

NOTICE OF PRIVACY PRACTICES OF NULINE CLINICAL TRIAL

NOTICE EFFECTIVE DATE: NOVEMBER 1, 2025

*This Notice describes how medical information about you may be used and disclosed and how you can get access to this information. **Please review it carefully!***

ABOUT THIS NOTICE AND OUR RESPONSIBILITIES

Nuline Clinical Trial ("Nuline") is required by law to maintain the privacy and security of your Protected Health Information ("PHI") and to provide you with Notice of our legal duties and privacy practices with respect to PHI. This Notice explains how Nuline will protect, use, and share your health information. It applies to all **Protected Health Information (PHI)** we create or maintain about you. Nuline, its employees, contractors, and business associates who are involved in providing and coordinating healthcare are all bound to follow the terms of this Notice of Privacy Practices ("Notice"). For more information visit: www.hhs.gov/hipaa/for-individuals/index.html.

Nuline is required to follow the terms of this Notice or any change to it that is in effect. We reserve the right to change our practices and this Notice and to make the new Notice effective for all PHI we maintain. If we do so, the updated Notice will be available at our practice location(s) where you receive healthcare services and treatment from us and posted on Nuline's website at <https://nulineclinicaltrial.com/>. Upon request, we will provide any revised Notice to you.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION

PHI is information that may identify you and that relates to your past, present or future physical or mental health or condition, the provision of healthcare products and services to you or payment for such services. This Notice describes how we may use and disclose PHI about you, as well as how you obtain access to such PHI. This Notice also describes your rights with respect to your PHI. We are required by HIPAA to provide this Notice to you.

HOW WE MAY USE AND DISCLOSE YOUR PHI

We use and share your PHI in several ways. This Notice gives examples but does not list every permissible use or disclosure. Certain PHI types, such as HIV, genetic, substance use, and mental health records, have special privacy protections under law, which we follow. Some states also have additional privacy protections. When both federal and state privacy laws apply, and a state law provides greater protection or broader rights regarding your information we will follow the more protective state law. For more on state law protections, contact the Privacy Officer.

I. Uses and Disclosures of PHI That Do Not Require Your Prior Authorization

Except where prohibited by federal or state laws that require special privacy protections, we may use and disclose your PHI for treatment, payment and healthcare operations without your prior authorization as follows:

TPO CATEGORY	HOW INFORMATION IS USED OR DISCLOSED WITH EXAMPLES
Treatment	We may use and share your PHI to provide, coordinate, and ensure you receive necessary treatment, medications, and services. This includes disclosing information to hospitals, other pharmacies, and healthcare facilities to help manage your care and ensure all involved parties have the details needed to address your healthcare needs.

	Example: We may disclose PHI to pharmacists, doctors, nurses, technicians, and other personnel involved in your care.
Payment	<p>We may use and share your PHI to obtain payment for the healthcare products and services you receive. This includes billing you or third-party payors, with bills containing information that identifies you and details about the services or medications provided. We may also disclose your PHI to other healthcare providers or HIPAA-covered entities for their payment purposes.</p> <p>Example: We may contact your insurer, pharmacy benefit manager or other healthcare payor to determine whether it will pay for healthcare products and services you need and to determine the amount of your co-payment.</p>
Healthcare Operations	<p>PHI may be used and disclosed for healthcare operations, which involve essential activities to operate healthcare businesses. PHI may be analyzed to improve the quality and efficiency of healthcare services, such as assessing outcomes related to specific healthcare conditions. Disclosure of PHI to other HIPAA-covered entities that have provided services to the individual may occur so they can enhance their healthcare services. PHI may also be used to generate de-identified data, removing all identifiers so the data no longer relates to an identifiable individual.</p> <p>Example: We may use your PHI to monitor the performance of the staff and pharmacists providing treatment to you.</p>

How else can we use or share your health information? We are allowed or required to share your information in other ways – usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your information for these purposes. For more information see: www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html

