Clear Informed Consent Template

Adapted from "Revised Clear Informed Consent Template," UAMS Center for Health Literacy, August 2020

Note to users: The template below will help you create your consent form so that it complies with Revised Common Rule requirements (effective Jan. 19, 2019). FDA-regulated studies need some additional elements; please review FDA requirements.

This new rule requires you to provide, **at the beginning**, "key information" that would help participants to decide if they should join the study. This will require you to develop content that is clear and understandable to your study population.

After you finish that section, move to the body of the consent form that will walk you through the rest of the elements needed for consent under the revised rule. You do not need to repeat the key information again in the body of the consent – **unless repeating it will help your study population**. That means you can alter or delete the parts of this template that you think are too repetitive and will not aid your audience.

- *Blue, italicized typeface is used for prompts asking you to insert study information.* (Make sure the typeface is not blue or italicized in the final consent form.)
- Red typeface is used for notices or reminders to delete if a part is not applicable to your study. **Delete everything that is not relevant to your study, as including it will only make it harder for research participants to understand what they are being asked to do.**
- Green typeface is used only in headers and footers to prompt you to put in study specific version or date information to ensure that correct documents are used.

Key Information for {Title of Study}:

This first part gives you key information to help you decide if you want to join the study. We will explain things in more detail later in this form.

We are asking if you want to volunteer for a research study about (*insert general description of study*). By doing this study, we hope to learn *(briefly describe the purpose of the study)*.

Please ask the research team if you have any questions about anything in this form. If you have questions later, contact the researcher in charge of the study, *(insert contact info here)*.

What will happen if I join the study?

If you join, your part in this research will last about *(state in hours, days, months, years)*.

During the study, we will ask that you *(very briefly summarize study activities in lay terms here. The point is to give an overview of the key things they will have to do. Use bullet points if needed)*.

Do I have to join this study?

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decide not to join. If you decide to take part in the study, it should be because you really want to volunteer.

If you are *(a patient/an employee)* at *(institution),* nothing about your *(health care/employment)* will change no matter what you decide. **Delete** this if the study is not seeking to enroll patients or employees.

What do I need to know to decide if I should join this study?

Here are some of the main things you should think about before choosing to join this study.

Main reasons to join the study

- ✓ *Using bullets, list the most important reasons why a person may want to volunteer {i.e. potential benefits to health, contributions to knowledge about a condition, etc.}*
- ✓

Main reasons not to join the study

- ✓ *Using bullets, state the most important reasons why a person may not want to join the study. Be sure to list the main risks AND inconveniences that may influence the decision.*
- ✓ *If alternative treatments/procedures are key to the participant's choice, discuss those that might be advantageous.*

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want to be in the study. Remember, it is okay to say no. You can still get your medical care/services here if you are not in the study (delete if not applicable).

[Follow the instructions in blue and the notices in red. Complete all sections applicable to your study. Write in clear, plain language (6th grade reading level or below). Clearly define the medical/research terms that you cannot avoid. Revise template language as needed for your individual study. Delete all instructions and notices. Delete sections and language that do not apply.

Informed Consent Form

- **We are asking you to be in a research study. You do not have to join the study.**
- Delete if not applicable: **You can still get your medical care here even if you are not in the study.**
- **Take as much time as you need to read this form and decide what is right for you.**

Why am I being asked to be in this research study?

- We want to learn more about *(insert condition/topic) or say "how to help people who have (insert condition)."*
- By doing this study, we hope to find out *(insert specifics, e.g. "whether a possible new treatment for [condition] helps people or not." Do not use the exact same language from the bullet immediately above).* **Delete** this bullet if it does not add anything.
- We are asking people like you, who *(have/are (insert condition or status if applicable, i.e. "Type I diabetes" or "healthy"))*, to help us.
- *(Insert total number of participants)* people *(insert age descriptor, e.g. adults 18 and older, or specific age range if that would aid understanding)* years old will be part of this study. (*IF MULTIPLE SITES ADD – "Of those (total #), XX will join the study at [this site]."*)

What if I don't understand something?

