



PATIENT TREATMENT FORM

EV-PURE+ / Exosome-Related Service Disclosure and Consent

Product-specific information, patient requirements, and acknowledgment of the proposed service

Patient legal name:	Date of birth:
Preferred phone:	Date of form:

Purpose and Your Individual Treatment Decision

This consent applies only to the treatment identified in this document and your completed treatment plan. Before you sign, PHO will identify the proposed service, responsible professional, clinical purpose, treatment area or route, expected course, material risks, reasonable alternatives, follow-up, and charges. You will need to review that information and ask for clarification before deciding. A signature on a general registration packet does not authorize an unspecified drug, dose, injection, procedure, or device treatment. This form supplements your General Consent for Evaluation and Treatment, HIPAA Notice of Privacy Practices, applicable Telehealth Consent, financial agreement, Good Faith Estimate notice, and patient portal terms. Separate legally required consent remains necessary.

PHO offers individualized evaluation and discussion of exosome-related and emerging therapies. The product addressed here is Vitti Labs EV-PURE+, supplied through RegenaMedix according to the records available to PHO. This disclosure explains that product, PHO's described service process, material risks, alternatives, financial requirements, and unresolved regulatory questions. EV-PURE+, EV-PURE, and VITTI-PURE will not be treated as interchangeable names. A different product or formulation requires its own identification and explanation.

Your clinician will explain why the proposed intervention is being considered for your particular condition or goal and what evidence supports that proposal. No cure, tissue regeneration, reversal of aging, improvement in immunity, pain relief, restoration of function, or other result is guaranteed. This document does not determine that you qualify for treatment or that treatment is authorized. Its signature records disclosure and your discussion decision; additional, legally sufficient treatment or research consent remains necessary before administration.

What the Supplier Documents Establish

The manufacturer's available EV-PURE+ materials describe a donated human umbilical-cord-derived tissue allograft intended for homologous use, meaning use that performs the same basic function in the recipient as in the donor. The materials describe non-conduit structural tissue, identify 1 mL and 4.5 mL product options, state that the product is DMSO-free, and present the manufacturer's position that it meets Section 361 human-cell and tissue-product criteria. Those descriptions are attributed to the manufacturer; they are not independent FDA approval findings or evidence that any requested use is suitable.

Available purchase and tracking records identify EV-PURE+ 4.5 mL. A supplied manufacturer report documents specified infectious-disease screening, sterility, endotoxin, environmental, and other test results for an identified historical lot. A result for that lot does not establish the contents, sterility, potency, safety, or expiration of a different shipment. PHO will match any product actually received to its own label, lot, tissue identifier, expiration, accompanying documents, and patient-specific order. Your record will identify the vial actually used rather than copy identifiers from a previous patient's record.

The available product sheet and supplier agreement state that the products are not FDA approved. Tissue-bank registration, accreditation, quality-system statements, supplier training, purchase, delivery, or a test certificate do not establish that FDA has approved your proposed treatment or that treatment is risk-free. PHO will not represent otherwise.

Government Requirements and PHO Responsibilities

Florida's Medical Consent Law, section 766.103, and the patient-rights requirements in section 381.026 govern applicable informed decisions and patient rights. Florida professional licensing laws and Department of Health and professional-board rules govern who can evaluate, prescribe, administer, or supervise your care. AHCA administers applicable clinic requirements under chapter 400, part X, chapter 408, part II, and implementing rules. Their application depends on the clinic's legal status and services. PHO will comply with applicable requirements, maintain required professional and facility authorization, and provide services within lawful scope and supervision. Agency oversight is not an endorsement or guarantee of your treatment result.

HIPAA and section 456.057 protect applicable health information and medical records. PHO will safeguard your information, document your care and decisions, and honor applicable access, confidential-communication, and complaint rights. Your signature is not a release of negligent care, a waiver of privacy rights, or permission for public marketing. Clinical photographs and special testing or sensitive-record disclosures will be addressed separately when required. PHO will apply any more protective law governing your record or service.

