The below template for developing an informed consent document to use in your research study is meant to provide structure and guidance to the process, not to serve as your exact informed consent document. Please remember to consult your institution and IRB for specific consent requirements, instructions and templates.

For the purposes of this document, guidelines within the template will be provided in italics. If this document is used to develop your informed consent form, please remember to delete the italicized instructions and insert your specific information.

Informed Consent Document Template and Guidelines

Informed Consent Form

(name of institution)

Title of Project: *(complete title of the project as it appears on the protocol and abstract)*

Principal Investigator: *(only one person may be named as principal investigator)*

Other Investigators:

Participant ID: _____

The Introductory Paragraph

Example Introductory Paragraph:

We invite you to take part in a research study *(title*) at *(location/institution*), which seeks to identify a more effective means of treating *(illness, condition*). Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate you must sign this form to show that you want to take part.

(*Note Common Rule requirement that Key Information essential to the decision to participate be presented first in the document and consent discussion*)

Some of the essential information you will need to make the decision whether or not to participate in the research study has been outlined below.

Approximately *(number)* people will take part in this research *(nationwide or worldwide)* and about *(number)* people are expected to take part at *(your institution)*.

If you decide to take part in this study your participation will last (*number of years/months*)

Section 1. Purpose of the Research

You have a history of headaches that have recurred for at least a year (or more). This has led to a diagnosis of migraines. We are doing research on a new drug called zavegepant (zah-VEH-juh-pant). In this study, our goal is to learn if it is safe and works well to treat migraines like yours.

Section 2. Procedures

This section discusses what you'll be doing if you agree to be in this study.

First in-person screening visit

At this visit, you'll sign this consent form. Next, we will ask about your migraines and medical history. If you are taking any medications or supplements, we'll need to know what they are. To learn about your current state of health, we will also perform medical exams. We will:

- Check inside your nose because the study drug will be inhaled
- Check your vital signs, like blood pressure, heartrate, temperature, and so on
- Take a blood sample to check your cholesterol, blood sugar, liver health, and so on
- Note your weight and height
- Ask for a sample of urine
- Give you a pregnancy test (for persons that were assigned female at birth)
- Check the health of your heart using a medical device called an ECG (no needles involved)
- Ask you about your mood and feelings

Randomization in-person visit

Randomization just means by chance, like flipping a coin. In this study, we will compare zavegepant's effect on migraines to that of a placebo. A placebo is a harmless substance that looks like the study drug but has none of the drug in it. Using a placebo helps researchers to assess if the new drug really works.

At this visit, a computer will choose if you will receive the study drug or the placebo. You have a fifty-fifty chance of getting the study drug. Once that's done, you will get:

- A handheld electronic diary. We'll explain how to use it.
- An Aptar UDS device; this is your inhaler device. We'll explain how to use that, too.
- One dose of the study drug or placebo for you to take home with you and use within the next 45 days. You will only take this dose if you have a headache that is **moderate** or **severe**.

End of treatment visit

You must return to the clinic for a final visit. We will perform the same exams that we did at your screening visit. These exams help us to understand what effect, if any, the study drug or placebo has had on your health.

How soon you come back depends on when or if you have used the dose we gave you. Did you use the dose within 45 days of receiving it?

- Yes. Return to the clinic within 7 days of using the dose. You must bring back your diary and Aptar device.

- No. Return to the clinic on day 46. You must bring back your diary, Aptar device, and study dose.

Section 3. Time Duration of the Procedures and Study

If you take part in this study, it lasts for about 11 weeks, broken down into three phases.

- Screening – 28 days. This is how long it will take us to find enough people who agree to be in the study. Your screening visit will last for about 3 hours.
- Treatment – 45 days. You go about your normal daily routine during this time.
- End of treatment – 7 days. Your actual visit will last for about 3 hours.

Section 4. Discomforts and Risks

You will not receive the results of the tests and exams you will undergo as part of this research study.

You may choose not to participate in this study due to the potential risks outlined below.

