



Opus Institutional Review Board

1175 Grimes Bridge Rd. Suite 300 Roswell, GA 30076
 678-736-7900 Fax 678-736-7949 Toll Free 877-346-8420
 info@opusirb.com

Initial Submission Application for the Investigator/Site

1. Sponsor, Protocol Name and Protocol Number	
	Sponsor Name
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is this an investigator initiated study?
	Protocol Name
	Protocol Number opus # (internal use)
Yes <input type="checkbox"/> No <input type="checkbox"/>	Opus IRB applies DHHS and FDA regulations to all research. Does the sponsor, researcher and/or the funding source want the review to include ICH-GCP (E6) guidelines?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is there potential for this protocol to be conducted under "planned emergency research?" (21 CFR 50.24; OHRP Guidance 97-01)
Yes <input type="checkbox"/> No <input type="checkbox"/>	Will advertisement/recruitment materials be utilized for this study?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Will subjects receive compensation for participating in this study? <i>(This application must include the amount and schedule of all payments, if applicable.)</i>

2. Principal Investigator (PI) Information	
	Principal Investigator's First Name
	Principal Investigator's Middle Name/Initial
	Principal Investigator's Last Name
	Corporate Name
	Principal Investigator's Mailing Address
	Phone
	Email

	PI Degree(s)
	Medical Specialty(ies)
	Medical License # :
	State:
	Expiration Date:
	DEA Registration # (if applicable): Expiration Date:
Yes <input type="checkbox"/> No <input type="checkbox"/>	Will the PI conduct research involving an investigational drug in the State of Massachusetts?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Are there any special laws governing medical research in your community or state? If Yes, please check all that apply Yes <input type="checkbox"/> No <input type="checkbox"/> State laws related to the use of Protected Health Information Yes <input type="checkbox"/> No <input type="checkbox"/> California Experimental Bill of Rights Yes <input type="checkbox"/> No <input type="checkbox"/> Mandatory IRB site visits Yes <input type="checkbox"/> No <input type="checkbox"/> Age of majority different than 18 Yes <input type="checkbox"/> No <input type="checkbox"/> Other <i>(Please list and attach additional information, if needed):</i>
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is the PI Board certified? If Yes, please list Board certification: (Note: A list of ABMS Boards is available at http://www.abms.org/About_ABMS/member_boards.aspx .)
Yes <input type="checkbox"/> No <input type="checkbox"/>	Has the PI received an FDA 483 within the last 5 years, or ever received a Warning Letter? If Yes, please attach all information related to the audit.
	List the number of ongoing studies in which the Investigator is listed as the PI?
	List the number of studies in which the Investigator is listed as a Sub-Investigator?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is the PI "Clinical Research Investigator" certified? (i.e. ACRP) If Yes, please list the certifying organization:
	How long has the PI been conducting research?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Has the PI ever had an IRB terminate a study for any reason, or impose any sanctions or restrictions on them?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Has the PI ever been placed on the Restricted / Disqualified or Debarment List, or on OHRP's Administrative Action List?

If Yes, please attach an explanation

Describe provisions for monitoring data to ensure the safety of participants is appropriate.

3. Sub-Investigator's Information

For each sub-investigator listed below, please attach a CV

Name of Sub-Investigator	Specialty	Degree	Medical License #	State
Yes <input type="checkbox"/> No <input type="checkbox"/>	Has any Sub-Investigator received an FDA 483 within the last 5 years or ever received a Warning Letter? If Yes , please attach all information related to the audit.			

4. Research Staff Information Personnel

Primary IRB Contact

Name	
Phone	
Fax	
Email	
Title	

Research Staff Information

Name	Title	Phone	Email	Years of Research Exp.

5. Training and Education

What training has the research staff had in the protection of human research subjects?

