INTEGREVIEW IRB

June 20, 2018

Principal Investigator: Thomas C. Marbury, M.D.
Sponsor: Aronora, Inc.
Protocol Number: 3G3-18-02
Study Title: "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy/Potency of a Single Dose of Xisomab 3G3, Administered at the Beginning of a Regular Hemodialysis Procedure, in Patients with End-Stage Renal Disease on Chronic Hemodialysis"

Dear Dr. Marbury:

A convened IRB meeting of IntegReview was held on the above-referenced date. The following full board action was taken on initial review of the above-referenced study:

Approved:
Principal Investigator
Investigative site(s) as submitted with initial submission documents
Protocol dated 25May2018; Amendment 1 dated 14June2018
Informed Consent, English language, dated June 20, 2018, (refer to IntegReview modifications as reflected on the following document containing revision marks)

The Board reviewed the Investigator's Brochure, Version 2.0 dated 24May2018, for the study drug(s), as appropriate.

IMPORTANT

- **The following changes in approved research may not be implemented until you have received approval from IntegReview <u>except</u> where necessary to eliminate apparent immediate hazards to the human subjects:**
  - **Protocol Amendments**
  - **Change in the Principal Investigator and/or Sub-investigators (only if the Sub-investigators will be performing study-related procedures that the PI is not qualified through expertise to perform)**
  - **Change in the address at the study site or the addition of a study site(s)**
- **Only Informed Consent documents <u>containing IntegReview's approval</u> stamp may be utilized:**
  - **There must be procedures in place to guarantee that consent has been voluntarily obtained and properly documented.**
  - **For participants that do not speak English, the informed consent document must be in a language understandable to them; Non-English speaking subjects may <u>not</u> be enrolled until the foreign language Informed Consent Document(s) has been approved by IntegReview.**
  - **Only IntegReview staff may initiate modifications to Informed Consent documents. The Informed Consent document for your site will be maintained in our computer files, and IntegReview will make all revisions following IRB approval.**

  - **Any modifications made to informed consents without prior IRB approval will be considered non-compliance and subject to, but not limited to, full board review, FDA review, suspension and/or termination of IRB approval.**
- **Only recruiting materials containing IntegReview's approval stamp may be utilized. All audio/video recording(s) must be submitted for IRB approval prior to broadcast.**
- **Revision requests should be submitted on IntegReview's forms, which are available in IRBManager.**
- **Visit our website at www.integreview.com for information on research regulations, reporting requirements, Investigator and research personnel training, etc.**

IntegReview approval for this study expires **June 19, 2019**.

In order to obtain extended IRB approval, IntegReview must receive your form for continuing review two weeks prior to the IRB expiration date. Appropriate forms will be forwarded to you approximately four weeks prior to the approval expiration date. Should the study end before you receive notification, submit a Closure Notification form.

REPORTING REQUIREMENTS

To ensure compliance with the applicable federal regulations as well as International Conference on Harmonisation (ICH), E6: Good Clinical Practice: Consolidated Guideline, and/or IntegReview's requirements, notification of the following are required for review/approval:

- **Report immediately:**
  - Changes in research that were initiated without IRB review and approval to eliminate apparent immediate hazards to the human subjects to ensure the continued safety and welfare of subjects
  - Modifications to previously approved documents
  - Receipt of investigator/site 483, Determination letter or Warning letter
  - If your license is suspended, revoked, placed on probation or restricted in any state or country
  - Safety information that may help to provide additional protections for subject's safety and well-being, throughout the course of the study and after study completion.
  - Communication of results from a research study to subjects when those results directly affect their safety or medical care
  - Reports of pregnancy
  - Data Monitoring Committee (DMC/DSMB) Reports
- **Report within 10 calendar days of discovery:**
  - Revisions to the Investigator's Brochure, as applicable
  - Revisions to the report of prior investigations, as applicable
  - Non-compliance – Failure by an investigator and/or sponsor to follow IntegReview's requirements, applicable regulations or to protect human research subjects, including but not limited to the principles of the Belmont Report
  - Serious non-compliance issues - non-compliance as defined as above and as determined to be serious in a way that adversely affects the rights and welfare of human subjects following the investigation and review by the IRB
  - Continuing non-compliance issues – A pattern of repeated non-compliance or serious non-compliance as determined by the IRB
  - Significant deviations – Significant deviations are those that deviate from the approved protocol, informed consent process and affect or potentially affect the safety of subjects. IntegReview does not consider protocol deviations to be different from protocol violations.
  - Unanticipated adverse device effects, as applicable

- Unanticipated problems should be reported regardless of whether they occur during the study, after the study completion, or after participant withdrawal or completion. Unanticipated problems involving risks to human subjects or others that are (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; (2) related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures in the research); and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Examples of problems or events that may meet the definition of unanticipated problems involving risk to subjects or others may include, but are not limited to the following:
  - Imminent threat of a reportable event that has not yet occurred
  - Information indicating a change to the risk/benefit ratio of the research
  - Death
  - Breach of confidentiality, including lost or stolen study documents/data

- **Report within 30 days of acquisition or discovery**
  - New or additional conflicts of interests
- **Submit prior to publication/distribution:**
  - Any modification(s) to the previously approved Informed Consent document
  - New and/or modifications to previously approved recruiting/miscellaneous materials to be seen or heard by subjects
- **Submit two weeks prior to IntegReview approval expiration date:**
  - Continuing review documents
- **Submit upon completion of the study:**
  - Notification of study closure

At its discretion, IntegReview IRB reserves the right to visit the study site.

IntegReview IRB is organized and operates in accordance with the applicable federal regulations, and ICH Guidelines for Good Clinical Practices, E6. In addition, Standard Operating Procedures have been created to ensure compliance with these regulations and guidelines.

If you have any questions regarding these procedures or if you wish to appeal the decision of the Board, you may address your comments to the IntegReview Chair. Your comments will be reviewed and discussed at the next convened meeting.