Example of a Discomforts and Risk Section for a Drug Study:

While in this study, you are at risk for side effects. Most of them are below, but they will vary from person to person. Many side effects go away after you stop taking the drug. In some cases, the side effects may be serious or lasting.

Zavegepant side effects.

More likely and mild:

- Headache
- Altered tastes, with all foods tasting metallic, sour, sweet, or bitter
- Dizziness
- Stuffy nose
- Back pain

Less likely:

- A blood clot forms in a blood vessel (vein or artery), blocking blood flow. This might threaten your life.
- Vertigo (feels like you're spinning) and feeling off balance

Important If you get the placebo (that has no drug in it), your symptoms or condition may get worse or not improve.

Other Possible Risks Associated With Participating in This Study

- Pain when drawing blood. This includes temporary pain from the needle stick. Also, bruising and bleeding might occur. Infection is rare, but possible.

Pregnancy Risks

There may be side effects or pains that we cannot predict, especially to a fetus or embryo. The drug in this study may affect an unborn baby. Because of this, you

should not become pregnant or father a baby while in this study. Your doctor will discuss this with you. Also, avoid breastfeeding a baby while in this study.

Section 5. Potential Benefits

Possible benefits to you

While we make no promises, you might benefit from being in this study as follows:

- Get pain relief from a severe to moderate migraine 2 hours after taking the dose. That relief might last for up to 2 days (48 hours)
- Get relief from nausea and light and sound sensitivity 2 hours after taking the dose
- Return to your normal routine within 30 minutes of taking the dose

In addition to the above, you will get:

- A free dose of the study drug or placebo
- Free medical exams

Possible benefits to others:

Migraines can reduce the quality of life for about 15% of adults. For those who have existing heart issues, using current migraine drugs comes with risks. Zavegepant works in a new way to relieve migraines while reducing the risks for the heart. This study will help researchers learn more about this new form of migraine treatment.

Section 6. Statement of Confidentiality

This section is required in all informed consent forms. This section must outline how all confidential information and or materials will be treated, stored, and maintained and for what lengths of time, as well as how materials will be disposed of at the end of the study period. Privacy and confidentiality measures must be addressed in this section.

This section must also include a statement containing the following language:

"A description of this clinical trial will be available on 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 the web site at any time".

6a. Privacy and confidentiality measures

Example Statement of Confidentiality:

Your research records that are reviewed, stored, and analyzed at *(your institution)* will be kept in a secured area in (*list where records are stored*). (*Include the following if specimens are collected for research purposes*) Your samples collected for research purposes will be labeled with (*list all that apply: a code number, your*

initials, etc.) and will be stored *(list where the samples will be stored and how they are secured).*

(For research records/samples that are sent outside of your institution, describe methods that will be used to ensure confidentiality. If records and specimens are sent to different entities or labeled differently, describe their confidentiality measures separately). For research records (and specimens) sent to (outside entity), you will not be identified by name, social security number, address or phone number. The records (and specimens) may include (list all that apply: a code number, your initials, date of birth, etc.). The list that matches your name with the code number will be kept in a locked file in (note location, such as PI's office).

OR

For research records (and specimens) sent to (outside entity), you will be identified by (list all that apply: name, social security number, address, phone number, date of birth, any other direct personal identifier, code number). The list that matches your name with the code number will be kept in a locked file in (note location, such as PI's office).

(Remember to include separate descriptions for records and specimens if they are labeled differently or stored differently or sent to separate entities.)

The following statement is considered mandatory for all research studies:

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

The following statement is for those studies that do not include section 6b.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, the following people/groups may inspect and copy records pertaining to this research.

The Office of Human Research Protections in the U. S. Department of Health and Human Services *(for drug/device studies, add the U.S. Food and Drug Administration)*

- The (your institution) Institutional Review Board (a committee that reviews and approves research studies) and
- The *(your institution)* Human Subjects Protection Office
- The National Institute on Aging, the funding agency, and its authorized representatives

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

(As applicable a statement that)

Your identifiers might be removed from the information obtained as part of this research study. This un-identifiable information may be used for future research studies or shared

with another investigator for future research studies without additional informed consent from you.