Federal product requirements include the applicable provisions of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and 21 CFR Part 1271. A product qualifies for regulation solely under Section 361 only if the applicable criteria or exception actually apply. Those criteria address minimal manipulation, homologous use, combination with other articles, and systemic effects or dependence on living-cell metabolic activity, with specified exceptions. A manufacturer's classification statement alone does not resolve whether the exact product and intended use meet those requirements. A qualifying Section 361 tissue product does not require the same premarket approval as a licensed biologic; absence of FDA approval alone does not resolve every tissue product's lawful status.

FDA's public exosome notice states that there are no FDA-approved exosome products and that exosomes used to treat diseases or conditions generally are regulated as drugs and biological products requiring premarket review. An investigational pathway, when required, must cover the actual product, protocol, indication, investigator, and treatment setting. PHO will obtain the applicable authorization and research oversight, including institutional review board approval and protocol-specific consent where required, before proceeding under that pathway. An IND permits investigation under its applicable conditions; it is not general marketing approval.

FDA's July 28, 2022 warning letter to Vitti Labs specifically included EV-PURE+ and challenged the Section 361 classification and manufacturing practices then reviewed. That historical letter is not a determination here that every later lot is defective or that PHO's present legal status has been adjudicated. It is a material regulatory issue requiring current verification rather than an assurance that the manufacturer's classification settles the matter. The records reviewed for this form do not establish a current authorization covering PHO's described IV use.

The supplier's 2021 announcement concerned an investigational combination of umbilical-cord stem cells and exosomes for COVID-19-related acute respiratory distress syndrome. It does not establish authorization for PHO's separate service, a different indication, or a different product. PHO will not claim participation in that trial without documentation. If product identity, lawful availability, intended route, or required clinical safeguards cannot be established, PHO will defer ordering or administration and discuss appropriate alternatives. This is a patient-safety and legal requirement, not a declaration that every emerging intervention is ineffective.

PHO Evaluation, Ordering, and Described IV Service

PHO does not maintain standing inventory of unassigned patient treatment products for anticipated resale. You will need to provide your health concerns and goals, accurate medical history, current medication and supplement list, allergies, prior treatment reactions, and available recent laboratory results. PHO requires relevant laboratory review before an anti-aging or general-health consultation; your clinician will identify additional tests and whether available results are sufficiently current. A SECA assessment will be incorporated when relevant. Your clinician will review your condition, contraindications, alternatives, and proposed plan before a patient-specific order is considered. Your payment does not replace clinical eligibility, lawful availability, or informed consent.

PHO reports that its previously used process involved EV-PURE+ administered intravenously after preparation with saline in a 500 mL saline bag, following supplier instruction and training given to Dr. Rolando Alvarez. This account identifies PHO's reported practice. The written preparation sheet supplied for this review does not specify IV infusion, a 500 mL dilution, infusion rate, or the clinical indication for that route. The reported process is not presented as a written, verified manufacturer IV instruction or a treatment order for you.

If an intervention is lawfully available and clinically appropriate, your physician will issue the actual patient-specific order identifying the exact product, amount, diluent, total fluid volume, route, rate or duration, treatment purpose, monitoring, and follow-up. The reported 500 mL preparation is not an automatic order for every patient. Your clinician will assess fluid tolerance and relevant heart, kidney, and other medical conditions. Your completed clinical plan will identify any difference

from supplier labeling or instructions and explain its significance before your treatment decision.

PHO reports providing this service at its clinic and, when arranged, at a patient location through a PHO physician or an appropriately licensed PHO registered nurse acting under a physician's order and required supervision. Naming those settings does not certify that every location or arrangement is authorized. Before administration, PHO will confirm the actual location, qualified personnel, lawful scope and supervision, handling and transport requirements, monitoring capability, and emergency-response arrangements. You will need to permit the agreed clinical access and provide a safe treatment area when care is arranged at your location. PHO will defer a session when the setting or your condition does not permit appropriate care. You will not prepare, dilute, share, or self-administer this product.