Failure to comply with the Code of Federal Regulations or the requirements or determinations of IntegReview IRB can result in suspension or termination of IntegReview approval.

Sincerely,

Angelica Martinez, CCRP
IRB Coordinator, Co-chair

APPROVED BY
INTEGREVIEW IRB
JUNE 20, 2018

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR COMPANY:	Aronora, Inc.
PROTOCOL NUMBER AND TITLE OF STUDY:	3G3-18-02: **"**A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy/Potency of a Single Dose of Xisomab 3G3, Administered at the Beginning of a Regular Hemodialysis Procedure, in Patients with End-Stage Renal Disease on Chronic Hemodialysis "
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/ INVESTIGATOR):	Thomas C. Marbury, M.D.
TELEPHONE NUMBER(S), DAYTIME AND AFTER HOURS:	(407) 240-7878

INTRODUCTION

You are being asked to participate in the above-named research study. Before agreeing to participate in this research study, it is important that you read and understand this informed consent document and ask any questions that you may have. This document describes, in detail, the following:

- purpose of the study;
- contact information if you have any questions;
- information about the study drugs used in the study;
- requirements for participating in the study;
- procedures to be completed during the study;
- benefits and alternatives to you as a study participant;
- potential risks and discomforts you may experience as a result of participating in this study;
- precautions you must take during the study;
- your right to withdraw from the study at any time;
- compensation you will receive for your time and travel.

Please take the time to read the following information carefully and discuss it with others. If this form contains any words that you do not understand, please ask the site medical team or staff to explain them to you.

If you have decided that you want to take part, you will be asked to sign the informed consent form. You will get a copy of the signed form. Your decision to take part in this study is voluntary. That means you are free to decide to join this study or not join this study, and refusal to join will not affect your medical care. You are also free to stop study drug dosing and study-related activities at any time and without any reason.

The pharmaceutical company sponsoring this study is Aronora, Inc. Orlando Clinical Research Center is being paid by Aronora, Inc. to conduct this study.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
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You must be honest with the study doctor about your health history or it may not be safe for you to be in this study.

In this document, you may see the terms "medication" and "treatment"; these are terms used in research studies as mentioned above, this does not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug and parts of the study where you will be receiving this investigational product.

PURPOSE OF THE STUDY

Aronora, Inc. is sponsoring this study of an investigational drug called xisomab 3G3. The National Institute of Heart Lung Blood (NIHLB), part of the National Institutes of Health (NIH), is funding the study. Investigational means that the drug being tested is not approved by the United States Food and Drug Administration (FDA) for general use in the United States, but may be tested in research studies such as this one.

Xisomab 3G3 is being developed for the prevention of treatment of thrombotic and thromboembolic diseases, such as venous thrombosis and thromboembolism.

Thrombosis is the formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system.

The purpose of this study is to evaluate the safety and tolerability of a single dose of xisomab 3G3 when injected through a port into the arterial dialysis line immediately after the start of a hemodialysis treatment.

Up to 24 men and women, ages 18 to 80 will be enrolled in the study at 2 centers in the United States.

The study will last about 7 weeks and will involve a screening period, a 14 day/13 night stay at the study site and 3 follow up visits.

STUDY DRUG DOSING

This is a randomized, double-blind, placebo-controlled study. Randomized means the study treatment you take will be chosen by chance (like flipping a coin).

Double-blind means that you and your study doctor will not know what study drug you are taking.

The placebo is a substance that looks like a drug, but has no drug in it.

Be aware that sometimes this form refers to both xisomab 3G3 and placebo as "study drug".

You and the study doctor will not choose which group you will participate in; however, this information can be obtained if needed in an emergency. The study drug you will receive will be assigned by chance, like the flip of a coin.

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If you agree to join this study and qualify, you will be assigned to 1 of 2 dosing groups as follow:

- Group 1: Infusion dose of 0.25 mg/kg xisomab 3G3 or placebo
- Group 2: Infusion dose of 0.5 mg/kg xisomab 3G3 or placebo

The amount of study drug/placebo you receive will depend on how much you weigh. There are 2 different doses: 0.25 and 0.5 milligrams of study drug for each kilogram of weight. A kilogram equals about 2.2 lbs. So, for example, if you weighed 70 kilograms (154 pounds), and you received (0.5mg/kg) your dose would be 0.5 times 70, which means you would receive 35 milligrams of study drug/placebo.

The study drug/placebo will be given to you on Day 1. The study drug/placebo will be injected through a port into the arterial dialysis line immediately after the start of a hemodialysis treatment.

SCREENING VISIT

Before any study procedures being performed, you will be asked to sign this informed consent. Before the study starts, you will be asked to do some procedures to find out if you qualify to be in the study. This process is called "Screening."

- You will be asked about your health, how you are feeling, your use of alcohol and tobacco products as well as your medical history.
- Your demographics will be collected (such as age, sex, race, ethnicity, date of birth).
- A full physical exam will be done.
- Your height, weight, body temperature, breathing rate and blood pressure and heart rate will be measured.
- You will be asked about any medications. (over the counter, prescription, herbal supplements or vitamins)
- You will have an electrocardiogram (ECG) to measure the electrical activity of your heart. You may be asked to remove your blouse or shirt for the ECG.
- Blood and urine will be collected for laboratory testing. (must be fasting for a minimum of 4 hours before clinical lab tests)
- You will have a test for alcohol and drugs of abuse.
- You will have a blood test for hepatitis B and C (an infection of the liver) and HIV. State law requires that positive test results for hepatitis/HIV be reported to a local health agency. You will be asked to sign a separate HIV consent.
    - The results of these tests are expected to stay confidential. There is a chance that a breach in confidentiality could happen; this means that people that were not originally supposed to have this information could see these results. For example, it is possible for a court of law to get health or study records without your permission. Please speak to the study staff or your personal doctor, if you want to know more about what it could mean to you if somebody outside of this research study has access to this information.
- If you are female, you will have a pregnancy test. Females who might be postmenopausal will have a blood test done to confirm that they are post-menopausal. If you are a female capable of becoming pregnant, you will not be eligible to participate in this study.