OR

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

For research involving biospecimens, a statement whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

(As applicable a statement that)

Your de-identified biospecimens obtained as part of this research study may be used for commercial profit. This commercial profit (will/will not) be shared with you.

6b. The use of private health information:

- *Section 6b is mandatory if the research creates, obtains, uses, and/or discloses identifiable health information about the research participants. The 18 identifiers are listed under HIPAA regulations.*
- *Do not include any part of Section 6b unless the research fits the above criteria.*

Example Statement of Use of Private Health Information:

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law as explained in the *(your institution)* Privacy Notice. If you have not received this notice, please request a copy from the investigator. At *(your institution)* your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research, you must allow the study team to use your health information. If you do not want us to use your protected health information, you may not participate in this study. *(When specific therapy is only available through the research, include these sentences:* The research-related therapy is investigational; therefore, it is not available unless you allow the use of your health information that is collected during this research study.*)*

(For blinded studies) People usually have a right to access their medical records. However, while the research is in progress, you may not be allowed to see or copy certain information that is related to this research study. This is only for the period of the research. You will be allowed to see that information when the entire research project is complete.

Your permission for the use, retention, and sharing of your identifiable health information will (*Describe the date or event that will trigger the expiration of this authorization e.g., "expire upon completion of the research study" or "expire when FDA approval of the study drug is obtained" or "will continue for the period of time necessary for the preparation of a related follow-up research study" or "continue indefinitely" or "will continue until the NIA notifies the investigator that the information is no longer*

needed."). At that time the research information not already in your medical record will be destroyed (*or "will be retained until (date) in order to (reason)" or "information identifying you will be removed from such research results at (your institution)").* Any research information in your medical record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information *(if applicable, add:* and your samples*)* at any time. You must do this in writing. Write to Dr*. (PI)* and let *(him/her)* know that you are withdrawing from the research study. *(His/Her)* mailing address is *(address)*.

If you withdraw your permission:

- We will no longer use or share medical information about you *(if applicable, add the following:* or your samples) for this research study, except when the law allows us to do so.
- We are unable to take back anything we have already done or any information we have already shared with your permission.
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information.

- *(List any and all medical information collected from or about the participant in connection with this research study, e.g. blood and other tissue samples and related tests, your medical history as it relates to the research study, x-rays, MRIs, questionnaires, etc.)*
- *Indicate the span of time from which the records are pulled, e.g., "since your diabetes was diagnosed", "the last five years", "only during the time span of the research study".)*

Representatives of the following people/groups within *(your institution)* may use your health information and share it with other specific groups in connection with this research study.

- The principal investigator, (*PI name*)
- The *(your institution)* Institutional Review Board
- The *(your institution)* Human Subjects Protection Office
- *(If using the Investigational Drug Pharmacy)* The *(your institution)* Pharmacy
- *(If applicable)* The *(your institution)* Financial Analyst for Clinical Research
- *(List every other class of persons or group affiliated with (your institution) (e.g., the research team, the study coordinators, etc.) who might need to use and/or disclose the participant's information in connection with this study.)*

The above people/groups may share your health information with the following people/groups outside *(your institution)* for their use in connection with this research

study. These groups, while monitoring the research study, may also review and/or copy your original *(your institution)* records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- *(List every other class of persons or group NOT affiliated with your institution (e.g. fellow researchers in this study at (list other institutions), outside data analysts appointed for this study, the Data Safety Monitoring Board appointed for this study, the National Institutes of Health, the Food and Drug Administration, etc., to whom the participant's information might be disclosed.)*
- *(If the study is international)* Representatives from regulatory agencies in other countries may also review your research record, including research-related medical reports and information, along with the NIA and/or the FDA.

Section 7. Costs for Participation

7a. Costs:

- *If there are costs to the participant that may result from participation in the research, include a statement describing any additional costs associated with study participation.*

7b. Treatment and compensation for injury:

- *Include your institution's mandatory wording for treatment for injury (see below).*

Example Cost for Participation Section:

(If there is no risk of physical injury to the participant, do not include this section.) Every effort to prevent injury as a result of your participation will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury.

