# Overview

This guidance document is designed to assist with development of an appropriate consent process. An appropriate consent process will effectively communicate the required elements of informed consent as described in US regulations (45 CFR 46.116) in a manner that consistently meets enterprise expectations for conducting Human Research.

# How to Use this Document:

* Review all information in this guidance document to ensure complete understanding of expectations
* Use the Required Elements of Consent Checklist to make sure all required elements are included in the documents that support your process and all considerations and guidelines have been met.
* Use the provided Template Language Compendium to find OHRA approved language for certain circumstances instead of re-inventing the wheel
* When drafting the first versions of your consent materials (forms, scripts, web layouts, etc.…) best practice is to engage with Adam Young and Peter Dumont in Optum Labs Legal and Privacy early in the process.

# What is Informed Consent?

Informed consent is not limited to the content of a single document. It is a process by which participants (both potential and active) are effectively educated about their involvement in research. When being asked to give informed consent to participate in research, potential research participants should be given enough information to decide whether they want to join the study and understand what it means to be a research participant. As the study progresses, the research team is responsible for maintaining participant engagement, education, and awareness. The team must ensure that any changes or new information related to safety, rights, welfare, or otherwise may affect willingness to participate are promptly and accurately shared with participants.

The ongoing process of maintaining informed consent is the primary mechanism for ensuring respect for persons, autonomy for those who are capable of self-determination, as well as protections for those with diminished autonomy who are not capable. Respect for persons is a basic ethical principle set forth in the Belmont Report.

# The Process and the Protocol

Consent forms, scripts and information documents cannot stand on their own in representing a consent process. Your protocol must fully and specifically describe what methods and processes you plan to use to obtain and maintain informed consent for all participants. The information communicated in consent and participant engagement or education documents must be fully aligned with the protocol. If a study is designed to be conducted without obtaining consent, this should be equally specified. The process you choose should adequately support the design of the protocol. This means a study limited to a single benign activity or interaction may have a very brief consent process whereas a complex study involving multiple steps, several procedures or long-term engagement (days, weeks, months, years) will need a more comprehensive consent process and participant engagement plan.

## Examples of common processes for obtaining consent to join a study:

* In person 1 on 1 discussion supported by a consent form (paper or electronic) that a participant will sign to indicate agreement to participate
* In person 1 on 1 discussion supported by a brief information sheet to get verbal agreement to participate
* Telephone or virtual discussion supported by a script to get verbal agreement to participate
* Online (website) self-guided review of comprehensive electronic consent form and educational materials with instruction to contact the study team with questions prior to agreeing
* Traditional mail or E-Mail invitation with detailed information sheet
* The process of obtaining consent may be waived entirely only if all five criteria of CFR 46.116 (f) are met:
  + Research presents negligible or minimal risk
  + Research could not be carried out without the waiver
  + There is a legitimate documented need for obtaining identifiable data
  + The waiver does not affect the welfare and/or rights of the participant
  + When appropriate, participants will be provided with information after the conclusion of the study (Debriefing)

Considerations for documents that will support your process:

* **Use of a long form Informed Consent document that requires participant signature**
  + The form must include all required elements of consent as described in this guidance unless the protocol specifically describes a necessary research objective for omitting certain information (Deception and incomplete disclosure are permitted in social and behavioral research to avoid bias. The protocol must fully describe this method and justify it. The IRB may request a de-briefing in these cases.)
  + All participants must be provided with a copy of the consent form that they signed
  + This method may be implemented with paper or electronic forms. Your protocol should specify your plan including how, where, when and by whom consent will be obtained.
  + Not EVERYTHING needs to be in the consent form. It is recommended that a consent form be sufficient for a person to decide to join, with a plan to provide more detailed education and instructional materials throughout participation. Consent forms that are very long, repetitive or are exactly as detailed as the protocol are burdensome and reduce comprehension.
* **Use of a script or information sheet to obtain consent without a signature** 
  + Scripts and information sheets must also include all elements of consent unless the protocol specifically describes a necessary research objective for omitting certain information
  + A signature may be waived for Minimal Risk studies only under the following circumstances:
    - the consent form is the only linking factor between the data and participant and is the only source of potential breach in confidentiality
    - study does not present the opportunity to obtain documented consent and will not include any face-to-face interaction (e.g. study activity is limited to a single phone call)
    - signing forms is not standard in the participant’s or LAR’s community or culture, and there is an alternative to applying signature to a consent form
  + Generally, where Verbal consent is obtained, participants must still be provided with written material representing what they have agreed to. This can be given in person or sent via email or traditional mail depending on study logistics and participant preference
  + Please note that the HIPAA Privacy Rule requires the individual’s written authorization for any research use or disclosure of protected health information (PHI). Therefore, if HIPAA authorization is required as part of research participation, A signature must be obtained.