After all screening tests have been done, if you are determined to be eligible to continue in the study, you will return to the clinic to check-in and start the evaluation period (7 days before dosing).

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STUDY PROCEDURES

Please note the exact schedule for the procedures described in this consent form are subject to change. Some procedures may not be performed, and some may be added or moved to other study days.

DAY -8 (Check-In) / EVALUATION PERIOD (DAY -8 THROUGH DAY -1)

You will come to the research clinic to begin the evaluation/confinement period. During the evaluation period (Day -8 through Day -1) you will have hemodialysis treatment according to your dialysis schedule.

Day -8:
The following procedures will be done:

- Your medical and medication history will be reviewed and updated if needed. Tell the staff about any prescription drugs, over-the counter medicines, herbal and vitamin supplements you are taking. This is very important.
- A physical exam will be done
- Your weight will be measured.
- Electrocardiograms (ECG) will be done.
- Your vital signs including blood pressure, heart rate, temperature and breathing rate will be measured.
- Blood and urine will be collected for laboratory testing.
- You will have a test for drugs of abuse and alcohol.
- If you are female, you will have a pregnancy test.

Day -7, Day -5, Day -3/ Hemodialysis day
The following procedures will be done:

- Your weight will be measured.
- Blood samples will be collected before and after hemodialysis for laboratory testing.
- Your vital signs including blood pressure, heart rate, temperature and breathing rate will be measured.
- You will be asked about any medications you might have taken or negative side effects that you might have experienced.
- Dialysate samples will be collected. Fluid which passes through the dialyzer will be collected. Dialysate sample will be taken for future analysis (e.g., assessment of urea or drug in the dialysate). Samples will be stored for up to 5 years).
- Fistula or graft for dialysis access will be assessed for bleeding and any abnormality (bleeding and visual assessment).

Day -6, Day -4, Day -2, and Day -1:
The following procedures will be done:

- You will be asked about any medications you might have taken or negative side effects that you might have experienced.
- Your weight will be measured.

By the end of the evaluation period the study doctor will determine if you are eligible to continue into the study. If you will not be able to continue in the study, the study doctor will explain why.

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The sponsor and study doctor reserve the right to make the final decision on subject selection for participation into the study. This may occur as late as just before dosing. Each subject will need to meet study requirements again at check-in.

DAY 1 (DOSING DAY) / HEMODIALYSIS DAY

While you are in the clinic, you will have the following tests done:

- You will be asked about any medications you might have taken or negative side effects that you might have experienced.
- Your vital signs, including body temperature, blood pressure, heart rate and breathing rate will be measured multiple times before and after receiving the study drug/ placebo.
- ECG will be done.
- Your weight will be measured.
- Blood and urine samples will be collected for laboratory testing before and after hemodialysis.
- A physical exam will be done.
- After an overnight fast of at least 4 hours, the study staff will give you the study drug. Refer to section "STUDY DRUG DOSING".
- Blood will be collected to find out the amount of study drug /placebo in your body. A sample will be obtained before you receive the study drug, then at up to 11 times after receiving the study drug.
- A blood sample will be collected for immunogenicity analysis (to found out your immune response).
- Dialysate samples will be collected.
- Bleeding and visual assessments will be completed.

DAY 2 AND DAY 4

The following procedures will be done:

- You will be asked about any medications you might have taken or negative side effects that you might have experienced.
- Blood samples will be collected to find out the amount of study drug /placebo present in your body.
- Blood sample will be collected for laboratory testing.
- Your weight will be measured.

DAY 3 AND DAY 5 / HEMODIALYSIS DAY

The following procedures will be done:

- You will be asked about any medications you might have taken or negative side effects that you might have experienced
- Your weight will be measured.
- Your vital signs, including body temperature, blood pressure, heart rate and breathing rate will be measured.
- Blood samples will be collected for laboratory testing.
- Bleeding and visual assessments will be completed.

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DAY 6 (DISCHARGE):

Discharge procedures will be completed on Day 6

- You will be asked about any medications you might have taken or negative side effects that you might have experienced.
- Your vital signs, including body temperature, blood pressure, heart rate and breathing rate will be measured.
- ECG will be done.
- A physical exam will be completed.
- Blood and urine samples will be collected for laboratory testing.
- Blood will be collected to find out the amount of study drug /placebo present in your body.

You will be discharged from the clinic after all the Day 6 procedures have been completed. You will be required to return to the clinic for a follow up visit on Days 8, 10 and 12 (Hemodialysis day)

During the study, you will be monitored closely for possible side effects. You will be asked about any symptoms or illnesses that you may experience. Additional physical exams may be performed at the discretion of the study doctor. You should report any changes in your physical or mental condition, or any side effects that you may have during the study. In addition, you will be asked to inform the investigator and/or study staff of any medications, procedures or therapies you are taking while you are participating in this study.

DAY 8 AND DAY 10/ HEMODIALYSIS DAY / FOLLOW UP VISIT

The following procedures will be done:

- You will be asked about any medications you might have taken or negative side effects that you might have experienced
- Your weight will be measured.
- Your vital signs, including body temperature, blood pressure, heart rate and breathing rate will be measured.
- Blood samples will be collected for laboratory testing.
- Bleeding and visual assessments will be completed.

DAY 12 / HEMODIALYSIS DAY /FOLLOW UP VISIT PROCEDURES

You will be required to return to the clinic on Day 12 for a follow up visit. Anyone who receives study drug/placebo will be asked to return for this visit.

- Your vital signs, including body temperature, blood pressure, heart rate and breathing rate will be measured.
- ECG will be done.
- A physical exam will be completed.
- Your weight will be measured.
- Blood and urine samples will be collected for laboratory testing.
- Blood will be collected to find out the amount of study drug /placebo present in your body.

