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**GUIDANCE DOCUMENT: INITIAL REVIEW (PROTOCOL)**

This guidance document is designed to assist in the completion of *FORM 100 Initial Review Protocol*. RCRC IRB reviews clinical investigations of FDA regulated products in accordance with the regulations at 21 CFR parts 50 and 56. *FORM 110* must be submitted for initial review of a single or multi site study. RCRC IRB does not utilize an expedited process for new research. All new research is reviewed via Full Board.

Single site studies: Complete and submit FORM 100 and FORM 110.

Multi-site studies: Complete and submit FORM 100, once the protocol has been approved you may submit individual Investigators (sites) using FORM 110.

In order for a comprehensive review to take place, each item on this document must be addressed. An attachment is required where indicated; you may include one separate document as an attachment that lists a response to each question answered yes. Incomplete submissions will result in a delay of the review. You may not begin research activities until you have received final written approval from RCRC IRB. Incomplete submissions are not acceptable and will result in a delay of the review

**RCRC IRB DOES NOT REVIEW RESEARCH THAT IS SUBJECT TO THE REGULATIONS AT 45 CFR 46.** If your research involves aspects that are subject to this set of regulations such as the request for the board to waive the requirement for informed consent, bio-behavioral, survey type research, or research that targets specific vulnerable populations please contact us for a referral to an appropriate IRB.

**RCRC IRB DOES NOT REVIEW RESEARCH FOR WHICH THE INVESTIGTOR HOLDS THE IND/IDE.**

**RCRC IRB DOES NOT REVIEW FEDERALLY FUNDED RESEARCH.** This includes research staff whose salary is funded in whole or in part by a federal fund or grant, or research that is being conducted on behalf of a government agency or department (e.g. NCI, NIH, DOE, DOD). If your research is funded in whole or in part by a federal fund or grant, RCRC IRB cannot be the IRB of record for your research. Please contact us for a referral to an appropriate IRB. RCRC IRB does not review requests from Investigators for an Exempt determination,

RCRC IRB will advise Investigators on the requirements of Emergency Use. Advice on seeking appropriate acknowledgment or approval for Emergency Use of a test article should not be misconstrued as approval. The Principal Investigator must submit a report to notify RCRC IRB within 5 working days after the emergency use of the test article in accordance with [21 CFR 50.23(c)].

**WHEN SHOULD THIS FORM BE SUBMITTED?**

The submission deadline is 12:00 noon central time on THURSDAY. The completed *FORM 100 Initial Review (Protocol)* and all supporting documents may be faxed to 512-747-6012; e-mailed to [rcrc@rcrc-irb.com](mailto:rcrc@rcrc-irb.com); or mailed to: RCRC IRB 706B West Ben White Blvd. Austin, TX 78704. Do not submit this guidance document.