# Required Features & Elements of Consent

The checklist has been supplemented with guidance and recommendations from the OHRA for how to effectively meet the regulatory requirements as well as internal expectations. There is a Template Language Compendium at the end of this document to help you with writing appropriate language for each element. Consent requirements have been divided into Tiers to explain their relevance. **Use this checklist to assess your documents prior to OHRA submission**.

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| **Features** **of an appropriate informed consent process & documents** |

**Each prospective participant will have sufficient time to consider participation before agreeing**

**Possibility of coercion or undue influence must be minimized**

* *this relates to compensation amounts, conflicts of interest, as well as research that is conducted by care providers who may offer participation to their own patients*

**Information must be presented in language that is understandable to the participant.**

All acronyms must be defined with first use in any document.

Medical / technical terminology or jargon should not be used. Replace or supplement with layman’s

terms

All materials should be written at a reading level suitable for 6th – 8th graders (Age 11-13)

* *MS Word offers Flesch-Kincaid Grade Level readability statistics to assess grade level. (1) Turning on readability assessment: File > Options > Proofing > Check ‘show readability statistics’ > Click ‘OK’ (2) Checking readability level: Review > Spelling & Grammar > Click through spelling/grammar errors > When complete the readability assessment box should appear)*

**Information must be presented in sufficient detail and must be organized and presented in a way that facilitates understanding of why one may or may not want to participate.**

* *When writing and reviewing consent materials, put yourself in the position of the participant. The audience are average individuals who have no prior knowledge of the study.*
* *When writing the consent materials be thorough in checking that all information aligns with information in the protocol especially regarding purpose, procedures, risks, and benefits.*

**Exculpatory language through which the participant is made to waive or appear to waive legal rights or release the researchers, the sponsor, the institution, or its agents from liability for negligence MUST NOT BE USED in consent documents, scripts, or discussions.**

* See examples here: [www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html).

**Consent must be documented with a signature, unless otherwise waived by the IRB**

* *If you are developing a consent process that will not include collection of a signature, your protocol should be clear on this point with rationale so that the IRB can appropriately grant a waiver. As noted above if your process requires HIPAA authorization then signature must be obtained.*

**\*\*\*The following items should be included on page 1 of consent forms & information sheets\*\*\***

The study title

* *Must align with title that appears on the protocol document.*

The OHRA assigned protocol number

Name the sponsor of the research

A document version number or version date.

* *This version number / date must be updated each time the form is amended. All consent amendments require OHRA approval.*

the Principal Investigators names and affiliations

Contact information for questions about the study

* *Contact information for each investigator is not required. Only provide contact information for anyone who should be contacted directly by a participant.*
* *If a central email or hotline has been created to support the study, the consent can be limited to providing just that*
* *If there are different contacts for different purposes (Questions, complaints, injury) be sure to make it clear in all areas what each contact is meant to support*
* *Greater than minimal risk research typically requires a 24-hour emergency contact*

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| **TIER 1 ELEMENTS** : relate to basic information about participating in research (always required) |

A statement that the study involves research

A statement that participation is voluntary and that the participant may refuse to participate/withdraw at any time without penalty or loss of benefits to which they would otherwise be entitled

* *Consent should also make clear that UHG employees are under no obligation to participate in research conducted by UHG*

Contact information for questions about research participant’s rights and welfare (OHRA or other IRB contact info)

A statement that significant new findings which may affect willingness to continue participation will be provided to the participant

An explanation of how to withdraw from the study

* *Be clear about who should be contacted and how in order to drop out*
* *If early withdrawal could expose the participant to risks, describe and how those risks will be minimized or prevented (e.g. in a drug study stopping suddenly may be dangerous. It may be necessary to titrate off the study medication or to transition them to alternate therapy).*

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| **TIER 2 ELEMENTS**: communicate specifics of the research being proposed (always required) |

An explanation of the purposes of this specific research

* *explain in simple terms the main purpose of the research. You can also use simple illustrations, diagrams, or figures if they are helpful in the explanation.*
* *The explanation of purpose should be given context with an explanation of why this person is being asked to participate.*

A description of the benefits to the participant or to others or statement of no expected benefit.

