, device, etc.] in [Choose: animals, patients with similar conditions], researchers believe it may be of benefit to subjects with your condition [or it may be as good as standard therapy with fewer side effects]. However, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. ***OR***

**\*Suggested Text, if applicable\*** If you are assigned to no treatment or treatment with placebo, you are not expected to directly benefit from participating in this research. ***OR***

You should not expect your condition to improve as a result of participating in this research. ***OR***

This study is not being done to improve your condition or health. ***OR***

It is hoped that knowledge gained from this research may benefit others with [Insert condition or disease] in the future.

* *Do not include payment for participation as it is not a direct benefit of the research.*
* *If applicable, add the benefits of the alternative procedures or treatments*

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1. **Conflict of Interest** *[include only if applicable]*
* *If the investigator is recruiting potential subjects from their own patients and/or from patients in a clinical program under their direction, it is recommended that the investigator disclose this dual-role in the informed consent.*

**\**Suggested Text\**** Your health care provider may be an investigator on this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from a clinician who is not associated with this project. You are not obligated to participate in any research project offered by your clinician. Your participation in this research study is voluntary and you do not have to participate. The decision to not participate will not affect your clinical care now or in the future.

* *Explain any involvement in developing the product being tested, any ownership interest/paid consulting/royalty or other significant financial relationship with a sponsor, manufacturer, vendor or other entity involved in this research.*
1. **Why am I being asked to participate in this research?**

You have been asked to participate in the research because [Insert protocol-specific text].

* *Explain why the potential subject is eligible to participate; for example, “…you have been identified by your doctor as having seizures that have not responded well to the currently available drugs.”*

Approximately [Insert number] subjects may be involved in this research at enter institution.

* *Complete the sentence with the maximum number of subjects you are requesting to be enrolled.*

*If a multicenter trial, add the total number of subjects anticipated and the projected number of research sites. For example, “…and [Insert number] at [Insert number] study sites in the United States (or within and outside the United States).”*

1. **Study Procedures: What will happen during this study?**

This research will be performed at [Insert protocol-specific text].

* *State the specific site(s) where the research will be conducted, including the room if possible.*

You will need to come to the study site [Insert protocol-specific text] times over the next [Insert protocol-specific text].

* *Fill in the total number of visits.*
* *Complete the sentence with how many days, months or years the total number of visits for this study will last.*

Each of those visits will take about [Insert protocol-specific text].

* *State in minutes or hours; if lengths of visits will vary, indicate the typical time and range of visit lengths.*

The study procedures are [Insert protocol-specific text].

* *After reading this section, the subject must be able to understand what will happen to them and what they will be expected to do as part of the research.*
* *Distinguish which items and services are experimental or for research purposes only and which are standard care for the subject’s condition and would occur whether or not they participated in the research.*
* *Describe the procedures chronologically using lay language and short sentences.*

*The use of subheadings, short paragraphs and/or bullets will help to organize this section and increase readability.*

* *Include the frequency, the length of time, and, if variable, the location of the procedure.*
* *Use nontechnical language**to describe medical terms, such as an electrical tracing of your heart for ECG or electrocardiogram, collection of blood from a vein in your arm with a needle for phlebotomy, and brain scan for CT or MRI of the brain. Volume of blood or urine to be obtained should be expressed in common measures such as teaspoons, tablespoons, or ounces and radiation exposure in equivalent measures, such as days of exposure to natural background radiation.*
* *Describe method for assignment to a specific treatment or intervention and chances of being assigned to a treatment or intervention. Include route of administration and dose schedule.*
* *Explain concepts such as placebo and randomization in lay terms (include odds of placement in each study arm after randomization).*
* *Include any additional instructions that subjects must follow. For example, subjects who will take a study drug at home may be instructed as to the storage of the drug, whether it should be taken with food, what to do if a dose is missed, and how to maintain a drug diary.*
* *Attach illustrative calendars, flowcharts, tables or pictures as appropriate.*
1. **What are the potential risks and discomforts?**

There may be risks from the study that are not known at this time. [Insert protocol-specific text]. ***OR***

The likely risks and discomforts expected in this study are [Insert protocol-specific text]. ***OR***

The less likely risks and discomforts expected in this study are [Insert protocol-specific text]. ***OR***

Rare but serious risks include [Insert protocol-specific text].