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- A pregnancy test for all females will be performed.
- You will be asked how you are feeling and about whether you have taken any medications since your last visit.
- Bleeding and visual assessments will be completed.
- A blood sample will be collected for immunogenicity analysis response.
- Dialysate samples will be collected.

Your participation in the study will be completed when all the study procedures and the review of the medical and safety evaluations have been done. You may require longer observation in the clinic or additional laboratory testing based on the effects of the medication or the results of the laboratory tests.

BLOOD SAMPLE COLLECTION

Blood samples may be drawn from an intravenous catheter (a tube that is left in your arm). The catheter will be inspected, maintained and may be changed, if necessary. If the use of the catheter is not possible, the blood samples will be taken by individual needle-sticks from a vein in your arm.

The total amount of blood drawn is up to 436 mL (a little less than 2 cup). For comparison, the standard blood donation is about 480 mL (about half liter, or two U.S. cups).

This total volume does not include discarded blood from pre-draws used to remove fluid from flushed catheters which is approximately 0.5 mL per blood draw. Additional blood samples may be drawn during the study if the study doctor considers it necessary for monitoring your health. It is possible that more than one attempt to obtain a blood sample may be necessary.

SUBJECT RESPONSIBILITIES

As a participant in this study, you have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- Provide truthful information about your health history.
- Complete all required visits.
- Participate in all study-related procedures as required by the study.
- Follow the restrictions listed in the section below.
- Use contraception as described later in this document.
- Report all changes in your health, side effects, and medical problems immediately to the site medical team, even if you do not think they are related to the study.
- Inform the site medical team or staff if you decide to discontinue your participation. If you decide to drop out of the study after receiving any study medication, you will be required to complete at least one follow-up visit.

RESTRICTIONS

For your own safety, it is important that you follow without exception the Clinical Research Center In-House Guidelines. Violations of these In-House Guidelines may make it necessary to remove you from the study. If you are taken out of this study because you are unable to follow the In-House Guidelines, you may not be asked to take part in other studies done at this research clinic.

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During your stay in the Research Center, you must follow the study rules about tobacco, alcohol, or any unauthorized drugs.

- Smoking is not permitted at any time in the building. Subjects are prohibited from smoking during study confinement.
- Food and beverages will be provided during your stay at the research center except when fasting is required. You will be served standard meals and snacks according to a strict daily diet and according to the study procedures. You may not bring your own food or beverages.
- You must not take certain medicines before and during the study. The study staff will discuss this with you. Please tell the study staff about all of the medications, drugs, and supplements you are taking. This includes any prescription or over-the-counter medications. If you have any questions about any medication, please ask the study staff before taking it.
- You must not have received a study drug or participated in another clinical trial within 30 days before Day – 8 of admission.
- Beverages or foods containing caffeine and/ or, xanthine (coffee, tea, cola, chocolate, etc.) are not allowed 48 hours before receiving the study drug and throughout the period of sample collection.
- You must not drink any alcohol (beer, wine, liquor) starting 48 hours before receiving the study drug and throughout the period of blood sample collection.
- You must not engage in strenuous exercise 48 hours before Day -8 and while participating in this study.

It is very important that you follow all the rules, restrictions, and instructions given by the staff. If you do not follow the restrictions or follow the guidance of the study staff, there can be a risk to your health and/or false study results.

VOLUNTEERING TO BE IN THE STUDY AND WITHDRAWAL OF YOUR CONSENT TO PARTICIPATE IN THIS STUDY

The study doctor, the sponsor company, IntegReview, or the FDA may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the study doctor's instructions
- If we find out you should not be in the study
- If the research study is stopped
- If participation in the research study becomes harmful to your health

It is your choice if you want to be in the research study. No one can force you to be in the research study. You may decide to stop your study participation which may include stopping any further assessments or contact by the study staff. This is considered a withdrawal of your consent from participation in this study.

It is important that you inform your study doctor of your decision to withdraw your consent by providing written notice to the study doctor. If you leave the study, no more information about you will be collected for this study. However, the sponsor will continue to retain and use all research results and any biological samples that have already been collected for the study evaluation (as per local regulations).

You can discuss further regular medical care with the study doctor. The choice to withdraw from research study will not affect your medical care.

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If you drop out or are removed from the research study after having taken the study drug, you may be asked to come back to the clinic for a follow-up visit. At this visit you will have discharge procedures performed and blood tests to ensure that there are no changes to your current health status. You will be asked about any changes in your health or in the medications you are taking.

POSSIBLE RISKS AND SIDE EFFECTS

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

The most common side effects in a 21 normal healthy volunteer study include injection site skin reaction, cough, increased diastolic blood pressure, and upper respiratory tract infection.

Because the study drug is investigational, there may be side effects that we do not yet know about. There may be rare and unknown side effects. Some of these may be life threatening.

The study drug (xisomab 3G3) is being developed to treat or prevent blood clots and, therefore, taking the study drug may increase your risk for bleeding or bruising. While the study drug has been developed specifically with the intent to reduce blood clotting inside blood vessels without increasing the risk of bleeding, risks of side effects in humans cannot be established without testing the effects of the study drug in human subjects.

The study drug is a therapeutic antibody and there are risks associated with taking this type of drug which include allergic reactions, such as rash, swelling, hives, difficulty breathing, blood pressure changes, among others. A severe and life threatening allergic reaction can occur.

Throughout the duration of the study, you will not receive heparin during your hemodialysis sessions. This may put you at a higher risk of developing clotting within the dialyzer cartridge during hemodialysis sessions. Because the study drug (xisomab 3G3) is being developed to treat or prevent blood clots, you may be less likely to develop blood clots during hemodialysis after receiving the study drug. However, if you are randomly selected to receive placebo you will undergo nine consecutive hemodialysis sessions without heparin anticoagulation, which may put you at a higher risk of developing a clotting within the dialyzer during hemodialysis.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Until you know how the drug(s) will affect you, you should use caution by avoiding stairs, not driving a car or working with machinery.

