**ATRIUM HEALTH**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

*This template is for studies approved on/after January 21, 2019 to comply with the revised Common Rule.*

***This page is for instructions – do not include this page in consent***.

*Instructions*

*Use* ***12-point font size*** *throughout consent*

*Only double space between sections.*

*All consent form pages must have a* ***bottom margin of 2 inches****; the blank space is for the addressograph. This format is required by Medical Records.*

*Section headers should be bolded, but not text in the section. The information in this template to be included in the consent is bolded, but should not be bolded in the actual consent*.

*[Enter with header format*

*[abbreviated study title on each page except not on 1st page]*

*[date written, or revision date*]

[*expiration date, or day before anniversary of approval or most recent continuing review*]

Page 1 of *[insert # ]*

**ATRIUM HEALTH**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

***[title of study]***

**INTRODUCTION**

*This section needs to contain key information about the study. Regulations state that the information must not be a list of facts. Instead, it should be focused and clear, written in conversational language so that after reading this section, a potential subject can make an informed decision to participate and proceed with the rest of the consent, or to not participate. COPY AND PASTING FROM THE WRITTEN STUDY PROTOCOL WILL NOT BE ACCEPTED.*

*Start with this:*

**Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is asking you to participate in this research study of (test article-drug, device, or treatment plan) at (dept/ practice) and Atrium Health (AH). You are being asked to take part because you have \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The purpose of this study is** *(short statement of purpose[s] and the research question(s).*

*Clearly state any information about what is investigational and if applicable, state:* **not Food and Drug Administration (FDA) approved at this time.**

*Continue with (but does not have to be in this order):*

* *The procedures involved (study drug/device, blood draws, CT Scans, office visits, how long they will be in the study)*
* *Describe randomization/placebo (and what a placebo is) if applicable*
* *How this research and procedures differ from the standard of care*
* *The most common risks. If applicable, include here any risks to pregnant women, embryo, fetus, nursing child, or children in general of study involves children (details on risks will be listed below in the body of the consent)*
* *State if there are known benefits to participation (do not include stipend)benefits MUST be factual and not exert any undue influence. Or, state that there are no known benefits*
* *A statement regarding alternatives available (list actual alternatives available in the body of consent below)*
* *Describe/give examples of what information about the subject will be collected for this research (more details below in Confidentiality section)*
* *Describe any costs the subject may have to pay*
* *Expected number of participants*
* *State that participation is completely voluntary*

*On each page*

*[Date of edition or revision:]* Date: \_\_/\_\_/\_\_\_

(*day before anniversary of approval or most recent continuing review*] Expiration: \_\_/\_\_/\_\_\_

Page 1 of \_\_\_

*If there is a sample storage (blood/tissue) section within this section or as a separate section, think of these things:*

* + *Does it say what samples will be used for?*
	+ *Where are they stored?*
	+ *Does it say if samples are identified or de-identified (confidential or anonymous) – linked or not linked?*
	+ *Will someone be contacting the subject – for what - who and why contacting?*
	+ *What happens to the samples if consent is withdrawn?*
	+ *Is language needed for rights in relation to product development from the samples?*

***Incorporate tissue consent if study is only for that purpose.***

***NOTE: The Introduction/Key information section satisfies many of the required elements of informed consent, these elements do not need to be repeated here unless otherwise noted.***

**ADDITIONAL/MORE DETAILED INFORMATION**

**SUBJECT RESPONSIBILITIES/EXPECTATIONS**

*List in bullet format what is expected of the subject. For example, follow instructions of Investigator and study staff, keep appointments, take medication as directed, keep diary as directed, tell Investigator/study staff of any side effects, etc.*

**RISKS**

*If the study is a randomized drug or device study, adapt the following language*:

**The study has several risks. First, you may be in the placebo (inactive medicine) group and have no active medicine for your condition for *(length of time).* Second, it is possible that you will get the new treatment but do less well than you have been doing. Third, because the treatment is new, we may not yet know all the side effects: something unexpected could happen. The known side effects are:**

*Inform the subject of all foreseeable risks and discomforts, such as expected and possibly rare side effects. There should be a clear itemization in the consent form of types of adverse experiences, the relative severities, and the expected frequencies.*