* *Identify each intervention/treatment/procedure with a subheading and then describe any reasonable foreseeable risks, discomforts, inconveniences and how these will be managed.*
* *In addition to physiological risks/discomforts, describe any psychological, social, legal, or financial risks that might result from participating in the research.*
* *If there are significant physical or psychological risks to participation that might cause the researcher to terminate the study, please describe them.*
* *When known, please provide approximate frequencies for likely, less likely and rare.*
* *If an individual receiving placebo, palliative, standard, wash out, or the experimental treatment is placed at an increased risk from the natural progression of their disease, this should be clearly stated along with precautionary steps taken by the investigators to minimize these risks.*
* *If participating in more than one research protocol may be problematic, add a statement that the subjects should inform the researcher if they are currently participating in another research study.*
* *Describe the risks of the procedures that will be performed for research purposes.*
* *Describe the side effects for each drug, device or biologic. These should be explained in lay language, and, if applicable, the side effects should be labeled according to frequency (e.g., likely, less likely, rare) and severity (e.g., serious, minor).*
* *The use of bullets to list the risks is encouraged.*
* *If there are risks to alternative treatments or procedures, list those as well*
* *If genetic testing will occur, the risks of inadvertent or inappropriate use or disclosure of individually identified genetic information should be described, including denial of employment or insurance of a research participant (or a relative or ethnic group or population) and psychosocial harms, such as stress, anxiety, or embarrassment resulting from inadvertent disclosure of information on family relationships, ethnic heritage, or potentially stigmatizing conditions.*
* ***If using an intervention at home – if you will be receiving drug, device or biologic at home: \*Suggested Text - Include the following if the subject will be receiving study drug, device or biologic at home\**** Please keep the study drug [or device]out of the reach of children or others who may not be able to read or understand the directions on the label. Do not let anyone else take the study drug besides you.
1. **Are there reproductive risks to participation in this study?**

***[This section is required only if applicable - delete paragraphs/sentences that do not apply]***

**If you are a woman:** Participating in this research may involve risks to pregnant women and/ or an unborn baby which are currently unforeseeable. To protect against possible side effects of the study [drug, imaging or other, please specify], if you are pregnant or nursing a child you may not take part in this study. *[the following sentence is required if a study drug is involved]*If you are a woman of childbearing ability, you and the study doctor must either agree on a method of birth control to use or you must agree to be abstinent (i.e., not have sex) throughout the study.

* *If applicable, specify the time period after stopping study treatment or completing study that contraceptive control should continue.*
* *Describe acceptable forms of birth control (i.e., oral contraceptive, double barrier method, abstinence, etc., if applicable).*

If you think that you have become pregnant during the study, you must tell the doctor immediately. ***[Add the following when true:]*** If you become pregnant, your participation will be stopped.

*[The following is required if a study drug is involved.]***If you are a man:**  To protect against possible side effects of the study drug to an unborn baby, you must not get a partner pregnant while taking the study drug and for [Insert the number of days/weeks/months] after the last dose.

You and the study doctor must agree on a method of birth control to use throughout the study or you must agree to remain abstinent, as applicable.

* *Describe acceptable forms of birth control (i.e., oral contraceptive, double barrier method, etc., if applicable).*
1. **What are the costs for participating in this research?**

There are no costs to you for the items and services which are experimental or for research purposes only. ***OR***

* *If the sponsor or others will not cover all costs related to the research, use the language in the following four paragraphs:*

If you take part in this study, you may have to pay extra costs. The following items and services will be provided to you free of charge by the [Insert study sponsor or others as relevant]. [List any items/ services, if any, that the Sponsor is paying for in full.]

* *Ensure that the cost terms of the clinical trial agreement, informed consent, and protocol all match*

You or your insurer will be responsible for paying for the cost of the following: [Itemize and estimate the charges that subjects participating in the research will be expected to pay if the charges are not paid by their insurance or other third payer].

* *List the items/services and estimate the charges that subjects participating in the research will be expected to pay*

If you have health insurance the insurance may or may not pay for your participation in the research. You will have to pay for any co-payments, deductibles or co-insurance amounts that your insurance coverage requires.