ADDITIONAL RISKS OR DISCOMFORTS

Blood Draws:

The risks of taking blood may include fainting, pain, nerve damage, redness, bleeding and/or bruising. Rarely, there may be a small blood clot or infection at the site of the needle puncture. If you feel faint tell the study staff right away.

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Two indwelling, intravenous catheters may be inserted in one arm to collect blood samples. An indwelling catheter is a special needle device designed to be placed in a vein, and then to remain in the vein for a period of time. This could cause: infection, pain, redness, bruising, nerve damage, local swelling due to IV fluid (saline/ heparin flush that will be used to keep the indwelling catheter open) accidentally entering the tissue rather than the vein, blood clots, which may cause inflammation, swelling and pain. It is possible that the catheter will stop working and may have to be replaced in a different vein.

Blood Pressure:

The blood pressure cuff may also cause discomfort or bruising to the upper arm.

Electrocardiogram (ECG):

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If the hair under the patches needs to be shaved, irritation from shaving also could occur. You may experience some skin irritation from the electrode adhesive or develop contact dermatitis (a skin condition caused by contact between skin and some substance) which may appear as lighter as or darker than the surrounding skin for possibly an extended period of time.

Digital Photos

In the event of any physical abnormal finding, digital photos will be taken of the areas. The photos will be taken in a manner so that there is no way you could be identified in the pictures.

Your image may be sent electronically to the sponsor. The photographs or electronic images will be labeled with your study number and not your name. People working for the Sponsor, the FDA, and IRB will have access to your photographs if they have a valid reason for seeing them. Valid reasons include but are not limited to, monitoring or auditing the study, to assess the skin condition or to determine the cause of the skin condition. When the study is over, your photograph or electronic image will be stored with the study files indefinitely. Your picture will not be used for teaching purposes and will not be published in any medical journal. You may be asked to have additional tests to assess the condition. The Study Doctor will discuss this with you before any other tests are done. You are giving the site permission to take photos of the area indicated by signing this consent form.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

The effects of the study drug on an unborn child are not known. Only females who are not able to get pregnant are allowed to be enrolled in this research study.

Females who are not able to get pregnant are defined as being permanently sterile (due to hysterectomy [removal of uterus], bilateral salpingectomy [removal of both ovaries and fallopian tubes], bilateral oophorectomy [removal of ovaries], or confirmed tubal occlusion more than 6 months before the first dose of study drug) or postmenopausal (defined as at least 12 months without a period without an alternative medical cause). If you think that you have become pregnant during the study, it is important that you inform the study doctor immediately.

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Male subjects must either be sterile (vasectomy with history of a negative sperm count following the procedure); practice total abstinence from sexual intercourse as the preferred lifestyle (periodic abstinence is not acceptable); use a male condom with any sexual activity; or agree to use a birth control method (such as one of the methods identified above for female subjects) from the time of Screening until 90 days after the last dose of study drug. Male subjects must agree not to donate sperm for a period of 90 days after the last dose of study drug.

Even if you use birth control during the study, there is a chance your partner could become pregnant. A pregnancy test is not always right, especially in the early stages of pregnancy. If your partner becomes pregnant, you must inform the study doctor immediately. The study doctor may request to track the pregnancy and report the outcome to the Sponsor.

Unknown Risks

There may be additional risks that are currently unknown and unanticipated related to taking the study drug. There may be rare and unknown side effects. Some of these may be life threatening.

You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. If new risks associated with the dosing of study drug are identified during the study, you will be told about them.

SAFEGUARDS

You must tell the study doctor about all of your past and present experiences with pain relievers, diseases, addictions, drinking habits, and allergies of which you are aware, and all drugs and medications which you are presently taking including vitamins and any herbal supplements.

POSSIBLE BENEFITS OF THE STUDY

You will not receive any direct benefit from participating in this study. This study may help physicians and scientists learn things about the study drug that will help others.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Your alternative is to not take part in the study.

CONFIDENTIALITY

Information about you and your participation in the study will be kept confidential according to applicable privacy laws and any policies of your study doctor and the sponsor. Your original study records may contain your name, address, health information and other personal data (“Personally Identifiable Information”). These study records will be kept by your study doctor as required by applicable law and the sponsor. These records may be held forever.

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USE OF YOUR STUDY RECORDS

The study results may be looked at to make sure the study is being done correctly. The sponsor may work with other companies and government agencies for reasons related to the study. In order for this to take place, these companies and government agencies will have access to the original records or the data contained in the records and may copy some of the information, which may contain your Personally Identifiable Information. These companies and government agencies include:

- Regulatory authorities including in other countries, such as the FDA
- Other government agencies
- IntegReview IRB
- Contracted Monitors/Auditors and other individuals or companies used by the sponsor to help with the study
- Affiliated companies of the sponsor

After the study doctor shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. If all information that does or can identify you is removed from your records, the remaining information may be used or shared for other purposes.

Your results will be coded with numbers and initials. Companies and government agencies (for example the FDA and IntegReview, the IRB for this research study) will not know your name unless it is necessary for purposes relevant to a study. The results of a study may be shown in publications or at meetings. You will not be identified by name. Under certain circumstances, some test results will be reported to health authorities as required by law. Note that once your test results or samples leave the US, they are not protected by the same laws in other countries.

The sponsor and its affiliated companies may use and disclose your records and health information collected for this study to conduct additional clinical or data research studies or to develop proposals for new studies. The sponsor also may use the information about you in the study to improve the design and efficiency of future research studies.

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

If a medical emergency happens, your study results may be given to emergency medical staff. If you decide to stop being in a study, the information already gathered will still be kept in the study database.

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.

NEW INFORMATION

You will be informed, in writing, of any new or important findings that are learned during this study that might influence your choice to start or remain in the study. You may be asked to sign an updated consent form.