Add, as a separate paragraph, one of the following statements regarding payment for direct costs of treating research-related injuries.

(If the institution will cover all costs of research-related injuries but did not provide consent form wording, include this statement as a separate paragraph) If complications or injuries occur that are the result of a medication, procedure or test required for this study, the *institution (include the names)* will reimburse the standard charges for the treatment of these complications or injuries. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

OR

(If the (investigator institution) will cover costs of research-related injuries not covered by the participant's insurance carrier but did not provide consent form wording, include this statement as a separate paragraph) If complications or injuries occur that are the

result of a medication, procedure or test required for this study, the *investigator*, *(include the name of institution if appropriate)* will reimburse the standard charges for the treatment of these complications or injuries, provided these charges have not been reimbursed by your non-governmental medical insurance or other third party. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

OR

(If the investigator institution has not agreed to cover costs of research-related injuries, include this statement as a separate paragraph) Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance, they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay.

(End this section with the following statement) You will not lose any legal rights by signing this form.

Section 8. Compensation for Participation

This section is required in all research studies. It should clearly describe any monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.).

Example of Compensation for Participation Section:

You will be given $(dollar amount) on each visit to compensate you for time and expenses for participating in this study.

(If participants do not receive any reimbursement for participation) You will not receive any compensation for being in this research study.

Section 9. Research Funding

- *Funding disclosure: Disclose what grantors, institution(s) (e.g., NIA) or companies are involved in the research through funding or grants. If none, say so.*
- *Conflict of Interest: Include information about any consultative or financial relationships the investigators may have with the NIA.*

Example Research Funding Section:

The institution and investigators are receiving a grant from *NIA (list any other grantors)* to support this research.

(For funding disclosure) The institution will be reimbursed by the NIA for use of this site's facilities and for the work the research staff does for this research.

Section 10. Voluntary Participation

Example Voluntary Participation Section:

Taking part in this research study is voluntary. If you choose to take part in this research, your major responsibilities will include (*Briefly list major responsibilities. NOTE: Do not include this sentence if there are no major responsibilities for the*

participant). You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

(Optional, if appropriate) Your investigator may take you out of the research study without your permission. Some possible reasons for this are: *(list possible reasons, for example: you did not follow the study instructions, etc.)*. Also, the NIA may end the research study early. If your participation in the research ends early, you may be asked to visit the investigator for a final visit.

(Optional, if appropriate) (For clinical studies) If you will be participating in another clinical trial at [Institution] or elsewhere while in this research, you should discuss the procedures and/or treatments with your physician or the investigators. This precaution is intended to protect you from possible side effects from interactions of research drugs, treatments or testing.

(Optional, if appropriate) During the course of the research you will be provided with any significant new findings that may affect your willingness to continue participating in this research.

Section 11. Contact Information for Questions or Concerns

- *Clarify the participant's right to have questions answered.*
- *Indicate whom to contact in case of further questions about the research or to report a research-related injury.*
- *Indicate contact information for questions about participant rights and privacy issues.*

Example Contact Information for Questions or Concerns Section:

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have developed an injury related to this research, contact *(Principal Investigator)* at *(phone number)*. *(If clinical protocol, add the next phrase)* or the *(study)* doctor on 24-hour call at *(phone number).*

(All informed consent forms should include this paragraph). If you have questions regarding your rights as a research participant or you have concerns or general questions about the research *(add the next phrase if using identifiable health information:* or about your privacy and the use of your personal health information*)*, contact the research subjects protection advocate in the *(your institution's)* Subjects Protection Office at *(phone number)*. You may also call this number if you cannot reach the research team or wish to talk to someone else.

For more information about participation in a research study and about the Institutional Review Board (IRB), a group of people who review the research to protect your rights, please visit the *(your institution's)* IRB's web site at *(website)*. Included on this web site, under the heading "Participant Info", you can access federal regulations and information about the protection of human research participants. If you do not have access to the internet, copies of these federal regulations are available by calling the *(your institution)* at *(phone number)*.