* *Indicate who will contact the insurance provider to verify coverage.*
* *Ensure that the cost terms of the informed consent matches the protocol.*

If you do not have insurance, you will be billed for the amount you have to pay.

1. **Will I be paid for my participation in this research?**

You will not be offered payment for being in this study. ***OR***

You will receive [Insert payment amount and method of payment (i.e. cash, check, gift card)] for each completed study visit. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of $[Insert total payment amount]. You will receive your payment within approximately [Insert length of time before payment is received (i.e. immediately, within 30 days - standard unless gift card is given in person) ] [Insert payment schedule (i.e., after each visit, at the end of the study, etc.)] by [Insert payment delivery method (i.e., direct deposit, in person, mail, etc.)].

* *Compensation should not be so large as to constitute undue influence or be coercive.*
* *Payment schedules should not contradict the subject’s right to withdraw at any time.*
1. **What if I am injured as a result of my participation?**

***[This section is required for research involving more than minimal risk]***

* *There are three options for this section:* ***1)*** *Full payment from Sponsor;* ***2)*** *Partial payment from Sponsor; or* ***3)*** *No payment for injuries.*
* *Delete the options that do not apply from the template.*
* *Do not delete any component of the Option chosen.*

***[Option 1 – Use for Industry Sponsored studies where the Sponsor has agreed to pay for injuries regardless of insurance and in non-Industry Sponsored cases where the Sponsor has agreed to pay for research-related injuries.]***

If you get ill or injured from being in the study, Indicate who will help will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Physicians name and telephone number.

* *For research involving greater than minimal risk, emergency contact information should be included here.*

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

If you get ill or injured as the direct result of being in this study, the [Insert sponsor name] will pay the costs for your medical treatment of the illness or injury if it:

1. Is not a medical condition that you had before you started the study;
2. Is not the result of the natural progression of your disease or condition;
3. Is not caused by your failure to follow the study plan; and
4. Is not proved to be directly caused by the negligence of a [insert involved provider organization(s)] employee. “Negligence” is the failure to follow a standard duty of care.

Insert sponsor or institution name has/have not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for insert sponsor or institution name to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a insert institution name employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

***[Option 2 – Use if the Sponsor will pay injury costs for uninsured subjects or subjects with Medicare/Medicaid and part of injury costs for privately insured subjects that are not covered and/or paid by their private insurance]***

If you get ill or injured from being in the study, Indicate who will help will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Physicians name and telephone number .

* *For research involving greater than minimal risk, emergency contact information should be included here.*

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

If you have a private health insurance plan, your plan will be billed for the costs of treatment. If there are any costs (??? Some of this is not true – treatment will be still rendered, but you may be responsible for treatment if the researchers are just collecting data?) that are not paid by your plan, the [Insert sponsor name] will pay these costs. You will still be responsible for any co-payments or deductibles required by your health insurance plan.

If you are covered by Medicare, Medicaid HMO plans or any other governmental healthcare insurance or if you are not covered by a health insurance plan, the [Insert sponsor name] will pay these costs. If you have Medicare or another governmental insurance plan, the Sponsor may request your Social Security number, as the Sponsor may have mandatory reporting requirements under the Medicare Mandatory Reporting provisions.

Insert sponsor or institution name has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for [insert involved provider organizations] to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a insert institution name employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

***[Option 3 – There is no plan to pay the costs for injuries]***

If you get ill or injured from being in the study, Indicate who will help will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Physicians name and telephone number.

* *For research involving greater than minimal risk, emergency contact information should be included here.*

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. [Include if applicable – The study staff will assist you in obtaining pre-authorization from your insurance company.] Costs not covered by insurance could be substantial.

Insert sponsor or institution name has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the [involved provider organizations] to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of a insert institution name employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

1. **Can I withdraw or be removed from the study?**

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at insert involved provider organizations. You will still receive standard of care treatment for your condition if you volunteer to withdraw.