**INSTRUCTIONS FOR COMPLETING RCRC IRB FORM 100**

A. Protocol Information	<ul style="list-style-type: none"> <li>• Provide the name of the Sponsor.</li> <li>• Provide the Protocol number as assigned by the Sponsor</li> </ul> <ol style="list-style-type: none"> <li>1. Provide the protocol version and date, the most current version must be submitted. If the most current version includes a protocol amendment, revision or clarification, that information must be noted. For Investigator initiated/written protocols: Please assign a version date to your protocol. This enables us to appropriately track which version is approved and current.</li> <li>2. Provide the therapeutic area such as the disease state and/or indication for the investigational agent under study (i.e. "cholesterol lowering drug for</li> </ol>
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	<p>hypercholesterolemia”).</p> <ol style="list-style-type: none"> <li>3. Indicate the funding source. Most research will be funded by the pharmaceutical industry; some may be privately funded. RCRC IRB does not review federally funded research. If this research is federally funded (in whole or in part) it cannot be reviewed by RCRC IRB. However, RCRC IRB may suggest an alternate IRB for your review. Please contact us for alternate IRB recommendations.</li> <li>4. Indicate the type of investigational agent being tested such as drug, device, or other FDA regulated product (e.g. biological, food/taste, cosmetic). For ALL studies with an IDE/IND etc. you must provide communication from the Sponsor or the FDA that verifies the number. The Protocol may also serve as verification if it is imprinted with the number.</li> <li>5. Indicate whether another IRB (local or central) has refused to review this protocol or has disapproved this protocol. If the answer is yes, describe the circumstances and include documentation if available.</li> <li>6. Indicate whether another IRB (local or central) has terminated this protocol. If yes, describe the circumstances and include documentation if available.</li> <li>7. Indicate whether an Independent Data Monitoring Board will review the research results, and the intervals that these findings will be made available to RCRC IRB, such as “annually” or “at 50% enrollment”.</li> </ol>
<p>B. Enrollment Information</p>	<ol style="list-style-type: none"> <li>1. Indicate the anticipated number of sites that will participate in this clinical investigation.</li> <li>2. Indicate the anticipated number of sites that will be submitted to RCRC IRB for review if known.</li> <li>3. Indicate the anticipated number of participants to be enrolled at each site.</li> <li>4. Indicate the anticipated length of participation in days, weeks, or months, and number of study visits that will take place in timeframe as determined by the protocol.</li> <li>5. Indicate the anticipated date that the study will begin enrollment (pending approval).</li> <li>6. Indicate the anticipated date that the study will be completed at all sites approved by RCRC IRB.</li> </ol>
<p>C. Drug Studies Only</p>	<ol style="list-style-type: none"> <li>1. Indicate the phase(s) of the study.</li> <li>2. Indicate whether this protocol represents the first time use in humans (if yes, a toxicology review will also be performed by a member of the Board). If this is not the first use but no human data is available, please check “first time”.</li> <li>3. Indicate the name of the first drug used in this research.</li> <li>4. Provide the Investigational New Drug (IND) number assigned by the FDA.</li> <li>5. Provide the name of the person or entity that holds the IND for this investigational drug (i.e. sponsoring company).</li> <li>6. Documentation from the Sponsor or the FDA that verifies the number. The Protocol may serve as verification if it is imprinted with the IND number. <b>The IND number must be supported by the commercial sponsor protocol, communication from the commercial sponsor, or communication from the FDA. The investigator brochure cannot be used for validation because investigator brochures are not specific to an IND.</b></li> <li>7. If the investigational use of the drug does not require an IND provide documentation (i.e. letter from the FDA). For drug studies: In accordance with [21CFR 312.2 (b)] indicate whether the clinical investigation is exempt because it is a clinical investigation of a drug product that is lawfully marketed in the U.S. and is exempt from one of the categories of exemption: <ul style="list-style-type: none"> <li><u>Exemption 1</u> <ul style="list-style-type: none"> <li>• The drug is lawfully marketed in the United States.</li> <li>• The research is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.</li> <li>• The research is not intended to support a significant change in the advertising for the product.</li> <li>• The research does not involve a route of administration or dosage level or</li> </ul> </li> </ul> </li> </ol>

	<p>use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.</p> <ul style="list-style-type: none"> <li>The research is conducted in compliance with the marketing limitations described in 21 CFR 312.7.</li> </ul> <p><u>Exemption 2</u></p> <ul style="list-style-type: none"> <li>A clinical investigation was for an <i>in vitro</i> diagnostic biological product that involves one or more of the following: <ul style="list-style-type: none"> <li>a) Blood grouping serum.</li> <li>b) Reagent red blood cells.</li> <li>c) Anti-human globulin.</li> </ul> </li> <li>The diagnostic test was intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.</li> <li>The diagnostic test was shipped in compliance with 21 CFR 312.160.</li> </ul> <p><u>Exemption 3</u></p> <ul style="list-style-type: none"> <li>A drug intended solely for tests in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160.</li> </ul> <p><u>Exemption 4</u></p> <ul style="list-style-type: none"> <li>A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.</li> </ul> <p>8. Indicate the version and date of the current Investigator's Brochure (or equivalent).</p> <p>9. Indicate whether the drug(s) used in this study are FDA approved for marketing. If yes, attach the package insert and indicate the date and/or version of the package insert.</p> <p>10. Indicate the class to which this drug belongs; this information may be found in the protocol or obtained from the study sponsor.</p>
D. Device Studies Only	<ol style="list-style-type: none"> <li>Indicate the name of the device used in this research.</li> <li>Provide the Investigational Device Exemption (IDE) number assigned by the FDA.</li> <li>Provide the name of the person or entity that holds the IDE for this investigational drug (i.e. sponsoring).</li> <li>Documentation from the Sponsor or the FDA that verifies the number. The Protocol may serve as verification if it is imprinted with the IDE number. <b>The IDE number must be supported by the commercial sponsor protocol, communication from the commercial sponsor, or communication from the FDA.</b></li> <li>Indicate whether the device meets the requirements for an <i>abbreviated</i> IDE. <ul style="list-style-type: none"> <li>The device is not banned.</li> <li>The device is not a significant risk device (this determination to be made by the IRB)</li> <li>If the study is investigator-initiated, determine that: <ol style="list-style-type: none"> <li>The sponsor (or investigator) will label the device in accordance with 21 CFR 812.5.</li> <li>The sponsor (or investigator) will comply with the requirements of 21 CFR 812.46 with respect to monitoring investigations.</li> <li>The sponsor (or investigator) will maintain the records required under 21 CFR 812.140(b) (4) and (5) and make the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10).</li> <li>The sponsor (or investigator) will ensure that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 21 CFR 812.150(a) (1), (2), (5), and (7).</li> <li>The sponsor (or investigator) will comply with the prohibitions in 21 CFR 812.7 against promotion and other practices.</li> </ol> </li> </ul> </li> <li>Indicate whether the device falls into one of the categories of exemption from an IDE. <p><u>Exemption #1</u> Is not a transitional device. Has been in commercial distribution immediately before May 28, 1976_Is being used or investigated in accordance with the indications in labeling in effect at that time.</p> </li> </ol>