*For consistency of definition, Risks and side effects related to the [procedures, drugs, interventions, devices] separate out by severity. OK to use percentages, or Common, or Likely*

*Notes for consent form authors regarding the presentation of risks and side effects:*

* *Using a bulleted format, list risks and side effects related to the investigational aspects of the trial. Side effects of supportive medications should not be listed unless they are mandated by the study or may amplify the risks of the investigational agent(s).*
* *Side effects that occur in less than 2-3% of patients do not have to be listed unless they are serious, and should then appear in the “rare but serious” category.*
* *Physical and nonphysical risks and side effects should include such things as the inability to work.*

***Whenever possible, describe side effects by how they make a patient feel, for example, “Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath.” Side effects need to be described or defined in as simple of terms as possible. Include symptoms if appropriate. Consider whether or not patient would be calling with every symptom****.*

* *For some investigational drugs/interventions/devices there may be side effects that have been noted during treatment however not enough data is available to determine if the side effect is related to the drug/intervention/device. Because the AH IRB needs to be informed of these possible side effects, this information, when available, is provided to the study chair. Inclusion of this information in the informed consent document is not mandatory. However, if included, these side effects should be listed under a separate category titled “Side effects reported by patients, but not proven to be caused by (drug/intervention/device)”. and should not be repeated here if they appear in a previous category. Similar to the other categories, these side effects should be listed in a bulleted format.*

*Where allergic reaction is a potential, as in all drug studies, use the following language*:

**As with all medications, side effects may include allergic reaction. Allergic reactions may range from minor itching or rash to major reactions which can result in death.**

*To cover blood drawing, use the following language*:

**Risks associated with blood drawing may include discomfort, pain, bruising, and infection.**

*If there is risk posed by reproduction or sexual activity during treatment, this should be disclosed in the RISKS section of the consent form.* This may be listed under RISKS with its own separate section –

**Reproductive Risks**

*Add risk to fetus if pregnancy is an exclusion criteria.*

*If placebo assignment poses any risk, that risk (not treating the condition) must be disclosed.*

*If the study is blinded, adapt the following language:*

**If you have problems that might be related to the (drug) (device) (treatment), your doctor may "break the code" to find out which group you are in. You would then no longer be in the study, [but you would still get $ per visit for the appointments you have kept].**

**EXCLUSION CRITERIA**

*Make a bulleted list of the exclusion criteria from the protocol. Emphasize conditions of which the investigator may not be aware, to allow appropriate self-exclusion by the subject; e.g., drug allergies, pregnancy, breast feeding, past medical history, etc. For brevity, do not list results of screening exams of which the investigator will be aware.*

**ADDITIONAL COST**

*List any drug, device, test, examination, etc., that may be free of charge.*

*Will company pay if insurance doesn’t.*

*If applicable, use the following language:*

**Your insurance company may not pay for research treatments. You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.**

**COMPENSATION**

*For research involving more than minimal risk, use the following language:*

**In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner.**

*If study sponsor has included language for payment of uninsured expenses, add this language****.*** *However, compensation language should not be exculpatory or imply any waiver of legal rights.*

**You do not waive any legal rights by signing this consent form.**

*Use “no other compensation” rather than specifics as lost wages.*

*Many companies now adding “will pay if follow guidelines, take med correctly, etc”. The AH IRB will not allow this language.*

*Payment to subjects for participating in research studies, but exercise caution to avoid any suggestion of coercion or undue influence. It is in violation of FDA standards to make the entire payment contingent upon completion of the study.*

*If the research subjects will receive any sort of stipend the following language must be added to the Compensation section verbatim. There are 2 choices, choose appropriate language.*

As a participant in the study, you will receive a stipend for each regularly scheduled study visit that you complete as allowed in the study. You will be paid for study visits that you complete, even if you do not complete the overall study.

Greenphire is a company working together with Atrium Health (AH) to manage the study participant payment process. You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto at the completion of each study visit. When a visit is completed, funds will be approved and loaded onto your card.  The funds will be available within 2 business days and can be used at your discretion.  You will be issued one card for the duration of your participation.

In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you, including;

***name***

***address***

***date*** ***of*** ***birth***

***email*** ***address (optional)***

***SSN***

***W9 or W8***.

All information is stored in a secure fashion on Greenphire’s system.  Your information will not be shared with any third parties and will be kept completely confidential.