* *If applicable, explain the consequences of a subject's decision to withdraw from the research and state whether withdrawal must be gradual, for reasons of safety, as well as the approximate time period; and*
* *Be sure that this aspect of terminating participation at the request of the investigator is noted in the section**“Will I be reimbursed for any of my expenses or paid for my participation in this research?” as well, and that the information in both sections is consistent.*

You have the right to leave a study at any time without penalty. If leaving could affect your safety, the investigator will provide information about recommended steps for leaving the study.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

* *They believe it is in your best interests;*
* *You were to object to any future changes that may be made in the study plan;*
* *If applicable, list any reasons specific to the study ( i.e., the sponsor of the research has decided to stop the research, if you experience a severe side effect, if you do not follow the study procedures or if new information is identified); and/ or*
* *Describe any other circumstances for withdrawal.*
1. **Genetic Testing** [If applicable]

[Insert protocol-specific text]

* *Describe the genetic testing to be performed (i.e., genome wide association studies or directed analysis of candidate genes, diseases or conditions to be studied, what will occur with samples and genetic data after study is completed, how will confidentiality be protected).*
* *Will the results of the genetic analysis be shared with others? If so, indicate who and the conditions for sharing? Will samples and data contain direct or indirect identifiers or be de-identified before sharing.*
* *If the genetic testing is optional and not required to participate in the main study, clearly indicate that the individual is not required to consent to the genetic analysis to take part in the main study.*
* *State whether or not the results (individual or group) will be provided to the subjects and, if so, under what circumstances and disclosure procedures.*
* *State whether genetic samples or data will be stored for future use. If so, the following information should be provided, as applicable:*
	+ *Types of subsequent research;*
	+ *Where samples or data will be stored (e.g., investigator’s lab, pharmaceutical company repository, \_\_\_\_\_\_\_\_\_\_\_\_\_ database);*
	+ *Who will have access;*
	+ *Will samples or data contain direct or indirect identifiers;*
	+ *Describe other data about subject (e.g., phenotype information) which will be provided to the databank, the repository or other investigators;*
	+ *Types of medical conditions or diseases to be studied;*
	+ *Duration of storage and how samples/data will be disposed of; if there is a plan to store indefinitely, state this.*
* *Describe procedures for withdrawing consent and having sample or data removed from the bank or database.*

***[The following check boxes should be used when applicable to document the subject’s consent to current or future use of samples or data for genetic analysis]***

[ ]  I agree to allow genetic testing to be performed on my blood [or tissue] sample for the current present research study.

Initials \_\_\_\_\_\_\_\_\_.

**[ ]** I agree to allow my [Choose: blood or tissue samples, genetic data] to be kept by [Specify name and location of bank, repository and databank] for use by other researchers for future genetic research to learn more about how to prevent, detect, or treat [Specify diseases or conditions].

Initials \_\_\_\_\_\_\_\_.

[ ]  I agree to allow my [Choose: blood or tissue samples, genetic data] to be kept by [Specify name and location of bank, repository and databank] for use by other researchers for future genetic research to learn more about how to prevent, detect, or treat other health problems.

Initials \_\_\_\_\_\_\_\_.

[ ]  I agree to allow the researchers to contact me about future genetic research.

Initials \_\_\_\_\_\_\_\_.

***[The following two paragraphs are only required if genetic testing is involved in the current project or is being authorized at a later date for banked tissues. Please delete if not applicable.]***

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

There is a risk that someone could get access to the genetic information we have stored about you. Genetic testing can create information about a subjects’ and their families’ personal health risks and can cause or increase anxiety, and/or interfere with your ability to get insurance or a job, and can even lead to discrimination.  Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives.  There are laws against this kind of misuse, but they may not give full protection. There may be other unforeseen privacy risks. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. These efforts are described in the section below called “What about privacy and confidentiality?”

***[When appropriate for research involving biospecimens, subjects must be informed of whether the research will (if known) or might include whole genome sequencing (WGS)]***

***[If your study involves whole genome testing, you must include the following text:]***

As part of the genetic study, a sample of your DNA may have Genome Wide Association Studies (GWAS) performed. This analysis creates a very detailed picture of your DNA for researchers. In addition, information regarding your DNA and clinical information about you will be sent to the National Institute for Health’s Genome Wide Association Study (GWAS) data repository, where it will undergo genome-wide analysis and be shared with other investigators for research purposes. DNA and information sent to the GWAS will help researchers better understand how genes affect the risk of developing diseases such as asthma, cancer, diabetes, and heart disease, and may lead to better methods to select the best treatment options. Before your information is sent to the GWAS data repository it will be de-identified, which means that we will remove any identifying information such as your name, date of birth, address, etc. Thus, researchers using your DNA and clinical data will not be able to link this information back to you.