DISCLOSURE TYPE	DESCRIPTION OF USE OR DISCLOSURE
Business Associates	We may use or share your health information with our business associates and allow them to use and share your health information when it is necessary to perform their services for us. An example of this is sharing your information with an outside billing company who bills your insurance company for us.
To Communicate With Individuals Involved in Your Care or Payment for Your Care	We may share your Protected Health Information (PHI) with family, friends, or anyone you designate if it relates to your care or payment. We also give access to your PHI to your legal personal representative, who can make healthcare decisions for you.
Public Health and Safety Issues (including FDA)	<p>We may disclose your PHI to public health or legal authorities charged with preventing or controlling disease, injury or disability, including the FDA. In certain circumstances, we may also report work-related illnesses and injuries to employers for workplace safety purposes.</p> <p>Food and Drug Administration (FDA): We may share PHI with FDA authorities regarding adverse events, product defects, or post-marketing surveillance to support recalls, repairs, or replacements.</p>
Workers' Compensation	We can use or share health information about you for workers' compensation claims.
Law Enforcement	We may disclose your PHI for law enforcement purposes as required or permitted by law; for example, in response to a subpoena or court order, in response to a request from law enforcement, and to report limited information in certain circumstances.
As Required By Law	We will disclose your PHI when required to do so by federal, state or local law.
Health Oversight Activities	We may disclose your PHI to an oversight agency for activities authorized by law. These oversight activities include audits, investigations, inspections, and

	credentialing, as necessary for licensure and for the government to monitor the healthcare system, government programs and compliance with civil rights laws.
Judicial and Administrative Proceedings	If you are involved in a lawsuit or a dispute, we may disclose your PHI in response to a court or administrative order. We may also disclose your PHI in response to a subpoena, discovery request or other lawful process instituted by someone else involved in the dispute, but only if efforts have been made, either by the requesting party or us, to first tell you about the request or to obtain an order protecting the information requested.
Research	<p>Researchers may be given limited access to your PHI remotely or on-site at Nuline so that they can develop and prepare research projects and identify patients who may potentially qualify to participate in clinical trials and/or research studies.</p> <p>Other uses or disclosures of your PHI for research purposes are permitted without authorization when your PHI is in the form of a limited data set or once an institutional review board or privacy board has reviewed the research proposal, determined whether you need to provide specific consent for the research use of your PHI and established protocols to ensure the privacy of your information, or determined that the researcher will be provided only with information that does not identify you directly.</p>
De-Identified Information	We may use your PHI to create "de-identified" information, which means that information that can be used to identify you will be removed. There are specific rules under the law about what type of information needs to be removed before information is considered de-identified. Once information has been de-identified as required by law, it is no longer subject to this Notice, and we may use it for any purpose without any further notice or compensation to you.
Coroner or Medical Examiner	We may release your PHI to coroners or medical examiners so that they can carry out their duties. This may be necessary, for example, to identify a deceased person or determine the cause of death. We may also disclose PHI to funeral directors consistent with applicable law to enable them to carry out their duties.
Organ, Eye, and Tissue Donation Organizations	Consistent with applicable law, we may disclose your PHI to organ procurement organizations or other entities engaged in the procurement, banking or transplantation of organs for the purpose of tissue donation and transplant.
Notification	We may use or disclose your PHI to notify or assist in notifying a family member, personal representative, or another person responsible for your care, regarding your location and general condition.
Disaster Relief	We may use and disclose your PHI to organizations for purposes of disaster relief efforts.
Fundraising	As permitted by applicable law, we may contact you to provide you with information about our fundraising programs. You have the right to "opt out" of receiving these communications, and such fundraising materials will explain how you may request to opt out of future communications if you do not want us to contact you further for fundraising efforts.
Correctional Institution	If you are or become an inmate of a correctional institution, we may disclose to the institution, or its agents, PHI necessary for your health and the health and safety of other individuals.
Avert Threats to Health or Safety	We may use and disclose your PHI when necessary to prevent a serious threat to your health and safety or the health and safety of the public or another person.
Military and Veterans	If you are a member of the armed forces, we may release PHI about you as required by military command authorities. We may also release PHI about foreign military personnel to the appropriate foreign military authority.

National Security, Intelligence Activities, Protective Services for the President	We may release PHI about you to federal officials for intelligence, counterintelligence, protection of the President, and other national security activities authorized by law.
Victims of Abuse or Neglect	We may disclose PHI about you to a government authority if we reasonably believe you are a victim of abuse or neglect. We will only disclose this type of information to the extent required by law, if you agree to the disclosure, or if the disclosure is allowed by law and we believe it is necessary to prevent serious harm to you or someone else.
Practice Directories	Nuline does not create or manage practice directories containing patient information that are used to inform others about a patient's location.

