



Sponsor/CRO Application*

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

Sponsor: _____ Protocol #: _____

Name of Submitter: _____

Title of Submitter: _____

Type of Research

- Social/Behavioral:**
- Tissue/Blood Bank:**
- Drugs and Biologics (see below #1):**
- Devices (see below #2):**
- Other:** _____

Additional Information for Drugs and Biologics

1. Is the drug or biologic being used in this research study approved by FDA: Yes No
 - a. If **yes**, state the approved indication(s): _____
 - b. If **yes**, is the drug or biologic being used in this study within one or more of its approved indication(s): Yes No
 - c. Is the IND Number available: Yes No
 - If **yes**, what is the IND number: _____
 - If **no**, explain: _____
 - d. Are you claiming exemption from IND regulation: Yes No
 - If **yes**, enter the qualification for IND exemption per 21 CFR 312.2(b): _____

(Claiming exemption from IND regulation may require additional documentation. Please contact Goodwyn IRB at (513) 793-8900.)

Additional Information for Devices

2. Device Class: I II III N/A
3. Is the device being used in this research study approved by the FDA: Yes No
 - If **yes**, cleared by: PMA 510K Other:
4. Is the device being used in this study within its approved, labeled indication: Yes No
5. Is an IDE approved: Yes No
 - If **yes**, what is the assigned number: _____
6. Has an IDE application been submitted (if no, answer the questions below): Yes No
 - a. Are you requesting a non-significant risk (NSR) determination: Yes No
 - If requesting a NSR determination, attach documentation to support the NSR claim.**
 - b. Is the device a drug delivery system that is being regulated by the FDA under an investigational new drug (IND) application: Yes No
7. Are you claiming exemption from IDE regulation: Yes No
 - If **yes**, enter the qualification for IDE exemption: _____

(Claiming exemption from IDE regulation may require additional documentation. Please contact Goodwyn IRB at (513) 793-8900.)



Study Information

8. Is this study funded (in whole or in part) by a federal department or agency: Yes No
 If **yes**, please attach a copy of the grant award letter.
 If **yes**, please attach a completed IRB authorization agreement with Goodwyn IRB identified as the organization providing review.
9. Have recommendations from any other IRB to modify/disapprove this protocol been made: Yes No
 If **yes**, please attach the IRB's review letter and an explanation about how the issues have been addressed.
10. Will it be necessary to suspend subjects' right of access to their health information while this research study is in progress: Yes No
 If **yes**, please provide the justification: _____
11. What is the age range of subjects for this study: _____

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.

Vulnerable Populations

12. Does the protocol design require the enrollment of any of the vulnerable populations (check all that apply):
- Adults with diminished decision-making capability.
 - Children / Minors.
 - Economically disadvantaged.
 - Illiterate / Educationally disadvantaged.
 - Physically handicapped.
 - Pregnant Women.
 - Prisoners.
 - Sponsor / site employees or their family members.
 - 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.
- a. For the vulnerable populations checked above, describe provisions required by the study plan for additional safeguards required to protect their rights and welfare:

- b. Are any of the vulnerable populations specifically excluded: Yes No
 If **yes**, list those specifically excluded: _____

Legally Authorized Representatives (LAR)

13. For this study, do you intend to allow enrollment of adult subjects unable to consent for themselves (if approved by the IRB): Yes No

Monitoring Plan

14. Will a Data Safety Monitoring Board (DSMB) be used for this study: Yes No
 If **no**, what is the sponsor's rationale for why a DSMB is not necessary:

 If **no**, describe the alternate data and safety monitoring plan:

15. How frequently will Sponsor/CRO representatives visit the research site(s) for routine monitoring:



Emergency Preparedness

16. Is emergency equipment / medication required at investigators' site(s) by this protocol or by this sponsor: Yes No

If **yes**, what equipment / medications are required: _____

17. How will the sponsor/CRO ensure that the Investigators/sites comply with these requirements:

Compensation and Medical Care for Research Related Injury

18. Does the proposed consent template contain an explanation of your policy regarding compensation / treatment for research related injuries: Yes No

19. Is there any conflict between the clinical trial agreements you have/are making with investigators and your policy as it is represented in the proposed consent template regarding compensation for injury: Yes No

If **yes**, please explain: _____

Investigator/Site-Generated Recruitment or Other Written Material

20. Do you require sponsor approval prior to IRB review of any investigator/site-generated subject materials: Yes No

(If the answer is "yes", 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.)

Investigator Meeting

21. Will there be/has there been an investigator meeting for this study: Yes No

22. Would you like a representative from Goodwyn IRB to attend and provide training: Yes No

23. When is/was the investigator meeting scheduled: _____

Contact for Communication with Goodwyn IRB

24. For questions regarding this submission/study please contact:

Name: _____ Title: _____

Company: _____

Street Address (1): _____

Street Address (2): _____

City: _____ State: _____ Postal Code: _____

Phone: _____ Email: _____

Invoices for IRB Services

25. Invoices for IRB services should be sent to:

a. Same as the contact person named above: Yes No

b. Someone else: Yes No

If invoices for services should be sent to someone other than the contact listed above, please enter the following contact information:

Name: _____ Title: _____

Company: _____

Street Address (1): _____

Street Address (2): _____

City: _____ State: _____ Postal Code: _____

Phone: _____ Email: _____

Delivery/Shipping Information

Correspondence and notifications from Goodwyn IRB may be generated and signed in electronic form. In addition to electronic notification, investigators are always provided a hard copy review notification (a print out of the electronic version). Any such print out accurately reflects the electronic original and shall be treated as an original.

26. Would you like the investigator to receive his/her hard copy via express service: Yes No

If **yes**, select your preference:

- Federal Express Priority Overnight
- Federal Express Standard
- Airborne Express
- UPS 2-Day
- UPS Next Day

Enter your billing account number: _____

Sponsor/CRO copies of review notifications 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.

27. Would you like the sponsor/CRO contact to receive hard copy as well as electronic review notifications: Yes No

List who else should receive a hard copy: _____

Recipients of Review Notifications

28. Recipients receive a delivery containing electronic review notifications. In addition to the primary contact for receipt of review notifications indicated above. List the names and emails of anyone else you would like us to give access to electronic IRB review notifications:

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 1) potential changes to the risks to benefit balance and 2) any unanticipated problems involving risk to human subjects or others that are detected during your monitoring of the research study, during any data and safety committee review, or that emerge up to two years after the study has ended and directly affect the safety of past participants.. This notification to the IRB must occur promptly and no later than 10 working days from the time of identification of the unanticipated problem. Sponsors/CROs must provide a summary report from any routine or urgent data and safety monitoring committee(s) review for this research study to the IRB.



Goodwyn Institutional Review Board, Ltd

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 of Sponsor Representative

I confirm that the information submitted in this form is true and correct

_____ Date: _____

Printed Name: _____