1. **Tissue Banking, Human Biological Materials including Blood and Blood Products**

***[This section should be included only if banking of tissue specimens is part of this research and includes Platelet Rich Plasma, Bone marrow, and any blood products.]***

[Insert protocol-specific text]

* *Explain purpose of banking and the types of research to be conducted with sample.*
* *Explain what types of specimens are involved.*
* *Where samples will be stored (e.g., investigator’s lab, pharmaceutical company repository, NIH GWAS database)*
* *Who will have access?*
* *Will samples contain direct or indirect identifiers and how will they be provided to other investigators (i.e., de-identified (identifiers irretrievably stripped) or coded)?*
* *Describe data about the subject (e.g., demographics, clinical information, outcomes,) which will be provided to the databank, repository or other investigators.*
* *Types of medical conditions or diseases to be studied.*
* *Duration of storage and how samples/data will be disposed of; if plan to store indefinitely, state this.*
* *Describe procedures for withdrawing consent and having sample or data removed from bank or database.*

***[The following check boxes should be used when applicable to document the subject’s consent to tissue banking]***

[ ]  I agree to allow my indicate whether the specimen are identifiable or de-identified [Insert applicable type: specific tissue, blood, other body fluid, DNA] to be kept by [Specify name and location of bank, repository and databank] for use by other researchers for future research to learn more about how to prevent, detect, or treat [Specify diseases or conditions].

Initials \_\_\_\_\_\_\_\_.

[ ]  I agree to allow my indicate whether the specimen are identifiable or de-identified [Insert applicable type: specific tissue, blood, other body fluid, DNA] to be kept by \_\_\_\_\_\_\_\_ [Specify name and location of bank, repository and databank] for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems.

Initials \_\_\_\_\_\_\_\_.

[ ]  I agree to allow the researchers to contact me about future research.

Initials \_\_\_\_\_\_\_\_.

1. **Future use of identifiable private information or identifiable biospecimen**

***[This section should be included if identifiable private information or identifiable biospecimens are involved in this research.]***

***[Include one of these statements]***

Your identifiers might be removed from your private information or your samples and after removal, your information or samples could be used for future research or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative. ***OR***

Your private information or samples collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

1. **Will your cells, tissues, blood or other biological materials be used to develop commercial products?**

If a commercial product is developed from the tissue or blood samples collected as part of this research project, the commercial product will be owned by [Insert appropriate entity]. You will not profit financially from such a product.

Cells obtained from your body may be used to establish a cell line which may be shared in the future with other researchers and which may be of commercial value. A cell line is one which will grow indefinitely in the laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce.

* *If any human materials (tumor tissue, bone marrow, blood, etc.) are used for establishing a cell line which may be shared with other researchers and which may in the future be of commercial value, the subject must be informed of the fact in the consent form.*

***[If applicable, Include 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]***

1. **What about your privacy and confidentiality?**

The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care) or if required by law.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by: ***[Retain the applicable items from this list and delete the others]***

* Food and Drug Administration (FDA) –[why would they look?? (give examples)]
* Office for Human Research Protections (OHRP)
* Funding Agency, such as the National Institutes of Health, Department of Defense—[why would they look (give examples)]
* Name of commercial sponsor or manufacturer of the drug, device or biologic
* Authorized Representatives of the Sponsor [provide name of Contract Research Organization and/or others]
* Vail Health Institutional Review Board, or
* [List any others].

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research.

* *Give a brief description of how personal information, research data, and related records will be coded, stored, etc., to prevent access by unauthorized personnel.*
* *If applicable, state that study information about the subject will be given to sponsor, coordinating center, or lead investigator and explain how data will be provided to them (i.e., with identifiers, coded or de-identified).*
* *If applicable, explain the final disposition of the research data.*
* *If data or biological specimens will be stored or provided to other investigators after study completion, explain measures to protect confidentiality.*
* *State if and when individual data will be stripped of all direct and indirect identifiers or destroyed following analyses of the data or publication of the findings or results.*

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

* *If photographs, videos, or audiotape recordings will be used, explain how the subject’s identity will be protected or disguised. Describe the subject's right to review/edit tapes, who will have access, and when they will be erased.*