None (see below)

Yes No CITI Training Modules

Yes No NIH Human Participants Protection Education

Yes No OHRP Training Modules

Yes No NCI Human Participant Protections Education for Research Teams

Yes No Other (Identify Training)

If **None**, it is the PI's responsibility to ensure all Sub-Investigators and Research Staff members are knowledgeable about good clinical practices (GCP) Specifically 21 CFR 312, sub part D or 21 CFR 812 Sub Part E and the [Belmont Report](#) .

6. Primary Research Site Location and Information

Site Name			
Site Address			
Mailing Address			
Site Phone			
Site Fax			
Contact for Site			
Contact Phone			
Contact Fax			
Contact Email			
Yes <input type="checkbox"/> No <input type="checkbox"/>	Are there adequate resources necessary to protect participants?		
<input type="checkbox"/>	Adequate time for the investigators to conduct and complete the research		
<input type="checkbox"/>	Adequate number of qualified staff		
<input type="checkbox"/>	Adequate facilities		
<input type="checkbox"/>	Access to a population that will allow recruitment of the necessary number of participants		
<input type="checkbox"/>	Availability of medical or psychosocial resources that participants may need as a consequence of the research		
Indicate the types of personnel and equipment available to treat life-threatening reactions, if they occur (Check all that are applicable):			
<input type="checkbox"/>	M.D. Available	<input type="checkbox"/>	Emergency Medications
<input type="checkbox"/>	R.N Available	<input type="checkbox"/>	Suction
<input type="checkbox"/>	CPR Certified Staff	<input type="checkbox"/>	Emergency 911 Access

<input type="checkbox"/>	Crash Cart	<input type="checkbox"/>	Administrative Only
<input type="checkbox"/>	Defibrillator	<input type="checkbox"/>	Oxygen
<input type="checkbox"/>	Other	<input type="checkbox"/>	Other

Name of Medical Facility to be used in the event of an emergency

Distance from Research Site (in miles)

Yes No Does PI have privileges at this facility?

Yes No Does a local IRB have jurisdiction over this site?

If Yes, Submit a "Transfer of IRB Obligation" Form or equivalent document. (available at www.opusirb.com)

What are the general community attitudes towards the conduct of research in your local community that Opus IRB should be aware of prior to reviewing this study for your site? Check one of the following:

Neutral

Positive

Negative

If Negative please explain:

Yes No Will the PI conduct research at more than one location?

If **Yes,** List the number of sites

If **Yes,** submit a Additional Site Form for each location where research will be conducted

**Note - If applicable, the number of sites listed in box 3 of the FDA 1572 must equal the number of sites submitted via this application and the accompanying SUPPLEMENTAL SITE FORM(s).*

7. Research Protocol

The purposes of the research

The scientific rationale

The procedures to be performed
A description of the procedures being performed already for diagnostic or treatment purposes
The risks and potential benefits of the research to participants

8. Informed Consent Information

Yes <input type="checkbox"/> No <input type="checkbox"/>	Will there be non-English speaking subjects enrolled?
--	---

If Yes, please explain how you will provide interpreters for all communication with the participant.

--	--

Yes <input type="checkbox"/> No <input type="checkbox"/>	Will you need for Opus IRB to have the consent document translated? (<i>additional fee</i>)
--	---

If Yes, provide languages required:

--	--	--	--

Who normally conducts the informed consent discussion with potential subjects? Check all that apply.

<input type="checkbox"/> Principal Investigator	<input type="checkbox"/> Research Nurse / Study Coordinator
<input type="checkbox"/> Sub-Investigator	<input type="checkbox"/> Other: (<i>please list</i>):

Yes <input type="checkbox"/> No <input type="checkbox"/>	Will subjects with legally authorized Representatives (LAR's) or a parent/guardian be enrolled?
--	---

If yes, how will you verify who constitutes a LAR or a guardian* in your state?