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ADDITIONAL COSTS

There will be no cost to you for participating in this research study.

PAYMENT FOR PARTICIPATION IN THIS STUDY

You will be compensated for your time and travel. If your research study participation is ended because of a positive drug screen, you will not get any compensation.

If after being enrolled in the research study, your participation in the study is ended for any other reason besides a positive drug screen, you will receive compensation based on the visits and/or days that you have completed. You will not receive payment for partially completed days/visits. Payment is outlined below.

Completion of Screening:	$50.00	Completion of Day 1:	$250.00
Completion of Day -8:	$125.00	Completion of Day 2:	$250.00
Completion of Day -7 :	$200.00	Completion of Day 3:	$250.00
Completion of Day -6 :	$250.00	Completion of Day 4:	$250.00
Completion of Day -5 :	$250.00	Completion of Day 5:	$250.00
Completion of Day -4 :	$250.00	Completion of Day 6:	$125.00
Completion of Day -3 :	$250.00	Completion of Day 8:	$125.00
Completion of Day -2 :	$250.00	Completion of Day 10:	$125.00
Completion of Day -1 :	$250.00	Completion of Day 12:	$125.00
			Total: $3625.00

Schedule of payments:

- 1st payment of $ 2000.00 within 7 days of Day 6 completion
- 2nd payment of $ 1625.00 within 7 days of Day 12 completion

If you choose to leave or are withdrawn from the study for any reason, you will receive payment within 7 days of your last study visit.

If you are requested to complete any unscheduled visits due to a side effect or safety follow up, you will receive $50.00 each additional visit for your time and travel.

In addition, you will be asked to read and sign a document entitled “Site Guidelines” which outlines penalties for certain violations of the rules for when you are staying at the clinic.

In agreeing to take part in this study, you will be acting as an independent contractor, not as an employee of Orlando Clinical Research Center. Payments made to you for taking part in this study will be reported to the IRS as income, as required by law. No taxes are deducted from your check. You are responsible for reporting this compensation on state and federal tax returns and for the payment of any taxes that are due on this compensation. You will be required to provide your Social Security number or tax identification number to Orlando Clinical Research Center. If you get more than $600.00 in one calendar year from Orlando Clinical Research Center, you will get a 1099 tax form the following January.

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IN CASE OF STUDY RELATED INJURY

It is important that you follow carefully all the instructions given by the study doctor and his/her staff regarding this study.

If you become ill or are physically injured as a result of participation in this study, please contact the study doctor right away and you will be treated or referred for treatment.

The sponsor Aronora, Inc., will pay the costs of this treatment to the extent that such treatment is not paid by your medical insurance or by third party or governmental programs. For this to happen, the injury, in the opinion of the study doctor and the sponsor must be confirmed to have been a direct result of your participation in this study in accordance with the study directions. No other financial compensation will be offered by the sponsor. No long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government. If you would like further information about compensation for research-related injuries, please ask the study doctor.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

You will not lose any of your legal rights to which you are otherwise entitled by signing this consent form.

CONTACT INFORMATION

If you have any questions, concerns, or complaints during this study, or if you think you may have experienced a research-related injury, you should contact the study doctor or study staff:

Thomas C. Marbury, M.D.
(407) 240-7878, 24-hours a day

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the study doctor or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	**OR**	**Email Address:**
Chairperson IntegReview IRB 3815 S. Capital Of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

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If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the study doctor to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE PERSONAL MEDICAL INFORMATION

A federal regulation called the "Health Insurance Portability and Accountability Act" (HIPAA) describes how protected health information (PHI) may be used, disclosed (shared), and made accessible to you. This privacy rule is designed to protect the confidentiality of PHI. Please read this form carefully as it describes your rights regarding the use or disclosure of your PHI under this authorization.

You are being asked to allow the use of your PHI because this study may be performed only by collecting and using this information. Your study records will be kept confidential as described in this form. Unless required by law, your name will not be disclosed outside the research clinic. Your name will be available only to the following people or agencies: the study doctor and staff; and authorized representatives of the study doctor; the sponsor and its affiliates and people or companies working for or with the sponsor, ethics committees (IRB), health authority inspectors, such as the US Food & Drug Administration; NIHLB and their contractors, study monitors and auditors; Emergency medical personnel and Authorized Clinical Research Organization representatives. The above mentioned individuals will use the personal information collected as part of this study, including your medical records ("Study Information") to check that the study is conducted correctly and to ensure the accuracy of the Study Information. These people are all obligated to maintain confidentiality by the nature of their work, or are bound by confidentiality agreements. If required, the Study Doctor may contact your personal physician to collect additional medical information and your past medical history.

The sponsor and the groups above will use your health information:

- to complete this research
- to evaluate the results of the study
- to check that the study is being done properly
- to obtain marketing approval for new products resulting from this research
- The sponsor and its affiliated companies may also use and disclose your de-identified records and health information collected for this study to conduct additional clinical or data research studies or to develop proposals for new studies or to improve the design and efficiency of future research studies.

The study doctor may only share your Study Information with people whom you have permitted to see it. However, once your Study Information is shared as authorized, it may no longer be protected by Federal or state law and may be re-disclosed without your permission.

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While participating in this study, the study doctor will replace your name with a special code that identifies you. This code, along with your study information, will be used by the study sponsor, and their representatives (the "Sponsor"), for the study purposes mentioned above and to help establish whether the study drug is safe and effective. The sponsor may share your coded information, as necessary, with other members of the Sponsor's worldwide group of related companies, people and companies who work with the sponsor and who work within the scope of this consent ethics committees and regulatory agencies such as the US Food & Drug Administration, the national health authorities.

In addition, if you withdraw from this study, you have the right to request of your study doctor that your blood samples be destroyed. If you request that your samples be destroyed, all data generated up to the time of the request will be used for the study, but no other additional data will be generated from your samples. The Sponsor is responsible for the destruction of remaining samples at the end of the storage period.