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

[Signature of participant]	[date]	[time]	[print name]
Signature of Participant	Date	Time	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you give permission for the participant to take part in this research.

[Signature of participant]	[date]	[time]	[print name]
Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative's Authority to Act for Participant:

[Description of the authority]

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

[Signature of participant]	[date]	[time]	[print name]
Signature of person who explained this research	Date	Time	Printed Name

Only approved investigators for this research may explain the research and obtain informed consent.

A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.

INSTRUCTIONS: The following applies to optional parts of the research only, e.g., storage of leftover tissue for future research, optional sub-studies, etc.

In addition to the main part of the research study, there is an optional part of the research. You can participate in the main part of the research without agreeing to take part in this optional part.

(For research involving optional storage of tissue for future research) Optional Tissue Storage for Future Use

As part of this study, we are obtaining (*tissue and/or blood and/or cells)* from you. If you agree, the (*researchers)* would like to store leftover sample(*s)* of your (*tissue and/or blood and/or cells)* so that your (*tissue and/or blood and/or cells)* can be studied in the future after this study is over. *(Add the following statement if storage is optional)* These future studies may provide additional information that will be helpful in understanding [disease/condition], but it is unlikely that these studies will have a direct benefit to you. The results of these tests will not have an effect on your care. Neither the investigator nor you will receive results of these future research tests, nor will the results be put in your health record. Sometimes tissue is used for genetic research about diseases that are passed on in families. Even if your sample(*s)* (*is/are)* used for this kind of research, the results will not be put in your health records. It is possible that your (*tissue and/or blood and/or cells)* might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur. If you have any questions, you should contact (*PI name)* at (*phone number)*.

(For linked samples) Your leftover samples will be labeled with (*list all that apply: "a code number", "your initials", etc.)*. These samples will be stored (*describe how the samples will be secured: "Dr. (PI's name)'s locked laboratory)* at (sample location). If you consent to the collection of samples of your (source of sample) (*e.g., blood, tissue, bone marrow)* for future research, the period for the use of the samples is unknown. If you agree to allow your (*tissue and/or blood and/or cells)* to be kept for future research, you will be free to change your mind at any time. You should contact (*PI name)* at (*phone number)* and let (*him/her)* know you wish to withdraw your permission for your (*tissue and/or blood and/or cells)* to be used for future research. Any unused (*tissue and/or blood and/or cells)* will be destroyed and not used for future research studies.

(For unlinked samples) Your samples will not be labeled with any of your personal information, such as your name or a code number. Once you give your permission to have your leftover samples stored, they will be available for use in future research studies indefinitely and cannot be removed due to the inability to identify them.

(Add the following tissue options or variations if storage is optional) You should initial below to indicate your preferences regarding the optional storage of your leftover (*tissue and/or blood and/or cells)* for future research studies.

a. Your sample*(s)* may be stored and used for future research studies to learn about, prevent, treat or cure *(disease/condition)*.

   ____ Yes ____ No

b. Your sample[s] may be stored and used for research about other health problems.

   ____ Yes ____ No

c. Your sample*(s)* may be shared with other investigator/groups without any identifying information.

____ Yes ____ No

Participant: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

[Signature of participant]	[date]	[time]	[print name]
Signature of Participant	Date	Time	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

[Signature of participant]	[date]	[time]	[print name]
Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative's Authority to Act for Participant:

[Description of the authority]

Person Explaining the Research: Your signature below means that you have explained the optional part of the research to the participant/participant representative and have answered any questions he/she has about the research.

[Signature of participant]	[date]	[time]	[print name]
Signature of person who explained this research	Date	Time	Printed Name

This document was created using the following resources:

CTN Best Practices

- Informed Consent Discussion Documentation
- Informed Consent Document Template and Instructions

Fuller Theological Seminary Graduate School of Psychology

- Informed Consent Template

National Cancer Institute

- Informed Consent Template for Cancer Treatment Trials (English Language)
- Learn about Clinical Trials – Informed Consent

SAMPLE HIPAA AUTHORIZATION LANGUAGE

Authorization to Use or Disclose (Release) Health Information that Identifies You for the Research Study

REQUIRED ELEMENTS:
If you sign this document, you give permission to the study doctor and research team at [Study Institution] to use or disclose (release) your health information that identifies you for the research study.