II. Uses and Disclosures of PHI That Require Your Prior Authorization

For certain health information, you can tell us your choices about what we share. If you have a clear preference for how we share your information in the situations described below, talk to us. Tell us what you want us to do, and we will follow your instructions.

DISCLOSURE TYPE	DESCRIPTION OF USE OR DISCLOSURE
Specific Uses or Disclosures Requiring Authorization	<p>We will obtain your written authorization for the use or disclosure of all of the following:</p> <ul style="list-style-type: none"> • Psychotherapy notes • Use or disclosure of PHI for marketing and for the sale of PHI, except in limited circumstances where applicable law allows such uses or disclosure without your authorization.
Research Publications and Presentations	Publications or presentations related to research and clinical trials conducted by Nuline will not include any information that could identify you personally unless you provide a separate, specific written authorization. Your initial authorization to participate in the research does not permit disclosure of your identity for publication purposes.
Other Uses and Disclosures	<p>We will obtain your written authorization before using or disclosing your PHI for purposes other than those described in this Notice or otherwise permitted by law.</p> <p>You may revoke an authorization in writing at any time. Upon receipt of the written revocation, we will stop using or disclosing your PHI, except to the extent that we have already taken action in reliance on the authorization.</p>

YOUR RIGHTS CONCERNING YOUR HEALTH RECORDS

When it comes to your health information, you have certain rights. This section explains your rights and some of our responsibilities to help you.

YOUR RIGHTS	DESCRIPTION & HOW TO EXERCISE YOUR RIGHTS
Obtain a paper copy of this Notice upon request.	<p>You may request a copy of our current Notice at any time. Even if you have agreed to receive the Notice electronically, you are still entitled to a paper copy.</p> <p>You may obtain a paper copy at the practice location where you obtain healthcare services from us or by contacting the Privacy Officer.</p>
Request and amendment of PHI.	If you feel that PHI we maintain about you is incomplete or incorrect, you may request that we amend it. We are not required to make all requested amendments.

	<p>To request an amendment, you must send a written request to the Privacy Officer. You must include a reason that supports your request. If we deny your request for an amendment, we will provide you with a written explanation of why we denied it.</p>
<p>Request a restriction on certain uses and disclosures of PHI.</p>	<p>You have the right to request additional restrictions on our use or disclosure of your PHI. by sending a written request to the Privacy Officer. We are not required to agree to the restrictions, except in the case where the disclosure is to a health plan for purposes of carrying out payment or healthcare operations, is not otherwise required by law, and the PHI pertains solely to a health care item or service for which you, or a person on your behalf, has paid in full.</p> <p>Certain PHI which must be used or shared for the purpose of carrying out clinical trials and research may not be restricted. In this case, you will be advised of this prior to participating in the trial and your written informed consent will be obtained.</p> <p>To request a restriction on use or disclosure, you must send a written request to the Privacy Officer with the specific information you are requesting a restriction for and to whom it should be restricted.</p>
<p>Inspect and obtain a copy of PHI.</p>	<p>To maintain the integrity of the research done during clinical trials, you will generally not have access to your PHI related to the trial until the study is complete. At the conclusion of the research and at your request, you generally will have access to your PHI that Nuline maintains in a designated record set. This includes the medical information or billing records used in whole or in part by your doctors or other health care providers at Nuline to make decisions about your diagnoses, care, and treatment.</p> <p>To inspect or obtain a copy of your PHI, you must send a written request to the Privacy Officer. If we maintain an electronic designated record set containing your PHI, you have the right to request to obtain the PHI in an electronic format if it is readily producible. You may ask us to send a copy of your PHI to other individuals or entities that you designate in writing if it clearly designates the recipient and location for delivery. We may deny your request to inspect and copy your PHI in certain limited circumstances. If you are denied access to your PHI, you have the right in certain cases to request that the denial be reviewed.</p>
<p>Receive an accounting of disclosures of PHI.</p>	<p>You can request a record of when, to whom, and why your health information was shared over the past six years, excluding disclosures for treatment, payment, healthcare operations, and certain other exceptions. One free report is provided annually; additional requests within 12 months incur a reasonable fee.</p> <p>To request an accounting of disclosures, contact the Nuline or the Privacy Officer.</p>
<p>Request communications of PHI by alternative means or at alternative locations.</p>	<p>You may ask us to communicate about health matters in a specific way or at a certain location, such as a different address or via email. Please note that email and other electronic methods may not be secure and could expose your PHI to unauthorized access.</p> <p>To request confidential communication, please send a written request to the Privacy Officer. Your request must tell us how or where you wish to be contacted. We will try to meet reasonable requests but may use your existing contact information if necessary after failing to reach you.</p>
<p>Right to choose someone to act on your behalf.</p>	<p>If you have appointed a medical power of attorney or legal guardian, that person can make decisions about your health information. We will verify their authority before acting on your behalf.</p> <p>You must provide Nuline with your signed Advance Directive, Power of Attorney, Guardianship, or another legal form that complies with state and federal law.</p>
<p>Be notified of a breach of PHI.</p>	<p>You have a right to be notified following a breach of your unsecured PHI.</p> <p>We will notify you in accordance with applicable law.</p>