* *Benefits can be individual or contributing general knowledge of a topic.*
* *Compensation is NOT a benefit*
* *In most cases, the outcome of the research / intervention under investigation cannot be presented as a benefit*

A description of the procedures (experimental procedures must be identified as such)

The expected duration of the participant's participation in this research including a clear indication of when

their participation will end

The circumstances when participation may be terminated by the investigator

A description of reasonably foreseeable risks / discomfort organized by Likely, Less Likely, Rare but Serious

A description of how privacy and confidentiality will be maintained

* *Consent must explain how confidentiality will be maintained. Be specific about how records will be secured to protect the identity of the participant. Explain how data will be de-identified; will code numbers be used? The content of this section will vary according to the research design and resources available to the study team. There may be cause for more or fewer protections depending on the nature of the research.*

Any costs to the participant for participating

* *If there is no cost to the participant, please include a clear statement to that effect*
* *List any products, procedures, tests or visits that are not covered by the study, stating how they will be paid for (i.e., self pay, insurance billing, third party payer, etc.).*

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| **TIER 3 ELEMENTS**: required for the indicated circumstances based on the design of the study. |

An explanation of any compensation/medical treatment available if injury occurs

*(required only for research where potential for physical injury exists)*

Contact information for who to call if injury occurs

*(required only for research where potential for physical injury exists)*

A statement in the risk section that there may be unknown or unforeseeable risks

*(required only for greater than minimal risk research)*

The approximate number of participants involved in the study

*(required only for greater than minimal risk research)*

A statement regarding whether *clinically relevant* research results will be disclosed to participants, and if so, under what conditions. If they will not, clearly state that.

*(Required only when design includes clinical procedures)*

If the research is subject to Food and Drug Administration (FDA) regulation, a statement indicating that FDA may inspect the records

If participants will be paid for participation and total compensation could equal or exceed $600 in a calendar year, participants must be informed that their social security number must be collected for tax purposes, and a description of the payment schedule may be needed.

* *If a participant earns $600 or more from research participation, those earnings must be reported to the IRS. Appropriate tax forms are required along with obtaining SSN for all participants. Please consult the OHRA if your project includes high compensation amounts.*

A description of alternatives to research that are available if any

*(required for research pertaining to investigational treatments)*

* *Generally, this is reserved for protocols that relate to treatment of active disease. This is to be sure that participants who are patients are aware that this experimental treatment is not their only option. If there are alternatives, present a brief list of the major approved alternative options such as drugs / devices / procedures. Consider, based on the indication and population, whether an alternative might include no active treatment but support and management of pain and other symptoms to be as comfortable as possible through the remainder of life. Participants who are patients being presented with research as a treatment option should be encouraged to discuss alternatives with their primary treating physician prior to agreeing to research. If the only alternative to participation is to not participate, this language is not needed.*

A statement that collected bio specimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this profit

*(required when study involves collection of biospecimens)*

A statement regarding whether the research will or might include whole genome sequencing.

*(required when study involves collection of biospecimens)*

A statement about whether the research involves plans for future use of the private information and/or specimens collected. This plan should be thoroughly discussed in the protocol. Future use refers to repositories & banking data and samples to be used for unspecified future research. It is not relevant to delayed testing or use related to the present protocol or additional aims for the same protocol. **Only one of the following 3 should be included**:

* 1. A statement that data and, if applicable, specimens will not be stored or distributed for future research studies. *(i.e. when this study is done all samples will be destroyed)*
  2. A statement that data and, if applicable, specimens will be de-identified, and could be stored and distributed for future research studies without additional informed consent.
  3. A statement that identifiable data and, if applicable, specimens will be stored and distributed for future research studies without additional informed consent. Additionally, the following elements are required if **identifiable** data and/or specimens may be stored and shared for future use:
     + A statement about which identifiers will be retained and shared with data/specimens.
     + The types of institutions or researchers that might conduct research with the data/specimens.
     + A description of the period of time that the data/ biospecimens may be stored, maintained, and used for research purposes. If indefinite, this should be stated.
     + A general description of the types of research that may be conducted with the data/ specimens.
     + A statement regarding whether subjects will or will not be informed of the details of any subsequent research, and that they may not have chosen to consent to the future research.
     + A statement regarding whether clinically relevant research results, will be disclosed to subjects, and if so, under what conditions.
     + Specifically related to the future use: A description of how confidentiality will be maintained during future storage/ sharing,
     + Reasonably foreseeable risks and benefits of future research use,
     + Contact information for questions about future use/storage and research related harms.