- This form may have words you do not understand. If you would like, research staff will read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.

- Please ask as many questions as you would like before you decide if you want to be in this study. If you decide to take part in the study, it should be because you really want to volunteer.

What will happen if I say yes, I want to be in this study? *(In this section, describe all study procedures completely and in clear, understandable terms. You probably will not have explained all of the details in the key information section, so be more specific here, while still being clear.* **Delete any suggested items that do not apply.***)*

First, we will see if you qualify to be in the study. We will *(describe the process for determining eligibility. Rewrite to past tense and summarize if subjects will have already been screened for eligibility before the consent process.)*

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If you qualify, we will do these things:

- Ask about *(describe items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take)*
- Give you a form with questions about *(describe the nature of the questions)* **Delete** if there is no form/questionnaire)
- Read the questions out loud and fill out the form with you, if you like. **Delete** if there is no form/questionnaire
- You do not have to answer any questions you do not want to answer. (**Note:** Change this statement if subjects must answer all questions to participate.)
- *If this is an interventional study, describe the intervention. Include a description, in simple lay terms, of the randomization, if relevant. Explain the probability of being assigned to each group, whether the assignment is blinded/masked, and if so, a statement that the researcher can break the blind in an emergency. Include a definition of "random" – "like a flip of a coin." and of "placebo" (e.g., "with no medicine in it, like a sugar pill")* (**Note**: if this bullet gets long, break into more bullets or sub-bullets. **Delete** this bullet if there is no intervention.)
- *Describe all procedures for visits, follow-up communications and specimen/information collection in chronological order. Include standard of care when that is part of the study protocol. Describe what procedures are experimental.* (**Note:** this part may get lengthy, so break these procedures into sub-bullets to aid understanding.)
- *Include the amount of time expected for visits/encounters and study activities.*
- *List the types of tests (including imaging, blood draws, physical exams, etc.).* (**Note**: if there are many tests for the study, break these into sub-bullets to aid understanding. Delete if there are no tests.)

- *Describe aspects of protocol that are optional, e.g., collection of certain specimens or health information, video or audio recording, etc.* **Delete** if there is nothing.

How long will I be in this study?

You will be in the study for *(insert the expected duration of the participant's involvement in the study.)* It will include *(number of visits)* that will happen *(describe the visit schedule)*.

Include information about duration of information collection after active study participation has ended if relevant, and specify the kinds of information; e.g., "We will continue to collect information from your medical records for the next 6 months after study visits end. This information will include….." **Delete** this if it is not applicable.

What if I say no, I do not want to be in this study?

- Nothing bad will happen because of what you decide.
- You can still get medical care at (this health center). **Delete** or edit as appropriate.

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

- You can stop being in the study at any time.
- Nothing bad will happen because you change your mind and leave the study.
- You can still get medical care at (this health center). **Delete** or edit as appropriate.
- If you decide to stop being in the study, *(describe what subjects should or must do, e.g. inform the study team, indicate whether there will be a final required visit, return anything, etc. Use sub-bullets if needed. Include contact phone or email.)*

Will it cost me anything to be in the study?

The study will not cost you anything. [If applicable: You or your insurance company will be responsible for the costs of your regular medical care, as usual. **Note**: If there are costs that may reasonably occur, change this statement to reflect those costs, e.g. parking costs, costs for medical supplies, etc.]

Will I be paid for being in the study? *Choose from these options; modify as needed:*

Yes. We will give you *(insert amount)*. This is to pay for your (insert what it will pay for, e.g. parking, travel, time, etc). You will be paid in *(cash, gift card, etc.)* at the end of (*each visit/end of the study)*. If you change your mind and decide not to be in the study, you will only be paid for the parts you completed.

If you get more than $600 in one year (January-December) from (*insert institution),* we may

send you a tax form if the law requires it *(edit to reflect your institution's policy)*. **Delete** if not applicable**.**

OR

No. You will not be paid for being in this study.