**Right to file a complaint
if you feel your rights
are violated**

If you feel we have violated your rights you may file a complaint. We will not retaliate against you for doing so.

You may file a complaint with our Privacy Officer, with the U.S. Department of Health and Human Services Office for Civil Rights, or with both.

CONTACT INFORMATION

(FOR FORMS, ADDITIONAL INFORMATION, OR TO REPORT A PROBLEM)

You may obtain forms for submitting written requests by contacting Thalyta Jones, Privacy Officer at Nuline via email at tjones@nulineclinicaltrial.com or by phone at 954-464-5111. You can also visit Nuline to obtain these forms. We will respond to your written requests on a timely basis in accordance with our written policies and as required by law.

If you have questions or would like additional information about Nuline privacy practices, you may contact Thalyta Jones, Privacy Officer via email at tjones@nulineclinicaltrial.com or by phone at 954-464-5111. If you believe your privacy rights have been violated, you can file a complaint with the Privacy Officer, with the Secretary of the U.S. Department of Health and Human Services, or with both. You will not be retaliated against for filing a complaint. You can reach the U.S. Department of Health and Human Services Office for Civil Rights by calling 877-696-6775, mailing the complaint to 200 Independence Ave. S. W. Washington, D.C. 20201, or by visiting their website at www.hhs.gov/ocr/privacy/hipaa/complaints/.

NOTICE OF NONDISCRIMINATION

Our Commitment to Equal Care

Nuline respects the rights and dignity of every person. In keeping with federal civil rights laws, we do not discriminate or treat anyone differently based on race, color, religion, national origin, ancestry, age, disability, sex, gender identity, sexual orientation, marital or family status, military service, political beliefs, or parental status.

Accessible Communication and Language Support

To ensure that everyone can access and understand our services, Nuline provides the following free of charge:

- Assistance for individuals with disabilities, such as qualified sign language interpreters and written materials in alternative formats (large print, Braille, audio, or other formats as needed).
- Language assistance for individuals with limited English proficiency, including

qualified interpreters and translated documents.

If you need any of these services, please contact Thalyta Jones at 954-464-5111 or by email at tjones@nulineclinicaltrial.com.

How to Report a Concern

If you believe Nuline has discriminated against you or failed to provide necessary communication assistance, you can file a grievance with the Compliance Officer and/or Privacy Officer using the contact information below.

If you need help filing a grievance, the Compliance or Privacy Officer can assist you throughout the process.

How to File a Civil Rights Complaint

You may also file a complaint directly with the U.S. Department of Health and Human Services, Office for Civil Rights (OCR) using the contact information below.

Contact Information

Nuline

Thalyta Jones
Privacy/Compliance Officer

1311 E. Atlantic Blvd.
Pompano Beach, FL 33060

Phone: 954-464-5111

Email: tjones@nulineclinicaltrial.com

U.S. Department of Health and Human Services

Office for Civil Rights

200 Independence Avenue, SW
Room 509F, HHH Building
Washington, DC 20201

By Phone: 1-800-368-1019 **TDD:** 1-800-537-7697

Online: ocrportal.hhs.gov/ocr/portal/lobby.jsf

Complaint Form: www.hhs.gov/ocr/office/file