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| **HIPAA Authorization Elements –** HIPAA authorization language may be incorporated into a consent form or be a standalone document. All HIPAA authorization language must be approved by a Privacy officer before use. |

Description of PHI to be used or disclosed that identifies the information in a specific and meaningful manner

The name(s) or other specific identification of person(s) or class of persons authorized use or disclose/share the PHI

The name(s) or other specific identification of the person(s) or class of persons who may receive the PHI or to whom the covered entity may make the requested disclosure.

Description of each purpose of the requested use or disclosure. Researchers should note that this element must be research study specific, not for future unspecified research

Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure. The terms “end of the research study” may be used for research, including for the creation and maintenance of a research database or repository

A Statement indicating The individual's right to revoke his/her Authorization in writing and either (A) the exceptions to the right to revoke and a description of how the individual may revoke his/her Authorization or (B) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices.

A Statement Indicating the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and if applicable, consequences of refusing to sign the Authorization.

A Statement Indicating The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information

Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the individual's authority to act for the individual is required.

# Template Language Compendium

# OHRA Preferred Page 1 Template

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| Includes all Page 1 items and all Tier 1 elements |
| |  |  | | --- | --- | | **Study Title** | Insert the title that appears on the protocol | | **Study Number** | Insert OHRA issued protocol number | | **Investigator(s) & Study Contacts** | List Names of investigators with affiliations (only include contact info if they are to be contacted directly by participants)  Include study contact name if other than investigator + contact phone number/Email address:  Include Emergency 24-hour phone if needed: | | **Sponsor** | Insert Sponsor Name | | **Form Version** | UHG-OHRA V02.2022 |   You are being invited to take part in a research study conducted by \_\_\_SPONSOR & COLLABORATOR\_\_\_  A person who takes part in a research study is referred to as a research participant. Before you agree to be a participant, you should understand what is being asked of you and what the risks are. Being a participant is voluntary, meaning you do not have to join the study and can stop at any time. If you choose not to participate, or to stop participating, you will not lose any benefits that you would normally get. Research is not a replacement for the care and medical advice you receive from your healthcare provider. During and after the study, you should continue to follow the care instructions you have received from your healthcare provider.  You will be given time to review this consent form that describes the study. You should ask the study team all questions you have before you agree. You will be given a copy of this form if you agree to volunteer. During the study, we may find information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available so that you can tell us if you want to stop participating.  If you no longer want to be in the study, please contact NAME at (email, telephone, mailing address)  This research is reviewed by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies to ensure they are being done with the safety and rights of research participants as a priority. You may contact the IRB if:   * You have questions about your rights as a research participant. * You have concerns or complaints about the research * You are unable to get in touch with the study team when you need their help   UHG IRB Website: www.uhgohra.com/participants  UHG IRB Email: ohra\_uhg@uhg.com  UHG IRB Phone: 1-800-860-5371 |

*(If a different IRB oversees this research, include their preferred contact info instead)*

# Required Elements of Consent Templates

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| **TIER 1 ELEMENTS TEMPLATES & GUIDANCE** | |
| **Study Involves Research** | You are being invited to take part in a research study. Research is not a replacement for the care and medical advice you receive from your healthcare provider. During and after the study, you should continue to follow the care instructions you have received from your healthcare provider. |
| **Participation is Voluntary** | Being a participant is voluntary, meaning you do not have to join the study and can stop at any time. If you choose not to participate, or to stop participating, you will not lose any benefits that you would normally get. |
| **IRB Review & Contact Info** | This research is reviewed by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies to ensure they are being done with the safety and rights of research participants as a priority. You may contact the IRB if:   * You have questions about your rights as a research participant. * You have concerns or complaints about the research * You are unable to get in touch with the study team when you need their help   You can contact the IRB at (insert IRB contact information)  If UHG IRB is overseeing the study, please include:  UHG IRB Website: www.uhgohra.com/participants  UHG IRB Email: ohra\_uhg@uhg.com  UHG IRB Phone: 1-800-860-5371 |
| **Significant New Findings** | During 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 the study. We will notify you as soon as possible if such information becomes available so that you can inform us of whether you would like to end participation. |
| **How to Withdraw** | You are free to leave the study at any time. Stopping will not interfere with your future care. **If you decide you no longer want to be in the study please contact NAME at (email, telephone, mailing address)** |

