

Goodwyn Institutional Review Board, Ltd.*Sponsor Form****Sponsor/CRO Application***

*Form must also be completed by a single site for a single-site (vs. multicenter) application.

Sponsor:

Protocol Number:

Type of Research:

- Social/Behavioral
 Tissue/Blood Bank
 Drugs and Biologics (see below)
 Devices (see below)
 Other (describe):

Additional Information for Drugs and Biologics

Is the drug or biologic being used in this research study approved by FDA: If yes, state the approved indications(s):	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, is the drug or biologic being used in this study within one or more of its approved indications(s):	<input type="checkbox"/> Yes <input type="checkbox"/> No
IND Number is available: If yes, what is the IND number:	<input type="checkbox"/> Yes <input type="checkbox"/> No
IND number is not yet available: <input type="checkbox"/> Explain:	
<i>(Claiming exemption from IND regulation may require additional documentation. Please contact Goodwyn IRB at (513) 793-8900.)</i>	
Are you claiming exemption from IND regulation: If yes, enter the qualification for IND exemption per 21 CFR 312.2(b):	<input type="checkbox"/> Yes <input type="checkbox"/> No

Additional Information for Devices

Device Class (select one):	
Is the device being used in this research study approved by the FDA: If yes, cleared by:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did you select "other" above: If yes, describe:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the device being used in this study within its approved, labeled indication:	<input type="checkbox"/> Yes <input type="checkbox"/> No
An IDE is approved: If yes, what is the assigned number:	<input type="checkbox"/> Yes <input type="checkbox"/> No
An IDE application has not been submitted (if yes, answer the questions below):	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are you requesting a non-significant risk (NSR) determination: If requesting a NSR determination, attach documentation to support the NSR claim.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the device a drug delivery system that is being regulated by the FDA under an investigational new drug (IND) application:	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>(Claiming exemption from IND regulation may require additional documentation. Please contact Goodwyn IRB at (513) 793-8900.)</i>	
Are you claiming exemption from IDE regulation: If yes, enter the qualification for IDE exemption:	<input type="checkbox"/> Yes <input type="checkbox"/> No

Submit completed form to: 9380 Main Street, Cincinnati, OH 45242 Fax: 513-793-2800 or 513-793-4800

Study Information

Is this study funded (in whole or in part) by a federal department or agency: If yes, please attach a copy of the grant award letter.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have recommendations from any other IRB to modify/disapprove this protocol been made: If yes, please attach the IRB's review letter and an explanation about how the issues have been addressed.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Will it be necessary to suspend subjects' right of access to their health information while this research study is in progress: If yes, please provide the justification:	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>Note: Studies that include subjects who are minors will require the addition of an Assent Statement and/or a separate Assent form with the submission of a study for review.</i>	
What is the age range of subjects for this study:	

Vulnerable Populations

Does the protocol design require the enrollment of any of the vulnerable populations listed below (check all that apply):	
<input type="checkbox"/> Adults with diminished decision-making capability. <input type="checkbox"/> Children / Minors. <input type="checkbox"/> Economically disadvantaged. <input type="checkbox"/> Illiterate / Educationally disadvantaged. <input type="checkbox"/> Physically handicapped. <input type="checkbox"/> Pregnant Women. <input type="checkbox"/> Prisoners. <input type="checkbox"/> Sponsor / site employees or their family members. <input type="checkbox"/> NO – none of the vulnerable populations.	
Vulnerable populations require additional provisions to protect their rights. Such provisions may be requirements of the protocol, protocol-referenced documents or expressed through site-level, procedural requirements for investigators. Regardless, the nature of these provisions must be documented.	
For the vulnerable populations checked above, describe provisions required by the study plan for additional safeguards required to protect their rights and welfare:	
Are any of the vulnerable populations specifically excluded: If yes, list those specifically excluded:	<input type="checkbox"/> Yes <input type="checkbox"/> No

Legally Authorized Representatives (LAR)

For this study, do you intend to allow enrollment of adult subjects unable to consent for themselves (if approved by the IRB):	<input type="checkbox"/> Yes <input type="checkbox"/> No
---	--

Monitoring Plan

Will a Data Safety Monitoring Board (DSMB) be used for this study:	<input type="checkbox"/> Yes <input type="checkbox"/> No
What is the sponsor's rationale for why a DSMB is not necessary:	
Describe the alternate data and safety monitoring plan:	
How frequently will Sponsor/CRO representatives visit the research site(s) for routine monitoring:	

Emergency Preparedness

Is emergency equipment / medication required at investigators' site by this protocol or by this sponsor: If yes, what equipment / medications are required:	<input type="checkbox"/> Yes <input type="checkbox"/> No
How will the sponsor/CRO ensure that the Investigators/sites comply with these requirements:	

Compensation and Medical Care for Research Related Injury

The proposed consent template provides an explanation of your policy regarding compensation / treatment for research related injuries:

Yes No

If no, please explain:

Investigator/Site-Generated Recruitment or Other Written Material

(If the answer is "yes" below, Goodwyn IRB will require investigators to obtain written sponsor approval prior to IRB review. To facilitate faster processing, please make sites aware that sponsor approval is required.)