The people, companies, and agencies listed above that have access to your information may be located in countries of the European Economic Area (EEA); the United States; and other countries around the world. You should be aware that some countries may not offer the same level of privacy protection as you are used to in the country where you live or where this study is conducted. However, the sponsor will keep any information it receives to the same standard of confidentiality as far as permitted by applicable local law.

The study information will be kept confidential within the limits of the law and used only for this study as well as combined with other studies as applicable, for pooled analysis and interpretation needed for any regulatory submissions linked to this compound. If the results of this study are published or presented in a meeting, you will not be named and nobody will be able to tell that you were in the study from the publication or presentation.

Your participation in this study is voluntary and you may cancel this consent at any time and without any reason and will not involve any penalty or loss of access to treatment or other benefits to which you are entitled. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends. This Authorization will not expire unless revoked. To revoke your Authorization, you must write to the study doctor, stating that you are revoking your Authorization to Use and Disclose Protected Health Information at:

Thomas C. Marbury, M.D.
Orlando Clinical Research Center
5055 S. Orange Avenue
Orlando, FL 32809

The sponsor will continue to retain and use all research results that have already been collected for the study evaluation. All biological samples that have already been collected may be retained and analyzed at a later date (as per local regulations).

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You have the right to review your Study Information and medical records and request changes to the Study Information if it is not correct. However, please note that during the study, access to Study Information may be limited if it weakens the integrity of the research. You may have access to the Study Information held by the Study Doctor at the end of the study.

If you have any questions about the collection and use of information about you, or would like to exercise rights that you may have regarding this information, you should ask your Study Doctor.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Japan, and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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PRIMARY CARE PHYSICIAN NOTIFICATION

If you agree, your primary care physician will be informed of your participation in the study. Indicate your choice by initialing only one (1) section below.

_____ Initials — I do not have a primary care physician

_____ Initials — I do not want my primary care physician notified

_____ Initials — I would like my primary care physician notified and below is my physician's contact information.

Physician's Name: _____

Address: _____

_____

Phone No.: _____

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

J. Do you authorize the use and disclosure of your medical information? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____ _____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____ _____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this informed consent to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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CONSENT FOR SUBJECTS WHO ARE VISUALLY IMPAIRED

The study subject has indicated that he/she is visually impaired. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____
Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information provided to the subject.

You will receive a signed and dated copy of this consent form to keep.

INTEGREVIEW IRB

MEMBERSHIP ROSTER
As of February 19, 2018

Sponsor Name: Aronora, Inc.	**Protocol Number:** 3G3-18-02
Principal Investigator Name: Thomas C. Marbury, M.D.	**Meeting Date:** June 20, 2018

C Denotes consultants (non-voting) assisting in the review of the study when the knowledge and expertise in a particular therapeutic area is not available among the voting members
A Denotes members abstaining from the vote
✓ Denotes (voting) members who were in attendance at the meeting and reviewed the study information

	NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
	[M] M. Alexander Kenaston, Chairman	Ph.D., M.S. (Toxicology), R.N., CIP	Scientific	Toxicology Research Scientist, representative for first time in human studies, Pharmacology/ Toxicology, Licensed Registered Nurse; previously employed as Project Manager, CRA and CRC for CRO	Non-affiliated Paid Consultant	Scientific members
	[M] Jami Brackeen, Co-chair	CST, CCRP	Scientific	IRB Coordinator, Co-chair, administrative support for IntegReview; former Quality Control Associate for IRB Regulatory Compliance; Certified Surgical Technologist	Full time Employee	Scientific members
	[M] Olga Obrda	B.S. (Chemistry)	Scientific	BD Representative; previously employed as Project Management and Business Development for CRO	Non-affiliated Paid Consultant	Scientific members

[M] Denotes regular Monday board members [T] Denotes regular Tuesday board members [W] Denotes regular Wednesday board members [Th] Denotes regular Thursday board members
[F] Denotes regular Friday board members Other members are alternates All regular Board members can serve as alternates on other Boards as specified by their positions (e.g. Scientific for Scientific)
Non-scientific members represent the general perspective of study participants
Note: In addition to our regular members, we have access to specialists in therapeutic areas not represented on this roster.

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Sponsor Name: Aronora, Inc.	**Protocol Number:** 3G3-18-02
Principal Investigator Name: Thomas C. Marbury, M.D.	**Meeting Date:** June 20, 2018

	NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
	[M] Bryson Michael Duhon	Pharm.D., BCPS	Scientific	Clinical Assistant Professor UT College of Pharmacy; Adjoint Professor at UT Health Science Center (UTHSCSA) Department of Medicine	Non-affiliated Paid Consultant	Scientific members
	[M] Ashley Hutson		Non-scientific	Previously volunteered as research subject in clinical trials; homemaker	Non-affiliated Paid Consultant	Non-scientific members
	[M] Karen Haslund	M.D.	Scientific	Licensed physician, Pediatrics	Non-affiliated Paid Consultant	Scientific members
	[T] Charles F. Ryan, Chairman	Ph.D., M.S. (Pharmacology & Toxicology), R.Ph.	Scientific	Representative for first time in human studies; Pharmacology, Toxicology, Radiation Safety, Radioisotope, Nutritional/Food supplements and Medical Foods	Non-affiliated Paid Consultant	Scientific members
	[T] Tonya Reed, Co-chair		Non-scientific	IRB Coordinator, administrative support for IntegReview; previously employed as a Project Assistant for CRO	Full time Employee	Non-scientific members
	[T] Sara Bartos	M.D.	Scientific	Licensed physician, Internal Medicine	Non-affiliated Paid Consultant	Scientific members
	[T] Marcy Goodfleisch	B.S., M.A. (Liberal Studies); Mediator (Civil & Family Dispute Resolution); Graduate work in Communications and English	Non-scientific	Adjunct University Professor; Ethicist; Management & Communication Consultant. Former Clinic Administrator for nationally recognized HIV Clinic and large FQHC community health center.	Non-affiliated Paid Consultant	Non-scientific members