- | | |
|---|--|
| <input type="checkbox"/> Legal counsel | <input type="checkbox"/> State Law Reference Materials |
| <input type="checkbox"/> State law Codes and Statutes | <input type="checkbox"/> Sponsor/CRO's |
| <input type="checkbox"/> Other | |

**Guardian is defined as an individual who is authorized under applicable or local law to consent on behalf of a child to general medical care.*

Yes No

Is a waiting period required between informing the prospective participant and obtaining consent?
If yes, explain:

Opus IRB requires a detailed explanation of the informed consent process. If your informed consent process is detailed in a standard operating procedure then please submit a copy of the SOP that applies. Include steps taken to minimize the possibility of coercion or undue influence and the information to be communicated to the prospective participant or the legally authorized representative.

Please provide contact numbers for informed consent document questions, or a research related injury event.

Daytime Phone Number

24 hour Phone Number

Please notify Opus IRB immediately with any changes to the preceding contact information.

9. Subject Compensation for Participation in Clinical Research Study

Yes No

Will subjects be compensated for their participation in the study?

What is the amount per completed visit?

What is the possible total amount that the participant may receive?

10. Confidentiality Information (HIPAA)

Describe how you will provide for the confidentiality of each participant's protected health information. Include information for electronic and paper related documents regarding storage, access, etc. If you have a standard operating procedure for handling PHI or HIPAA, submit a copy of the related SOP.

11. Privacy

Describe your research site's policy for protecting your subjects' physical privacy. If you have a standard operating procedure for handling a subject's privacy, submit a copy of the related SOP.

12. Enrollment

Identify the number of subjects you plan to enroll

Identify the approximate ethnic makeup of the population from which you plan to recruit for research (percentages should add up to 100%):

% African American

% Asian

% Caucasian

% Hispanic or Latino

% Native American

% Pacific Islander

% Other (*please specify*)

Yes No

Will you recruit any minors for research? (persons under the site state's age of majority)

* Unless waived by Opus IRB, assent is required for all minors. Submit a copy of your SOP for your assent process.

Yes No

Will you enroll any subjects from the following categories of vulnerable groups?

If Yes, check all that apply.

Children

Economically Disadvantaged

Educationally Disadvantaged

Employees of the Sponsor

Employees of the PI/site

Mentally Disabled

Nursing Home Residents

Pregnant Women or Fetuses

Physically Handicapped

Prisoners

Traumatized/Comatose

Visually Impaired/Illiterate

Other:

Include a copy of your SOP detailing additional safeguards that will be used to protect the rights and welfare of each vulnerable population selected.

13. Recruitment Practices Information

Identify the following methods the PI will use to recruit subjects for this study:

- Existing patients
- Referrals
- Advertising
- Other *(please specify)*:

**All recruitment materials must be approved by Opus IRB. Any new/additional recruitment materials must also be approved by Opus IRB Prior to use.*

14. Who Should Opus Bill for IRB Services?

Corporate Name
Mailing Address
Phone Number
Email
Attention To

**It is the responsibility of the site and/or the sponsor to notify Opus IRB of any changes in the billing information.*

15. Principle Investigator Statement of Compliance

As Principle Investigator I certify that the information set forth on this submission form is accurate to the best of my knowledge and that I will abide by the obligations set forth below. Check each box and sign below to signify your willingness to comply with these requirements.