***[The statement below is required for clinical trials. Please consult the checklist provided by ClinicalTrials.gov*** [***https://prsinfo.clinicaltrials.gov/ACT\_Checklist.pdf***](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf) ***to determine if your study should be registered with ClinicalTrials.gov.]***

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. law.  This web site will not include information that can identify you.  At most, the Web site will include a summary of the results.  You can search this Web site at any time. Results of the research will be posted on clinicaltrials.gov

***[If there is a Certificate of Confidentiality for this study, delete any template language that refers to releasing data or subject information “required by law,” and include the following paragraphs.]***

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

1. **What happens if new information becomes available about the study?**

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

***[Please include a statement regarding whether clinically relevant results, including individual research results, will be disclosed to subjects, and if so under what conditions]***

***If clinically relevant results will be returned, insert the following:***We may learn things about you from the study activities that could be important to your health or to your treatment. If this happens, this information will be provided to you. ***[Insert a description of the types of research results that may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.]*** The results will not be placed in your medical record. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

***[If clinically relevant results will not be returned, insert the following]:*** When data/biospecimens/images are collected and analyzed, there is the chance of finding something unexpected. The results from the data/biospecimens/images we collect in this research study may not be the same as what you would receive as a part of your regular health care. Because of this, you will not be informed of any unexpected findings. The results of your data/biospecimens/images will not be placed in your medical record. If you believe you are having symptoms that may require care, you should contact your primary care physician.

1. **Who should I contact if I have questions about the research?**

Contact the researchers [Insert names and titles] at [Insert phone number(s)] or email address [Insert email address(es)]:

* if you have any questions about this study or your part in it,
* if you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
* if you have questions, concerns or complaints about the research.
* *If the researcher is a student, also include the faculty sponsor's name and telephone number.*
1. **Who should I contact if I have questions about my rights as a research subject?**

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Vail Health IRB Office at 970-479-5137 or email at irboffice@vailhealth.org.

1. **What if I am employed by the same organization as the investigator?**

***[This section is required if employees are being recruited]***

Your participation in this research is in no way a part of your duties, and your refusal to participate will not in any way affect your employment with [insert employer organization] , or the benefits, privileges, or opportunities associated with your employment. You will not be offered or receive any special consideration if you participate in this research.

1. **Authorization to use and disclose Protected Health Information**

The purpose of this section is to give your permission to the research team to obtain and use your patient information. Your patient information will be used to do the research named above.

***[Include the following paragraph ONLY if it applies to your research otherwise delete this paragraph]***This document is also used for parents to provide permission to the research team to obtain the patient information of their minor children, and for legally-authorized representatives of subjects (such as an appropriate family member) to provide permission to the researcher to obtain patient information of individuals who are not capable themselves of providing permission. In such cases, the terms “you” and “your patient information” refer to the subject rather than the person providing permission.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form.

You do not have to sign this permission form. If you do not sign it, you will not be allowed to join the research study. Your decision to not sign this permission will not affect any of your treatment, any other treatment, healthcare, enrollment in health plans or eligibility for benefits.

**What information will be obtained and used?**

“Patient information” means the health information in your medical or other healthcare records. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birthdate, and medical record number.

By signing this form you are giving permission to the following organization(s) to disclose your patient information for use in this research.

***[Some examples are listed here. Delete covered entities from this bulleted list that are not sources of patient information for this project and add any additional covered entities.]***

* Vail Health (includes Shaw Cancer Center, Howard Head and all Diversified Services clinic locations)
* Vail Valley Surgical Center
* The Steadman Clinic
* Vail Summit Orthopaedics

***• [Name any other applicable organization or provider that is not covered in the list above]***

**What information will be released for research use?**

If you give your permission and sign the last page of this form, you are allowing the health care providers indicated above to release the following medical records containing your Personal Health Information to the researchers for use in this project. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

The specific information that will be released and used for this research is described below*:*

*[Keep only those items below that you ABSOLUTELY need to conduct this research project. Delete everything in this list that you will not use or need to conduct the research.* ***BY LAW****, the information must be limited to the minimum necessary information needed to accomplish the purpose of the research.]*