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| **TIER 2 ELEMENTS TEMPLATES & GUIDANCE** | |
| **Explanation of Purpose** | The purpose of this study is to . This research study is not meant to be a form of treatment. You are being asked to participate because. |
| **Description of Benefits** | There is no anticipated benefit for you directly from participating. However, your participation and support of the research may contribute to a future benefit to society if our results can be used to improve treatment of others with this condition. |
| **Description of Procedures -Guidance** | This section of the consent form should describe the interactions and procedures that will take place in order of occurrence. Protocols that involve multiple interactions or a series of procedures over several days, weeks or months usually benefit from a table presentation of the procedures that have been described. Use of a table must be in addition to the list of procedures that include a layman’s description of what each procedure is. The table is also a good place to make it clear how much time each procedure or study visit will take.  *Example*  *Day 1:*   * *Screening blood draw – A nurse in the lab will draw about 2 teaspoons of your blood from a vein in your arm. This blood will be tested to see if your diabetes is controlled well enough to be a part of the study.* * *Intake survey – you will use a tablet to fill out an electronic survey about your health and diet. This is partially for safety to be sure you don’t have any other conditions that should prevent you from being in the study. It also helps us place you in a group within the study.* * *CGM Demo – This study asks that you to wear a Continuous Glucose Monitor (CGM). A CGM is a small flat device that you apply to your skin like a sticker. Under the sticker a very fine needle like wire is inserted into your skin. The wire measures and records the amount of glucose (sugar) in your blood while you wear it. The study team will demonstrate the CGM and teach you how to wear it.*   *Procedure Schedule:*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | ***Procedure description*** | *Day 1* | *Day 2-9* | *Day 10-16* | *Day 17-23* | *Day 24-30* | | *Screening blood draw* | *10 Min* |  |  |  |  | | *Intake Survey* | *15 Min* |  |  |  |  | | *CGM Demo* | *10 Min* |  |  |  |  | | *Wear CGM* |  | *24 hrs/day* | *No CGM* | *24 hrs/day* | *No CGM* | | *Food diary* |  | *Daily* | *Daily* | *Daily* | *daily* | |
| **Duration / End of participation** | The study is expected to end after all participants have completed all visits, and all information has been collected. If you complete the entire study, your participation is expected to last about X Days/Weeks/Months/Years. Your participation will end after you either tell the study team you no longer want to be in the study or after X event/procedure/visit has been completed.  Your participation in this study may also be stopped at any time by the investigators, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because;   * The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision. * You have not followed study instructions.   + - * You are unable to complete the needed study activity       * You become ineligible for the study       * The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study. |
| **Risks or discomforts** | If the only risk is loss of confidentiality: This research does not present any risk of physical harm to you.   * If the procedures section does not describe the risks of each procedure, this separate section of the consent form should describe any anticipated risks associated with the procedures as well as risks and side effects of any drugs and devices that are part of the research. * For research that includes investigational treatments (drugs or devices), always include a statement indicating the potential for unknown risks * The risk of loss of confidentiality should always be included. * When a procedure or intervention has multiple risks always divide them into categories of:  |  |  |  | | --- | --- | --- | | **Likely** risks / side effects | **Less likely** risks / side effects | **Rare but Serious** risks / side effects | |
| **Privacy & Confidentiality** | There is always a small risk that the information collected about you could be lost or stolen. We will do our best to make sure that the personal information we get during the study will be kept confidential. However, we cannot guarantee total confidentiality. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Every precaution will always be taken to protect your information, including… |
| **Cost to participant** | Option 1: There is no cost for you to participate. All procedures and materials will be paid for by the research sponsors and collaborators.  Option 2: You are responsible for any deductibles or applicable co-pays for routine & standard office visits, scans and blood work that occur during your participation. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance. |