Will being in this study help me in any way?

If no direct benefit is expected, insert the following: We do not think that being in this study will help you personally. But it may help people with *(insert condition)* in the future. What we learn may help in the following ways:

- *(using a bulleted list, describe potential benefits to others with the condition in the future, excluding compensation and provision of healthcare)*.

If there is a possibility of personal benefit, insert this language: Being in the study may or may not help you, personally. But even if it does not help you, it may help people with *(insert condition)* in the future. What we learn may help in the following ways:

- *(using a bulleted list, describe direct or potential benefits to both the individual and to others with the condition, excluding compensation and provision of healthcare)*.

What are the risks of being in this study?

The risks for this study are no more than what happens in everyday life. **Delete** this if the study is greater than minimal risk.

The risks of joining this study are:

- *(Describe the possible harms/risks to the participant and relative chance of occurrence and severity.)*
- *For drug or device studies, there needs to be something like this statement "This study may involve risks that are not currently known."* **Delete** if N/A.

There are also side effects and things about being in the study that might affect you, such as:
Note: Add in any expected inconveniences that might make being in the study hard on people, such as the following (**delete** the examples & highlighting and add in what applies to your study).

- The questions asked may make you sad or upset.
- You will have to avoid exposure to sunlight for four months
- All of your hair will fall out
- You will not be able to drink alcohol for six months

Insert details regarding accommodation or referrals, e.g., for counseling, if applicable.
Otherwise, **delete.**

There is also the risk that someone could find out that you were in the study and learn something about you that you do not want others to know. We will do our best to protect your privacy, as explained in more detail later in this form.

What if I get sick or hurt while I am in this study*? If the study is **greater than minimal risk**, include an explanation as to whether or not any compensation and/or treatment is available for injury.* **Delete** if this is a minimal risk study. *If more than minimal risk, choose from the following, and modify to fit your study:*

- If you get hurt or sick when you are here for the study, we will help you get the care you need. This may include first aid, emergency care, and any follow-up care you need.
- If you are not here and get hurt or sick, and you think it is because of the study, do these things:
  - ✓ call your doctor – or if an emergency, call 911
  - ✓ give your doctor or ER staff
    - the name of this study – *(insert name of study)*
    - the name of the head researcher for this study – *(insert researcher name)*
    - a copy of this form if you have it
  - ✓ call *(insert the name and 24 hour phone # of a medical member of the research team, if available)*

Also, if more than minimal risk choose from these options:

- This treatment will be billed to you or your insurance company. No other form of payment is available.

  OR

- *Insert details of agreement negotiated with sponsor*

Reminder: You do not give up any of your legal rights by agreeing to be in this study or by signing this form.

What are the alternatives to being in this study?

You do not have to be in this study.

Choose from these options; modify as needed:

There are no alternatives to being in this study because it does not involve any treatment or other procedures that may help you.

OR

If you decide not to join this study, you have the following other options: *(using bullet points, describe alternative treatments, standard of care, or courses of action that are available to the subject.)*

-

Can I be taken out of the study even if I want to continue? **Delete** this section if N/A, for example, in a study that involves only a single, brief, low-risk interaction with the subjects.

Yes, the study doctor (or head researcher) can take you out of the study if:

- You do not follow study instructions.
- It is not in your best interest to continue.
- The study is stopped for any reason.
- *List any other applicable reason, e.g. the test article becomes unavailable, etc.*

What information will be collected about me in the study?