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	[T] Michael D. Aldridge	Ph.D. (Nursing Education), R.N., CNE	Scientific	Assistant Professor of Nursing; previously employed in various Nursing roles for pediatric intensive care unit, including Specialty Education Coordinator for pediatric ICU, previous experience as an IRB member	Non-affiliated Paid Consultant	Scientific members
	[T] Christine du Castel	M.D.	Scientific	Medical Advisor; previously licensed to practice General Medicine in France	Non-affiliated Paid Consultant	Scientific members
✓	[W] Carolyn Hensler, Chairman	B.S. (Physical Education)	Scientific	Quality Assurance and Quality Control Administrator for CRO; previously employed as a Clinical Research Monitor; and Project Manager	Non-affiliated Paid Consultant	Scientific members
✓	[W] Angelica Martinez, Co-Chair	CCRP	Non-scientific	IRB Coordinator, administrative support for IntegReview	Full time Employee	Non-scientific members
✓	[W] Raymond Carr	R.Ph.	Scientific	Staff Pharmacist	Non-affiliated Paid Consultant	Scientific members
✓	[W] Christopher P. Martin	Pharm.D., M.S., BCPS	Scientific	Clinical Assistant Professor, Division of Pharmacotherapy UT; Clinical Pharmacy Coordinator; Assistant Professor University of Oklahoma Health Sciences Center, College of Pharmacy	Non-affiliated Paid Consultant	Scientific members
	[W] Robert A. Blum	Pharm.D.	Scientific	Various experience as a principal investigator for research studies	Non-affiliated Paid Consultant	Scientific members
✓	[W] William K. Rawlinson	M.D., FCCP, FAASM	Scientific	Licensed physician, Pulmonary, Critical Care and Internal Medicine	Non-affiliated Paid Consultant	Scientific member
	[Th] Frederick Kopec, Chairman	J.D., B.A. (Philosophy)	Non-scientific	Licensed, Practice of Law, Ethicist	Non-affiliated Paid Consultant	Non-scientific members

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	[Th] Bridget Briseno, Co-chair		Non-scientific	IRB Coordinator, administrative support for IntegReview	Full time Employee	Non-scientific members
	[Th] Michael Romain	M.D.	Scientific	Licensed physician, Internal Medicine	Non-affiliated Paid Consultant	Scientific members
	[Th] Mary O'Connell		Scientific	Quality & Regulatory Affairs Manager; previously employed as Clinical Research Recruiter, Data Associate, Coordinator and QC Auditor for CRO, IRB Administrator, Emergency Medical Technician Paramedic	Non-affiliated Paid Consultant	Scientific members
	[Th] Matthew Pfeiffer	Ph.D. (Pharmacology & Toxicology)	Scientific	Project Manager and CRA for CRO; Representative for first in human studies; clinical and research experience; Pharmacology, Toxicology, CNS, Infectious disease, Metabolic/Endocrine Disorders, Oncology	Non-affiliated Paid Consultant	Scientific members
	[Th] Susan Parker Ginnings	R.Ph.	Scientific	Previously employed as Hospital Pharmacy Supervisor	Non-affiliated Paid Consultant	Scientific members
	[F] Mary Ruwart, Chairman	Ph.D. (Biophysics); B.S. (Biochemistry)	Scientific	Research Scientist, Drug Delivery Systems, Diabetes, GI Diseases, Drug Metabolism	Non-affiliated Paid Consultant	Scientific members
	[F] Francine Lopez, Co-chair	B.S., CCRP	Non-scientific	IRB Coordinator, administrative support for IntegReview	Full time Employee	Non-scientific members
	[F] Laurajo Ryan	Pharm.D., MSc (Clinical Investigations), BCPS, CDE	Scientific	Clinical Associate Professor of Pharmacotherapy UT Austin, Department of Medicine UTHSCSA, Clinical Pharmacist Specialist South Texas Veterans Administration	Non-affiliated Paid Consultant	Scientific members

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	[F] Dennis Brannon	R.Ph., B.S. (Animal Science)	Scientific	Clinical Research Consultant, Director of Pharmacy; Executive Director Clinical Development; previously employed as Senior Project Manager and CRA for CRO	Non-affiliated Paid Consultant	Scientific members
	[F] Bennie C. Lopez	MBA	Non-scientific	Representative for adult and juvenile prisoner population; Teacher with Austin ISD Alternative Learning Center; previously employed as Corrections Officer and retired military	Non-affiliated Paid Consultant	Non-scientific members
	[F] Patricia M. Houser	M.D.	Scientific	Licensed physician; Family practice	Non-affiliated Paid Consultant	Scientific members
	Victoria Govea	CCRP	Non-scientific	Management support for IntegReview; former IRB Coordinator, Co-chair for IntegReview	Full time Employee	Non-scientific members
	Lynn Goldman	B.S. (Nutrition), MSHP (Healthcare Administration), RD, LD, CCRP	Scientific	Management support for IntegReview; former IRB Coordinator, Co-chair; previously employed as Research Coordinator, Health Care Administration and Education, Clinical Nutrition, Registered Dietician/Certified Pediatric Nutrition Specialist	Full time Employee	Scientific members
	Christina H. Walker	M.D., B.S.	Scientific	Physician	Non-affiliated Paid Consultant	Scientific members
	Rosa S. Sandoval	B.S. (Chemistry), CCRP	Scientific	IRB Operations Supervisor; Former Senior IRB Coordinator, Co-chair and administrative support for IntegReview; previously employed as Clinical Research Coordinator and Medical Research Assistant for University	Full time Employee	Scientific members
	Levi Machado	CCRP	Non-scientific	IRB Training Administrator; former IRB Coordinator, Co-chair; previously provided administrative support for IntegReview	Full time Employee	Non-scientific members

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