Do you require sponsor approval prior to IRB review of any investigator/site-generated subject materials:

Yes No

FDA Form 1572

Does the sponsor require a completed FDA Form 1572 from Investigators participating in this study:

Yes No

Investigator Meeting

Will there be/has there been an investigator meeting for this study:

Yes No

Would you like a representative from Goodwyn IRB to attend and provide training:

Yes No

When is/was the investigator meeting scheduled:

Contact Information:

For protocol, consent form, and safety issues please contact:

Name:

Title:

Company:

Street Address (1):

Street Address (2):

City:

State:

Postal Code:

Phone:

Email:

For administrative issues, correspondence, and receipt of approval documents please contact:

Name:

Title:

Company:

Street Address (1):

Street Address (2):

City:

State:

Postal Code:

Phone:

Email:

Sponsor/CRO copies of approval documents and real-time study/investigator start-up and status reports are accessible through Goodwyn IRB Secure File Services. You may also choose to receive hard copies of all written notifications from the IRB.

In addition to the electronic copies delivered online, please provide hard copies of all documents to the contact above:

Yes No

Please deliver electronic copies of review notification to the follow additional contacts:

Shipping Information

Correspondence and notifications from Goodwyn IRB may be generated and signed in electronic form. In addition to electronic correspondence and notifications, hard copy (printouts) of the same are always provided to the investigators. Any such printouts accurately reflect the electronic original and shall be treated as originals.

Would you like the sponsor/CRO to receive hard copy as well as electronic form:

Yes No

If yes, list who should receive the hard copy:

Sponsor/CRO copies of approval documents and real-time study/investigator start-up and status reports are accessible through Goodwyn IRB Secure File Services. You may also choose to receive hard copies of all written notifications from the IRB.

In addition to the electronic copies delivered online, please provide hard copies of all documents to the contact above.

Correspondence and notifications from Goodwyn Institutional Review Board, Ltd. may be generated and signed in electronic form. In addition to electronic correspondence and notifications, hard copy (printouts) of the same are always provided to the investigators. Any such printouts accurately reflect the electronic original and shall be treated as originals.

Shipping Information:

Would like the investigator/Sponsor/CRO to receive hard copy via express service?

Investigator: Yes No

Sponsor: Yes No N/A (will not receive printed copy from the IRB)

CRO: Yes No N/A (will not receive printed copy from the IRB)

If yes to any above, provide the information below:

Check your preference:

Federal Express Priority Overnight

Federal Express Standard

Airborne Express

UPS 2-Day

UPS Next Day

Your Billing Account Number:

Invoices for IRB Service:

Invoices for IRB Service should be sent to:

Primary Contact Above

Other (specify below)

Name: _____ Title: _____

Company: _____

Address: _____

City: _____ State: _____ Postal Code: _____

Phone: _____ Email: _____

Agreement to Terms and Signature:

By signing below, the sponsor agrees to and affirms compliance with the following terms:

The sponsor/CRO is responsible for selecting only qualified investigators, with sufficient time to conduct the research properly and the appropriate potential to recruit the required number of suitable subjects, as appropriate experts to conduct the research study. Sponsors/CROs must comply with all requirements regarding research activities, including federal, state, local, and IRB requirements. Only complete and accurate information should be submitted to the IRB for review and approval.

Sponsors must evaluate and ensure that the appropriate resources and infrastructure to support the conduct of clinical research are maintained at the site(s). The site(s) must be in compliance with the sponsor's requirements for handling medical emergencies. The site(s) must store research records in such a way as to protect the privacy and confidentiality of subject information.

Each sponsor/CRO should ensure that the manufacture and formulation of the investigational product conforms to federal regulations. If the study will utilize a comparator, ensure that manufacture and formulation of the comparator also conforms to federal requirements. Each sponsor/CRO should also ensure the appropriate control (storage, dispensation, and accountability) of the investigational product at the site(s) as required by federal, state, and local law.

Sponsors/CROs (and Principal Investigators) must submit to the IRB in writing any unanticipated problems involving risk to human subjects or others. This notification to the IRB must occur promptly and no later than 10 working days from the time of identification of the unanticipated problem.

The sponsor/CRO must ensure by adequate site selection methods and ongoing monitoring that the study staff at the research site(s) are conducting research in compliance with Regulatory and IRB Requirements.

Signature: _____ **Date:** _____
(Sponsor/CRO Representative)

Title: _____ **Company:** _____