During the study, we will need to learn private things about you, including *(using bullets, explain the private information you will learn about them during the study and **delete** the rest.)*

- General contact and background information about you, such as *(insert the general info required, e.g. name, address, telephone number, and other demographic information.)*
- Medical information about you, such as *(explain clearly; use sub-bullets if necessary, for example, "results of exams, lab tests, imaging, and questionnaires, and your response to study treatment and side effects.")*
- Personal information, such as *(describe; this would include non-medical information such as information about your past, etc.)*
- For studies involving biospecimens, include this: If you agree (**Note:** if collection is **required** for participation, drop "if you agree" and add a sentence "You must agree to this collection to be in the study" at the end of this paragraph.), we will collect blood samples or tissue samples from you. (*Include a brief description of how you will get these samples, e.g. "we will get these samples during the normal blood draws for the study." Indicate in lay terms the amount of blood or tissue, e.g. "about a tablespoon, or a piece about the size of a pencil eraser.")*

If biospecimens are collected, include one of the following: otherwise **delete**

We will not use the samples we collect from you for commercial profit. They will only be used to help us learn *[insert the main purpose of specimen collection]*.

OR

We (*or someone else; please specify*) may use the samples we collect from you for future research. *[If this is expected, insert how you expect to use it. If it is not immediately expected, but you want to preserve the option, insert "However, we currently have no specific plans to do so."]* We *(or someone; clarify)* may eventually profit from the research done with your samples. You *(will/will not)* share in this profit. **Delete** the language about profit if no commercial use/gain is expected.

If the current study involves genetic testing and/or whole genome sequencing, please include the following, edit as appropriate. Otherwise, **delete**

We will use your samples for genetic testing. This testing will look at the genes that may be responsible for *(explain in clear, understandable terms)*.

Delete if N/A: We will do a genetic test called whole genome sequencing using your samples. This process allows us to see your entire genetic code. This code is what determines things specific to each person, such as hair and eye color and risks for diseases.

Who will see this information? How will you keep it private? *(Explain using some of the options below, modify as needed.)* **Delete** those that are N/A.

- The local study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We *(will/will not)* take your name off information and study samples that we collect from you during the study. We will give your information and study samples a code, so that no one can identify you.
- Include if the study involves genetic testing; otherwise, **delete**. All of your genetic test results will be labeled with *(indicate if they will have direct identifiers, a code, or be anonymized).*
  If coded or anonymized, add the following language: We also want you to know that even though we will *(choose one: "give your test results a code"/"remove anything that can identify you")*, those results are unique to you. As technology changes, it may become possible for people to identify you from these results.

- *If data are to be shared with a sponsor, choose one of these; edit as appropriate*. **Delete** if N/A.

  We will share your *(insert study information and samples--specify what kind)* with the sponsor, *(insert name of sponsor)*.

  Select one of the following, delete the other*; modify as needed:* But the sponsor will only see a code number instead of your name. OR This will include your name and other information that can identify you.

- When we share the results of the study *(insert details here, e.g., in medical journals)*, we will not include your name or anything else that could identify you.
- There are people who make sure the study is run the right way. These people may see information that identifies you. They are
  - ✓ *Insert study sponsor or funding source **if** they will get identifying information*
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ Philadelphia Department of Public Health Institutional Review Board
  - ✓ Other institutional oversight offices
  - ✓ *Insert any other applicable group that may access the records or provide oversight*
- State law requires that we tell the authorities if we learn about possible child abuse or that you might hurt yourself or someone else.

For studies involving **genetic testing**, include this section. Otherwise, **delete**:

Are there extra privacy risks because of the genetic testing?

Yes. Genetic testing involves certain risks. *Adapt the following text to the current study. If the genetic information created as part of this study may be shared outside the study team and/or uploaded to a publicly available database, make sure risks associated with that sharing are addressed.* Genetic testing can sometimes reveal information about you or, in some cases, your family members, since genetic conditions may be shared among relatives. If someone else learns about this information, there is a risk of being discriminated against, feeling stigmatized, or having trouble getting a job or insurance. Your genetic information is unique to you. So even if it does not include your name or other identifying information, there is also a risk someone could trace your information back to you. While the researchers think the chance of someone being able to identify you through your genetic information alone is small, this risk may change in the future as people find new ways of tracing information.