Product Handling and Contraindication Review

The supplied EV-PURE+ preparation sheet requires aseptic handling, inspection of package integrity, immediate use once thawed, and use before the product's expiration. It distinguishes the contents from the outside of the vial, instructs against sterilizing the contents, and specifies one patient on one occasion with unused portions discarded. These are professional handling requirements, not instructions for you to prepare the product yourself. PHO will use the instructions applicable to the actual supplied product, verify their suitability for the proposed procedure, and document any necessary clarification before use. Damaged, expired, incorrectly identified, or otherwise compromised product will not be administered.

The available sheet identifies known hypersensitivity to EV-PURE+ as a contraindication and warns against use in areas of active infection or in patients with likely active infection or other conditions that create substantial risk. You will need to tell PHO about fever, current or recent infection, immune suppression, immune or autoimmune disease, cancer history or treatment, pregnancy or breastfeeding, clotting or bleeding problems, heart or kidney disease, all medications and supplements, and any previous donor-tissue, infusion, or allergic reaction. PHO will assess the significance for your actual plan and explain whether additional evaluation, postponement, or another approach is required. This disclosure does not establish safety for children, pregnancy, breastfeeding, or other populations not adequately studied.

Material Risks, Evidence Limits, and Possible Outcomes

Potential risks depend on the actual product, processing, intended use, route, dose, and your health. Donor-derived material and processing introduce risks of contamination, infectious-disease transmission, immune or inflammatory reaction, allergic reaction including anaphylaxis, variable composition or activity, and unknown long-term effects. Screening and testing reduce specified risks but do not eliminate every infectious agent, processing defect, or adverse response. No numerical risk rate or product potency is established by this form.

IV access and infusion add risks of pain, bruising, bleeding, infiltration or leakage into surrounding tissue, vein irritation, phlebitis, infection, and an air embolism if air enters the circulation. Infusion-related reactions and inappropriate fluid volume or administration can cause serious complications. PHO will explain risks specific to your actual infusion and medical history and monitor according to the completed plan. A reaction can require stopping treatment, emergency medication, transfer, hospitalization, or further care, and severe complications can be fatal.

FDA has reported serious harm associated with unapproved regenerative products, including life-threatening infections, blindness, neurological events, and tumor formation. These reports concern varied products and uses; this form does not claim that each outcome has occurred with EV-PURE+ or PHO's described IV process. Your clinician will distinguish general warnings from risks supported for the proposed product and use. Unknown risks cannot be fully listed.

Exosome-related research does not establish benefit for every tissue product, route, health goal, or diagnosis. Supplier statements about biological mechanisms or an absence of previously reported reactions do not guarantee clinical benefit or the absence of future reactions. PHO will discuss relevant evidence and its limitations for your specific proposed use. You could receive no benefit, experience worsening symptoms, incur additional costs, or require other treatment. Declining or discontinuing an emerging intervention remains an available choice.

Your Preparation, Monitoring, and Aftercare Requirements

Before a scheduled session, you will need to complete the clinician's required testing, disclose changes in your condition, and review the completed preparation instructions. Do not stop prescribed medication or change a dose merely because this form lists a possible concern. Follow only the individualized directions your treating professional gives you and request clarification before proceeding if you do not understand them. PHO will explain preparation, monitoring, activity restrictions, follow-up timing, and any additional laboratory requirements in your clinical plan; this document does not invent a universal fasting or hydration regimen.

During treatment, immediately tell the administering professional about nausea, fever, chills, rash, dizziness, pain, breathing difficulty, chest discomfort, or any new symptom. After treatment, promptly report new or worsening symptoms, including fever, chills, dark urine, chest or lower-back pain, or a painful, red, swollen, or draining IV site. The supplied manufacturer

sheet identifies several of these symptoms for immediate physician contact. For a potentially serious reaction, obtain urgent assessment; for an emergency, follow the 911 instructions below. You will need to complete required reassessment and monitoring, even if you feel well, and inform PHO if you cannot complete them.