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| **TIER 3 ELEMENTS TEMPLATES & GUIDANCE** | |
| **Injury Language** (please note that injury language is often dictated by a contract so this language may not be applicable) | If you think you have been injured as a result of taking part in this research study, please contact NAME ,EMAIL,TELEPHONE, MAILING ADDRESS as soon as possible.  We will help you get the care you need to treat injuries directly resulting from taking part in this research. Those care providers may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury. However, you may also be responsible for some costs. In some cases, the study sponsor may cover portions of the cost for care of injury.  There are no plans to pay you or give you other compensation for the injury. If you feel this injury was caused by an error on the part of the investigators or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by agreeing to participate. |
| **Unforeseeable Risks** | It is possible that other risks may exist that we didn’t expect and didn’t cover in this document. |
| **Number of participants** | The study is seeking to enroll X# of participants across X# of sites in the US and internationally. |
| **Return of results** | Option 1: Results from TEST X are for research purposes only, so you will not receive any results.  Option 2: Results from TEST X will be given to you. You can decide if you would like to let your doctor know about those test results. All interpretations and test results should be reviewed by a medical professional for clinical decision-making.  Option 3: Results from TEST X will be given to the primary care doctor you identified |
| **Alternatives to research** | Joining this research study is not your only option. Instead of joining this research you could:   * + - * Find another research study       * Talk to your care team about X available standard treatment, drug, procedure |
| **Commercial profit from biospecimens** | The samples of (*blood, saliva, urine, tumor biopsy, etc..*) collected during this research may be used to make medical discoveries, including new tests, therapies, or other commercial products or services that could result in profit. If this were to happen, you would not get any part of the profits. |
| **Whole Genome Sequencing** | This research may include whole genome sequencing. Whole genome sequencing is a laboratory process that allows scientists to create a complete map of your genetic codes. These codes can help to identify whether it is possible for you to develop certain diseases. This happens by finding the specific gene markers within the code that are known to be associated with the disease. |
| **Future Use Language**  (please see full guidance above on requirements) | Option 1: Research data and samples from this study will not be stored or shared for use in future research. When the study is completed, any leftover or residual samples will be destroyed. The data will be archived and no longer linked to any information that could identify you.  Option 2: Research data and samples from this study may be stored or shared for use in future research without additional informed consent. The data and samples will be de-identified meaning, they will no longer be linked to any information that could identify you. |
| **FDA Oversight Language** | This study is being overseen by the Food and Drug Administration (FDA) and they may review your research records including information that could identify you. |
| **Payment for Participation** | Option 1: You will not be paid for your participation  Option 2: You will be paid for participating in the study. Payments may total up to X$$ if all expected procedures are completed. Payment will be made with (cash, gift card, etc…)  Since payment may be $600 or more, the study team must collect your Social Security number and provide tax forms for you to report this income to the IRS. |

# Other Template Language

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| **UHG/UHC/Optum employee language** | If you are an employee of UnitedHealth Group, UnitedHealthcare, or Optum, your decision regarding participation will have no consequences for your employment. |
| **Research Delivered in Standard of Care setting** | Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits or change to the level of care you normally get. You may also decide to discuss the study with your family, friends, or other doctors. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. |
| **Statement of Consent (for signature area)** | By signing below, you indicate that (1) you have read, understood, and agree to the terms of this Research Consent Form, (2) agree to participate in the Study, |
| **Statement of Consent & HIPAA Authorization (for signature area)** | By signing below, you indicate that (1) you have read, understood, and agree to the terms of this Research Consent Form & HIPAA Authorization, (2) agree to participate in the Study, and (3) authorize the use and disclosure of your protected health information as described in the HIPAA Authorization section of this form. |
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| **Signature area formatting for Adult Consent** | |

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| Name of Adult Participant (Print above) | Signature of Adult Participant | Date |

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| Name of Person Obtaining consent (Print above) | Signature of Person Obtaining consent | Date |

For adult participants unable to consent, permission is given by the Legally Authorized Representative (LAR)

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| Name of LAR (Print above) | LAR Signature | Date |
| Description of LAR authority to serve as the participant’s representative (spouse, parent, guardian, power of attorney, Etc.): | | |

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| **Signature area formatting for Minor Assent and Parental Permission** |

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| Name of Child Providing Assent (Print above) | Child’s mark confirming assent (optional) | Date |

|  |  |  |
| --- | --- | --- |
| Name of Parent giving permission (Print above) | Signature of Parent giving permission | Date |

|  |  |  |
| --- | --- | --- |
| Name of Person Obtaining assent (Print above) | Signature of Person Obtaining assent | Date |

References:

[The Belmont Report – Respect for Persons](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#:~:text=Three%20basic%20principles%2C%20among%20those,of%20persons%2C%20beneficence%20and%20justice.)

[HHS Common Rule Requirements for Informed Consent (45 CFR 46.116)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116)

[FDA Required Elements for Informed Consent (21 CFR 50.25)](https://www.ecfr.gov/cgi-bin/text-idx?SID=4f96cc6c906fb30e26219a0a36a788c9&mc=true&node=sp21.1.50.b&rgn=div6)