*(**If** results will be returned to the individual, include this;* otherwise, **delete***)* If you receive the results of the genetic testing, you might be upset about what you might learn about risks to your health or your family members' health. For example, you might feel concern about a possible genetic disorder that has not shown up yet.

If neither the results of planned testing nor incidental findings will be returned to the individual, include this (otherwise delete): The genetic testing will be done for research purposes only, and we do not plan to return any results to you or your doctor.

If genetic data/samples will be shared with the sponsor or other investigators, add the following (otherwise delete): "We may share the genetic information we learn from this study with….. *[e.g., the sponsor—name the sponsor; other researchers at [institution]; other researchers across the country; etc.]*. This information will not include anything that identifies you, such as your name or any other personal information about you."

If** data will be shared with other centralized databases such as dbGaP, add the following;* otherwise, **delete)* Some of your genetic information may be sent to other scientific or commercial databases for other researchers to use. This could include the one maintained by the National Institutes of Health *(revise name as needed)* or other similar databases. This information will not include anything that identifies you, such as your name or any other personal information about you. As mentioned earlier, your genetic information is unique to you. So there is still a risk that someone could link this back to you. The risk of this is small now, but may change in the future as technology changes.

The Genetic Information Nondiscrimination Act (GINA) is a federal law that makes certain uses of genetic information illegal. The law makes it illegal for health insurance companies, most health plans, and many employers to discriminate against you based on your genetic information.

Note that GINA does not apply to other types of insurance such as life, disability, or long-term care insurance. Also, it does not apply to companies with fewer than 15 employees.

Where and for how long will my information and samples be kept? (**Delete** "and samples" if no samples will be taken or kept.)

Include all that apply; edit/delete language as needed:

- Your information and samples (delete "and samples" if the study involves no samples) will be labeled (describe how; with a code, a name, some other method?) and kept (where)?
- Once we give your information and study samples a code, we will keep the key to this code in a locked file. (**Delete** "and study samples" if no study samples will be kept.) *If relevant add:* Your study information and samples will be stored by the sponsor, [reiterate name of sponsor], for [indicate how long].
- Only *(insert appropriate parties)* will be able to link it to you.
- *(Describe how long info and samples will be stored & when it will be destroyed. Also indicate if the key to the code will be destroyed while info and samples are retained.)*

For patients, choose from these options; modify as needed (**Note**: ACH requires a copy of the ICF in the MR)*:*

- We *(will also/will not)* put information about you from the study in your medical record. *(Describe what information will be put in the participant's medical record, if applicable.)*

If I stop being in the study, what will happen to my information and samples collected in the study? (<u>Delete</u> "and samples collected" if no samples involved)

Choose from these options; modify as needed:

- We *(will /will not)* be able to take your information and samples out of the study after it has started. (**<u>Delete</u>** "and samples" if no samples involved)

  OR

- If you wish to have your information and samples taken out of the study, call (*insert head researcher name*) at (*insert phone #*). (**<u>Delete</u>** for FDA-regulated research. **<u>Delete</u>** "and samples" if no samples involved.)

Will my information or samples from the study be used for anything else, including future research? (<u>Delete</u> "or samples" if no samples involved.)

Choose from these options; modify as needed: **<u>Delete</u>** any that do not apply.

No. Your information *(insert "and samples" if applicable)* will be used only for this study. It will not be used for future research, either with or without identifiers. (Note: if you include this language, you will not be able to use the data or samples for anything else in the future, even if all identifiers are later removed.)

OR

Yes. *Add "If you agree below," to the beginning of the next sentence if subjects will be able to opt out.* We will use your *(explain what will be used and why the information and/or samples are needed.) (If the participant must agree to future use, add: "*You must agree to this future use of your samples/information to be in this study." *Edit as needed.)* (If you will use for future research, then continue below. Otherwise, **<u>delete</u>** the bullets.*)*

- *Explain the types of future research anticipated, where/how the information will be stored, steps to minimize risks to confidentiality, and a reminder of how subjects may request to withdraw use of their information.*
- *Indicate whether the information/biospecimens will include identifiers during either storage or future use. If you say the info/samples will be anonymized, add language clarifying they cannot be removed after the identifiers are removed.*
- *If information/biospecimens may be shared outside of the current study team, then include this statement, modify as needed:* Your information and samples may be shared

with other researchers, who are not part of this study. *[Indicate whether they may be from outside the institution. If others may use the info for future research, include something like, e.g. "Those researchers will not seek your consent at that time."]*

If there is a possibility of future genetic research, include: We may use your samples for future genetic studies that may include whole genome sequencing.