PHO will document the product actually administered, relevant lot and tissue identifiers, expiration, order, preparation, operator and supervision, treatment location, monitoring findings, reactions and actions, discharge condition, and follow-up instructions. PHO will stop administration when clinically indicated, assess symptoms, initiate the appropriate response, and complete applicable supplier and government adverse-event reporting. Reporting is not a promise that a specific reaction will occur or a substitute for immediate care.

Alternatives, Privacy, and Your Voluntary Choice

Your clinician will explain medically appropriate alternatives for your actual condition, including established treatment, observation or no elective intervention, medication, rehabilitation or physical therapy, specialist evaluation, surgery when appropriate, and a lawfully available clinical trial. The choice and comparative risks will be addressed individually. You have the right to seek a second opinion and take reasonable time to review information. Declining exosome-related care will not prevent otherwise appropriate PHO services. Do not delay necessary conventional or emergency care because of an anticipated emerging-therapy benefit.

PHO will use protected clinical records for your care and maintain appropriate product traceability. Disclosures to a supplier, regulator, or another organization will have a lawful purpose and comply with applicable privacy requirements. This signature does not authorize public testimonials, identifiable marketing photographs, or unrestricted supplier access to your medical record. Research-related use of your information will require the applicable separate authorization or other lawful basis; treatment consent alone does not authorize every research disclosure.

PHO is an outpatient practice and does not provide emergency medical services or an after-hours or on-call emergency clinical service. For chest pain, severe breathing difficulty, throat or tongue swelling, loss of consciousness, stroke symptoms, or another emergency, call 911 or go to an emergency department immediately. Do not wait for a PHO appointment, portal, email, text, voicemail, or community-message response. For non-urgent questions, contact 561-778-8121 during clinic operating hours and use the approved clinical communication method for health information.

Patient-Specific Charges, Refunds, and Appointment Rules

PHO's own services are cash-pay. You will need to pay the disclosed consultation fee immediately after your consultation. If you choose a treatment package, the full disclosed price is due at purchase unless PHO approves a written installment agreement requiring at least 50 percent down and specifying the remaining amounts and due dates. A recurring plan requires separate, completed payment authorization; this clinical signature does not authorize recurring billing. PHO will provide applicable Good Faith Estimates and itemized charge information. Outside laboratories, pharmacies, or other providers will have their own billing terms; insurance use for outside services does not mean PHO accepts insurance. You will need to verify coverage and expected outside costs before authorizing those services; coverage is not guaranteed.

PHO does not maintain standing inventory of unassigned patient medications or treatment products for anticipated resale. Relevant evaluation, laboratory review when required, treatment selection, consent, and payment precede your patient-specific order. Your order or invoice will identify the purchase, price, fulfillment terms, and the point at which an authorized order becomes noncancelable. Not every medication is compounded.

PHO's final-sale and no-refund policy is a clinic business policy, not a government rule requiring every healthcare purchase to be nonrefundable. PHO will not voluntarily accept medication or healthcare-product returns or refund an authorized purchase after its disclosed patient-specific order commitment. PHO will not voluntarily refund consultation, assessment, procedure, or treatment services already partially or fully provided. Individual preparation, pharmacy or supplier costs, professional time, shipping, refrigeration, sterility, storage, contamination, tampering, and product integrity can make the incurred costs nonrecoverable. A change of mind, discontinued treatment, missed follow-up, or an undesired result alone does not create a voluntary refund for those authorized costs.

PHO will evaluate prepayments for unprovided services, unused package portions, unavailable products, or canceled future care under the actual written agreement and applicable law; they are not automatically forfeited. PHO will correct established billing errors, unauthorized or duplicate charges, and legally required refunds. Section 456.0625 and section 408.12, where applicable, require qualifying patient overpayments to be refunded within 30 days after determination. Good Faith Estimate remedies and other non-waivable rights remain protected. Report a billing or fulfillment concern promptly; contacting PHO does not eliminate an external dispute right or extend a legal deadline.