**Federal Regulations about payment of research subjects require that you fill out a form called a W-9 form. The W-9 is a tax form that asks for information including your name and Social Security number.**

**Choosing to complete a W-9 is up to you. If you decide you do not want to complete a W-9 form, you can still be in this study. Choosing not to fill out a W-9 will not harm your relationship with your doctor or Atrium Health.**

**But if you choose not to complete the W-9 form, you cannot receive any payment.**

**OR**

As a participant in the study, you will be paid for stipends and reimbursed for expenses as allowed in the study.  You will be paid stipends and reimbursed for expenses as allowed in the study associated with study visits that you complete, even if you do not complete the overall study.

Greenphire is a company working together with Atrium Health (AH) to manage the stipend and allowable expense reimbursement process. You will be issued a Greenphire ClinCard, which is a debit card that will receive funds associated with your participation in the study. Funds can be loaded for two purposes:

1. **Planned Visit Stipends:** When a planned study visit and/or milestone is completed that is associated with a patient stipend, funds will be loaded onto your ClinCard within 2 business days of the completed visit or milestone.
2. **Allowable Expenses and Unplanned Visit Stipends:** When you have incurred allowable expenses for participation in the study, or are due unplanned visit stipends, these expenses will be reviewed for approval. Once approved, funds will be loaded onto your ClinCard within 2 business days.

All funds loaded onto your ClinCard can be used at your discretion.  You will be issued one card for the duration of your participation.

In order to load funds via the ClinCard, certain information about you is required, including;

***name***

***address***

***date*** ***of*** ***birth***

***email*** ***address***. (optional)

**W9 or W8**

**SSN**

All information is stored in a secure fashion on Greenphire’s system. Your information will not be shared with any third parties and will be kept completely confidential.

**Federal Regulations about payment of research subjects require that you fill out a form called a W-9 form. The W-9 is a tax form that asks for information including your name and Social Security number.**

**Choosing to complete a W-9 is up to you. If you decide you do not want to complete a W-9 form, you can still be in this study. Choosing not to fill out a W-9 will not harm your relationship with your doctor or Atrium Health.**

**But if you choose not to complete the W-9 form, you cannot receive any payment.**

**WITHDRAWAL**

*Use the following language:*

**Your participation in this study is completely voluntary. You should feel not feel pressured to be a part of this study. If you decide not to be in the study, this will not harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.**

*If there is storage of any samples (blood, tissue) be sure it is stated here or in the section where they are being asked to consent to storage, what will happen to samples if they withdraw from the study.*

*State any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. State the medical consequences of a subject's decision to withdraw from the research.*

*Use the following language:*

**We will tell you about new medical findings that may affect your willingness to continue in the study.**

**CONFIDENTIALITY**

*Use the following language: [insert appropriate information]the FDA/other government agencies language may not be altered:*

**The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied (***by the drug/device manufacturer if applicable,***) by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.**

*If you wish to collect the subject’s email address or phone # for text messages, place the request here with a space to write email address.*

*For Email address, you must include this statement:*

*For text messages, you must include this statement*

*This statement below is required in informed consent documents for applicable clinical trials involving drugs, biological products or medical devices, or a combination thereof. It cannot be altered or placed on a separate page. It cannot go in the Authorization section.*

**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 this Web site at any time.**

*BELOW ARE NEW REQUIRED ELEMENTS IF APPLICABLE*

*For research that involves the collection of identifiable private information or identifiable biospecimens, include 1 of the following statements:*

* *A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.*
* *OR*
* *A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.*
* *NEW ADDITIONAL ELEMENTS (include if applicable)*
* *Commercial profit: A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subjects will or will not share in this profit.*
* *Clinically relevant results: A statement whether clinically relevant research results, including individual research results, will be disclosed to subject and, if so, under what conditions.*
* *Genome sequencing: For research involving biospecimens, 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).*

***Certificate of Confidentiality***

*See section 2.2 of AH IRB Policy and Procedure Manual*

*Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH) and other DHHS agencies to protect identifiable research information from forced or compelled disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in civil, criminal, administrative, legislative, or other proceedings, whether federal, state, or local.*