Include if asking for permission for future research. Otherwise, **delete** the box.

My information collected in this study may be used in future research *(insert specific type here, if known or limited by participant)*.

___ Yes ___ No

Any of my biological samples collected in this study may be used in future research *(insert specific type here, if known or limited by participant)*.

___ Yes ___ No

_____ _____

Your name (please print) Your signature

Will you tell me the results of the study?

Include the correct option below; **delete** the rest. *Insert anything needed and not covered below.*

Yes. Once the study is done, we will send you a summary of all the results and what they mean. We will not send you your individual results from the study. **Delete** *parts that do not apply, such as if you won't explain what the results mean. If you will provide individual results, then change the last sentence.*

OR

No. We will not tell people in the study about what we find. However, we plan to publish the results in an academic journal. (What we publish will not include anything that can identify you though.)

Will you tell me anything you learn that may affect my health? [Include if applicable for the study. Otherwise, **delete** this section.]

Yes. If we learn something about you that might be important for your health, we will tell you.

OR

No. *(Insert explanation of reasoning if there is one: otherwise, just say no.)*

If genetic testing, integrate the following into your yes/no language; otherwise, **delete**:

The genetic testing we will do in this study is for research purposes only. We will not return any results to you or tell your doctor about them. (***If*** *results of the planned genetic testing will be returned to the individual, or if incidental findings will be returned to the individual, then specify that instead.*)

What if new information comes up about the study?

We will tell you if we learn anything that may change your mind about being in the study.

[If the study is a clinical trial, otherwise delete this section] Where can I find more information about this clinical trial?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time. **(Note:** For studies that require ClinicalTrials.gov registration by law, this exact clause must be included. If your study will be registered for publication purposes (i.e., ICMJE requirements) and not because of a statutory requirement, then this clause does not have to be included.)

What if I have questions?

- Please call the head researcher [study coordinator] of the study – *(insert researcher name and phone #)* – if you
  - ✓ have any questions about this study
  - ✓ feel you have been injured in any way by being in this study
- You can also call the Philadelphia Department of Public Health [PDPH] office that supervises research if you cannot reach the study team, have questions about your rights as a research participant, or want to speak to someone not directly involved with this study. To do so, call the Research Participant Coordinator at 215-685-0869, or email research.participant.DPH@phila.gov.

By signing the document, I am saying:

- ✓ I agree to be in the study.
- ✓ I know that joining this study is voluntary.

- ✓ Someone has talked with me about the information in this form and answered all of my questions.
- ✓ I have been asked if I wish to talk directly to the study doctor. (**Delete** if not applicable)

I know that:

- ✓ I can stop being in any and all parts of the study at any time and nothing bad will happen to me. (**Delete** "any and all parts of" if they cannot drop out of parts of the study.)
- ✓ I can still get medical care here no matter what I decide. (Delete if not applicable.)
- ✓ I can call the office that supervises research (PDPH Institutional Review Board) at 215-685-0869 if I have any questions about the study or about my rights.
- ✓ I do not give up any of my legal rights by signing this form.

I agree to be part of this study:

_____ _____
Your name (please print) Your signature

_____
Date

_____ _____
Printed name (person obtaining consent) Signature (person obtaining consent)

_____
Date

Delete if not applicable:

I agree to be contacted for future *(insert specific type here)* **research related to this study.**

___ YES ___ NO

_____ _____
Your name (please print) Your signature

_____
Date