You will need to cancel at least 24 hours before your scheduled appointment start. PHO will charge \$25 for cancellation less than 24 hours before that time, including a rescheduling request that cancels the original appointment within that period. If you arrive or connect more than 10 minutes late, PHO will classify the appointment as a no-call/no-show and charge \$20; calling ahead does not extend the arrival limit. Failing to attend without canceling also carries the \$20 no-call/no-show fee.

Cancel by calling 561-778-8121 or using the scheduling method specifically identified in your confirmation. Give your name and appointment date and time and retain the message or confirmation. PHO will document receipt and will not impose a patient cancellation or no-show fee for a PHO cancellation or PHO system failure. These scheduling fees do not mean an unperformed treatment was provided. Appointment cancellation does not cancel a separate recurring plan or committed product order.

Before an authorized order or service commitment, PHO will explain which charges are for consultation, product, supplies, administration, travel or location services, and follow-up, as applicable. Additional emergency or outside care can create separate charges. Your agreement and invoice will identify the actual amounts; this form does not create an undisclosed fee. If an investigational pathway applies, any charge for an investigational product must meet the applicable legal requirements and authorization. A financial agreement cannot establish product authorization or eliminate a legally required remedy. Lack of guaranteed benefit does not excuse negligent care, an unauthorized charge, or misrepresentation.

Patient Acknowledgments and Recorded Decision

You have the right to ask questions, seek another opinion, decline the proposed treatment, and withdraw consent to future treatment. Tell PHO immediately if you do not want to proceed or do not understand an instruction. Withdrawing consent does not undo care already provided or lawful charges already incurred. If necessary testing, monitoring, or consent is not completed, your professional will explain whether care must be delayed, modified, or stopped and will address appropriate follow-up and continuity of care. PHO will retain the specific completed form, signing date, recorded decisions, and verified representative authority in the appropriate record. You can request a copy. Sign only after the patient-specific information is completed and your questions have been addressed; do not sign a blank authorization.

By signing, you acknowledge review of the identified product, PHO's described process, the distinction between supplier claims and verified authorization, material risks and uncertainties, alternatives, patient responsibilities, and financial terms. Your signature does not confirm facts that PHO has not verified, waive a professional standard of care, or convert an unapproved product into an FDA-approved treatment.

Your signature acknowledges this disclosure and the decision recorded below; it does not authorize administration while the lawful basis or patient-specific requirements remain unresolved. Before any administration, PHO will complete the necessary product-specific clinical and regulatory verification and obtain the separate treatment or research consent required for the actual authorized intervention. That consent will identify the procedure and material patient-specific information and will not be inferred from a general registration or purchase. PHO will retain the completed discussion record and disclose a material change before seeking a new treatment decision. You can decline further evaluation, discussion, ordering, or treatment.

Specific Product Discussion and Regulatory Record

PHO will complete these patient-specific details with you, or identify the attached completed clinical plan, before you sign. Unused fields will be identified as not applicable with the appropriate explanation. A blank field is not consent to an unspecified treatment.

Exact product, vial size, manufacturer and supplier; document version:	Your condition / goal, proposed indication and evidence discussion reference:
Planned product amount, diluent, volume, route and rate / duration; order reference:	Proposed date / location; physician, administering professional and supervision:
Applicable legal pathway and dated verification reference; unresolved items:	Research sponsor / protocol / IRB and separate consent reference, if applicable:
Your specific contraindications, material risks, alternatives, preparation and follow-up:	Itemized price / order commitment / estimate and charging basis, if applicable:
Your decision: ☐ Discussion only ☐ Defer ☐ Decline ☐ Proceed to separate consent after requirements verified	Your questions and responses; clinician completing discussion / date:

Your signature acknowledges this disclosure only. Separate verified lawful treatment or research consent is required before administration.

Patient / authorized representative signature:	Date: _____ Time: _____
Printed name:	Representative relationship and verified authority, if applicable:
Clinician completing treatment discussion / instructions:	Clinician signature and date:

PHO will record the specific form version and signing details. For electronic signing, PHO will retain the identity, date and time, document, recorded decision and applicable representative authority. You can request a copy.