<input type="checkbox"/>	I agree to follow the protocol and its amendments, appendices, investigator brochures/device manuals, and any other Sponsor related materials. I will not implement any changes in the conduct of the research without prior written approval by Opus IRB.
<input type="checkbox"/>	I agree to conduct this study in compliance with all federal regulations, state and local laws, ICH Guidelines for GCP, and HIPAA regulations, and any other applicable regulations regarding research with human subjects.
<input type="checkbox"/>	I agree that either I or someone under my supervision will verbally explain the approved "Subject Informed Consent" form to all potential subjects before obtaining their dated signature and before performing any study related procedures.
<input type="checkbox"/>	I agree to ensure the circumstances of the consent process minimize the possibility of coercion or undue influence.
<input type="checkbox"/>	I agree that any delegated tests, procedures and the dispensing of drugs or implementation of devices as required by the protocol will be performed by individuals who are qualified by education, licensure and/or the governance of the local medical board to perform these procedures.
<input type="checkbox"/>	I agree that the privacy of the subject and the confidentiality of the study data will be maintained by both by myself and my research staff.
<input type="checkbox"/>	I agree that I will spend sufficient time to maintain appropriate oversight of the research protocol and the research staff including recruitment, selection of study participants, and study conduct to appropriately delegate research responsibilities. I also agree that I have adequate data and safety monitoring in place for ongoing research.
<input type="checkbox"/>	I agree to report any and all unanticipated problems involving risk to study subjects to Opus IRB.
<input type="checkbox"/>	I agree to report to Opus IRB any significant protocol deviations within 10 business days of the site's knowledge of the event.
<input type="checkbox"/>	I agree to make myself available to discuss concerns and complaints regarding research subjects with all persons involved with this research protocol.
<input type="checkbox"/>	I agree that Opus IRB has the right to audit/visit the study site at any time with 10 business days notice.
<input type="checkbox"/>	I agree to make a reasonable effort to ascertain the reason(s) a participant withdraw prematurely from the clinical trial, while fully respecting the participant's rights.
<input type="checkbox"/>	I agree to provide and ensure all research staff provides all the disclosures and follow the requirements pertaining to consent covered by ICH-GCP (E6).
<input type="checkbox"/>	I agree to maintain an up-to-date curriculum vitae and other relevant documentation requested by the sponsor, the IRB, or the regulatory authority.
<input type="checkbox"/>	I agree to be familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.
<input type="checkbox"/>	I agree to report all serious adverse events (SAEs) to the sponsor except for those SAEs that

	the protocol or other document (e.g., investigator's brochure) identifies as not needing immediate reporting; and follow the regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB.
<input type="checkbox"/>	I agree to provide written reports to the sponsor, the IRB, and, where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
<input type="checkbox"/>	I agree to inform the organization, sponsor, and the IRB if I terminate or suspend a clinical trial without prior agreement of the sponsor.
<input type="checkbox"/>	I agree to promptly notify the sponsor if the IRB terminates or suspends approval of the clinical trial.
<input type="checkbox"/>	I agree to inform the organization and the IRB with a summary of the trial's outcome; and the regulatory authority with any reports required upon completion of the clinical trial.

16. Principle Investigator's Attestation – Service Agreements

As Principal Investigator I attest the service agreement/contract with the sponsor, contract research organization or other funding agreement contain the following elements. Check each box and sign below to signify your compliance with these requirements.

<input type="checkbox"/>	Description of who will provide care and who is responsible for paying for the care/procedures/tests required by the protocol.
<input type="checkbox"/>	The sponsor will promptly report to the organization any findings that could <ul style="list-style-type: none"> • Affect the safety of participants. • Influence the conduct of the study or alter the IRB's approval to continue the study.
<input type="checkbox"/>	The sponsor will send data and safety monitoring plans and reports to Opus IRB.
<input type="checkbox"/>	The time frame for providing routine and urgent data and safety monitoring reports to Opus IRB is specified.
<input type="checkbox"/>	The sponsor will follow the Organization's policies and procedures regarding the publication of findings from sponsored research.
<input type="checkbox"/>	Steps followed to communicate findings from a closed research study to the investigator or organization when those findings directly affect participant safety.
<input type="checkbox"/>	Specify requirement that investigator or the organization conducting the research forward to Opus IRB findings from a closed research study that directly affect participant's safety.
<input type="checkbox"/>	The sponsor will communicate any study results that could directly affect participant safety for two years after the completion of the study.

Signature of Principal Investigator (Required)

Signature Date (Required)

Printed Name of Principal Investigator (Required)