The health information that we may use or disclose (release) for this research includes:

- Name
- Address
- Phone number
- Date of birth
- Medical history
- Data collected during your participation in study visits, including all test results
- ***[Customize based on the information to be used or disclosed for the research study]***

The health information listed above may be used by and/or disclosed (released) to the following authorized users:

- Representatives of The National Institute on Aging, the funding agency, and its authorized representatives
- Representatives of ***[CRO name]***.
- Representatives of ***[IRB name]*** (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research, if applicable.
- A data safety monitoring board which oversees this research, if applicable.
- ***[Customize based on the design of the research study]***

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Please note that:

- You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.
  You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the study team may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to: [name of the Study PI) and contact information].
  This Authorization does not have an expiration date [or as appropriate, insert expiration date or event, such as "end of the research study."]

_____	_____
Signature of participant or participant's personal representative	Date
_____	_____
Printed name of participant or participant's personal representative	If applicable, a description of the personal representative's authority to sign for the participant

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OPTIONAL ELEMENTS:

Examples of optional elements that may be relevant to the recipient of the protected health information:

- Your health information will be used or disclosed when required by law.
- Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions.
- No publication or public presentation about the research described above will reveal your identity without another authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.
- **When the research for which the use or disclosure is made involves treatment and is conducted by a covered entity:** To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that [name of the covered entity] maintains in a designated record set, which means a set of data that includes medical information or billing records

used in whole or in part by your doctors or other health care providers at [name of the covered entity] to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by [name of covered entity]. If it is necessary for your care, your health information will be provided to you or your physician.

- If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

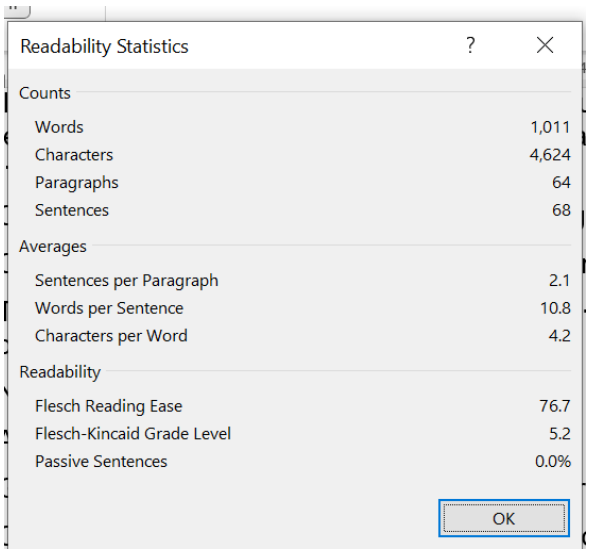
  This document was created based on the NIH HIPAA Authorization for Research: https://privacyruleandresearch.nih.gov/authorization.asp

Discussion of the protocol to ICF process

- What did you find particularly easy or difficult about translating each section? It was difficult to find out if participants would get the results of their screening visits. Adverse events weren't in section 8, like I expected. Instead, I found them in the Summary of Clinical Experience. My background writing at grade levels 8 to 11 made this a relatively easy process. I really enjoyed this and would love to specialize in this kind of medical writing.

- Which techniques of plain-language writing did you use in developing your ICF excerpt?
    - Write shorter sentences
    - Avoid words with three or more syllables when possible
    - Use simpler terms for medical conditions
    - Aim for a conversational tone
    - Have one main idea per sentence
    - Use lists if needed

- How did your ICF excerpt score on the Flesch-Kincaid scale? Reading Ease: 76.7. Grade Level: 5.2. Do you feel that this score accurately reflects the readability of your writing? Yes.



- Did this assignment give you any new insight into the experiences of potential clinical trial participants? It heightened my empathy, which made me think of adding a pronunciation aid for the drug name. Also, my admiration increased for those who choose to take the risks. Society owes them a huge debt.