*Effective October 1, 2017 a CoC will be issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after December 13, 2016*

* *The CoC will be issued as a term and condition of award*
* *There will be no physical certificate issued*

*For examples of Certificate of Confidentiality informed consent language, follow this link.*

[*https://humansubjects.nih.gov/coc/suggested-consent-language*](https://humansubjects.nih.gov/coc/suggested-consent-language)

*Text or Email*

*Some studies request an email address or mobile number for text messaging.*

*These forms of communication should contain only the minimum necessary PHI.*

*Use this language when requesting email address or text message communications.*

TEXT MESSAGE COMMUNICATION. I authorize Atrium Health and its representatives (including third-party agents if applicable) to contact me by text at the number I provided. I understand that I am responsible for the standard text message rate of my carrier. Texting is not to be used for emergency situations.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium

Health and its representative (including third-party agents if applicable) to send me information, reminders, and messages using this means of communication. I authorize Atrium Health to send me unencrypted messages using this means of communication, and I understand and accept the risks associated with doing so. Email is not to be used for emergency situations.

**AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION**

 *Applicable language from below will be incorporated into all informed consent documents in order to be compliant with the Federal HIPAA guidelines for authorization. This section will also be used as Authorization for Release of Identifiable Health Information for Research Purposes. Subjects must sign this section in addition to the full informed consent document.*

If you wish to participate in this research study, you must sign this Authorization. By signing this Authorization, you **[insert participant’s name in parenthesis]** give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

**[*Insert a description of the research study, such as the title.]***

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to [*keep the applicable groups for the research study]:*

* Study investigator and research staff
* Study sponsor and/or its associated companies
* Regulatory or other governmental authorities of the United States or other countries based on this study
* Other persons or agents authorized by the study sponsor
* Atrium Health employees
* Other persons or agencies as required by law or allowed by federal regulations
* Data coordinating centers that will receive and process PHI; and/or;
* Institutional Review Boards or Data Safety and Monitoring Boards.

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the Sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to: [*Insert Principal Investigator’s physical address, phone, and fax number*].

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) 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 Atrium Health: 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 study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by the you in writing as described above.

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

**Signature of participant or participant’s Legally Authorized Representative**

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

**Printed name of participant or participant’s Legally Authorized Representative**

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

**Date**

**FINANCIAL INTEREST OF INVESTIGATOR**

*If there is potential for conflict of interest because of payment to investigators, this must be disclosed in the consent form by inserting appropriate language from the "Typical Conflict of Interest Language" (except in the case of #4).*

**QUESTIONS**

*Use the following language:*

**The researchers doing the study at Atrium Health are Drs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. You may ask them any questions you have now. If you have questions later, you may contact Drs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at:**

**Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Atrium Health**

**1000 Blythe Boulevard**

**Charlotte, NC 28203**

**Telephone (area code) \_\_\_-\_\_\_\_**

**The Institutional Review Board is a group of people who review the research to protect your rights. If you have questions about the conduct of this study or about your rights as a research subject, you may call the chairperson of the Institutional Review Board of Atrium Health for information regarding patients' rights in a research study. You can obtain the name and number of this person by calling (704) 355-3158 or by email at:** **IRBInfo@atriumhealth.org**

*If a large white space is left on a page add:*

**(This space intentionally left blank.)**

**CONSENT**

*Use the following language:*

*We do not allow the utilization of the term “I understand” because we do not have any way of validating this.*

**I have read the above information. I have asked any questions I had, and those questions have been answered. I agree to be in this study and authorize the use of my personal health information.** *(If applicable, insert agreement to follow required birth control for female and male and any breast feeding language. Include if extends beyond study drug treatment.)***I will receive a signed copy of this form.**

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

**Patient [or Legally Authorized Representative] Date**

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

 **Print Name**

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

**Patient [or Legally Authorized Representative] Signature Date**

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

**Signature of Person Obtaining Consent Date**

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

**Print Name of Person Obtaining Consent**

*[Add a "Witness" printed name and signature when applicable.]*

**Identity of legally authorized representative (check one):**

**\_\_\_Next of Kin**

**\_\_\_Parent/Guardian**

**\_\_\_Healthcare Power of Attorney**

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