* All medical records ***[This is almost never used. You may choose “All records” ONLY if the research requires the entire medical record be used.]***
* Hospital discharge summary
* Radiology records
* Medical history / treatment
* Consultation
* Diagnostic imaging report
* Radiology films (like X-rays or CT scans or MRI’s)
* Laboratory / diagnostic tests
* EKG reports
* EEG reports
* Psychological testing
* Pathology reports
* Operative reports (about an operation)
* Pathology specimen(s) and/or slide(s)Dental records
* ***[List any other records used in protocol or delete this bullet]***

***[Insert the following section if appropriate. Delete the types of information you do not need for your research.]***

To release the specific information listed below, you need to also write your initials next to the type of information. This is your specific permission for release of this information, which is required by Federal and state laws. The federal rules bar any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

\_\_\_\_\_\_\_\_\_\_ Sexually transmitted disease

\_\_\_\_\_\_\_\_\_\_ AIDS or HIV

\_\_\_\_\_\_\_\_\_\_ Behavioral or mental health/illness, including psychotherapy notes

\_\_\_\_\_\_\_\_\_\_ Drug or alcohol abuse, diagnosis, or treatment

***How will my patient information be used?***

The following groups of people may also be able to see your health information and may use that information to conduct this research:

* The research team for the research described in the Consent Form;
* Vail Health Institutional Review Board (VH IRB);
* Others who are required by law to review the quality and safety of the research, including U. S. government agencies such as The U.S. Food and Drug Administration (FDA) or the Office of Human Research Protections;
* The Sponsor of this research including any persons or companies that are working with or for the Sponsor.
* ***[Insert other parties that may receive the information as applicable. For example: Laboratories, Data & Safety Monitoring Boards, federal funding agencies or other entities. Delete if non-applicable.].***

Your patient information will be used and/or given to others for the following reasons:

* To do the research
* To study the results, and
* To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

The researcher will use your patient information only in the ways that are described in the research consent form that you sign and as described in this HIPAA Authorization.

You can ask questions about what the research team will do with your information and how they will protect it.

The privacy laws do not always require the receiver of your information to keep your information confidential. After your information is given to an organization that is not subjected to the privacy laws, e.g. a research organization, there is a risk that it could be shared without your permission.

***Optional Research Activity-Banks and Repositories***

[ ]  There are no optional research activities

[ ]  The research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

By initialing this sentence, I am choosing to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.\_\_\_\_\_\_\_\_\_\_\_\_\_\_(initials)

***How long will this authorization be valid?***

This permission for the researchers to obtain your patient information: ***[Select and insert the single option that applies to your research, and provide the required information. Delete the other options. If you are uncertain, choose a date that provides plenty of time for your work to be completed.]***

Ends on **[insert date].**

Ends when the research ends and any required monitoring of the study is finished.

Ends when **[insert description of event or other circumstance. Examples: one year after death; one year after you reach age 50].**

Ends **[Insert “no end date”]**

***Cancelling your permission:***

You may change your mind at any time. To take back your permission, you must send your **written** request to:

***[Name of researcher or appropriate research staff person]***

***[Address information]***

If you take back your permission, the research team may still keep and use any patient information about you that they already have. But they can’t obtain more health information about you for this research unless it is required by a federal agency that is monitoring the research.

If you take back your permission, you will need to leave the research study. Changing your mind will not affect any other treatment, payment, health care, enrollment in health plans, or eligibility for benefits.

**Consent to take Part in Research and Authorization for the Collection, Use, and Disclosure of Health Information**

***[A signature is a required element of consent and HIPAA Authorization – you must apply for a waiver of documentation if not included. Delete this statment.]***

**Signature of Subject or Legally Authorized Representative** [*delete “or Legally Authorized Representative” if not applicable]*

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research and authorize the use of my health information as outlined above. I will be given a copy of this signed and dated form.

|  |  |
| --- | --- |
| **Signature of Subject** | **Date** |
| **Print Name of Subject** | **Date of Birth** |
| **Signature of Parent or Guardian (*if applicable)*** | **Date** |
| **Print Name of Parent or Guardian (*if applicable*)** | **Subject Age if 14-17** |

# Statement of Person Obtaining Informed Consent andResearch Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

|  |  |
| --- | --- |
| **Signature of Person Obtaining Consent** | **Date (must be same as subject’s)** |
| **Printed Name of Person Obtaining Consent** |  |