	<p><u>Exemption #2</u> Is not a transitional device. Was introduced into commercial distribution on or after May 28, 1976. The FDA has determined it to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976. Is being used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalent.</p> <p><u>Exemption #3</u> Is diagnostic device. The sponsor will comply with applicable requirements in 21 CFR 809.10(c). The testing:</p> <ol style="list-style-type: none"> <li>a) Is noninvasive.</li> <li>b) Does not require an invasive sampling procedure that presents significant risk.</li> <li>c) Does not by design or intention introduce energy into a subject.</li> <li>d) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.</li> </ol> <p><u>Exemption #4</u> The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.</p> <p><u>Exemption #5</u> The device is a custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.</p> <ol style="list-style-type: none"> <li>7. Indicate whether another IRB has made a risk determination for this device.</li> <li>8. Indicate whether participants will be charged for the device. If participants are charged the amount must not exceed the cost of manufacture and testing of the investigational device.</li> <li>9. Indicate whether the FDA is aware of, and in agreement with the amount to be charged.</li> <li>10. Include the device manual or equivalent.</li> <li>11. Include a patient/participant user's manual if applicable.</li> <li>12. Include the report of prior investigations if available.</li> </ol>
<p>E. Informed Consent Document Information</p>	<ol style="list-style-type: none"> <li>1. List all proposed informed consent document(s) included with your submission. For studies that will allow enrollment of children (as defined by your state) you must prepare and submit a proposed <i>assent</i> document for the Board's review. Alternatively, this information may be included in your proposed informed consent document. Indicate whether you are submitting a stand-alone assent, or if assent language is incorporated in your Informed Consent Document.</li> <li>2. Indicate whether you plan to obtain permission for children to participate at your site, from individuals other than parents. Indicate from whom you plan to obtain permission, for instance: (a) both parents, unless one parent was deceased, unknown, incompetent, or not reasonably available, or when only one parent had legal responsibility for the care and custody of the child, or (b) one parent even if the other parent is alive, known, competent, or reasonably available, and shares legal responsibility for the care and custody of the child.</li> <li>3. Will you seek permission for children from individuals other than parents?</li> <li>4. Indicate whether you are submitting a stand-alone HIPAA authorization document for review. RCRC IRB will review HIPAA Authorization language when included in the consent document or as a stand alone document.</li> <li>5. Indicate whether you are requesting translation of the documents <u>once approved by the Board</u>. RCRC IRB does not accept pre-translated documents.</li> <li>6. List the language(s) into which the documents shall be translated.</li> </ol> <p><b>Note: It is the sole responsibility of each investigator to obtain HIPAA Authorization from each study participant according to the guidelines of the covered entity to which the Investigator belongs.</b></p>
<p>F. Recruitment Material</p>	<ol style="list-style-type: none"> <li>1. Indicate whether template recruitment material is being submitted at this time.</li> <li>2. Indicate the specific types of template recruitment material being submitted.</li> <li>3. Indicate whether you are requesting RCRC IRB to translate this material <u>once approved</u></li> </ol>

	<p><u>by the Board</u>. RCRC IRB does not accept pre-translated documents.</p> <p>4. List the language(s) into which the documents shall be translated.</p>
G. Study Material	<p>1. Indicate whether study material will is being submitted at this time. Study material includes, but is not limited to participant screening tools, participant diaries, participant educational material, survey instruments, questionnaires, and any non-cash gift items for long term retention. Single sites must also include this information when completing <i>FORM 110</i>.</p> <p>2. Indicate the specific types of study material that you are submitting.</p> <p>3. Indicate whether you are requesting translation of the documents <u>once approved by the Board</u>. RCRC IRB does not accept pre-translated documents.</p> <p>4. List the language(s) into which the documents shall be translated.</p>
H. Administrative Information	<ul style="list-style-type: none"> <li>• Indicate the Primary Contact for this clinical investigation (sponsor, CRO, or other).</li> <li>• Provide the name of the CRO if a CRO is managing IRB submissions for this clinical investigation. Indicate the preferred contact information for phone calls and correspondence.</li> <li>• Provide the accounts payable contact information; this is the individual who shall receive all invoices for RCRC IRB services.</li> </ul>
I. Certification Statement	<p>The person completing this information must sign this section to attest that the information provided is true and accurate and indicate their title or position, such as the Project Manager or Research Coordinator.</p>
J. List of Attachments	<ul style="list-style-type: none"> <li>• Conduct a thorough review of this list to ensure that all required attachments or explanations are included.</li> <li>• Failure to include all required documents will result in a delay of the review.</li> <li>• An attachment is <u>required</u> where indicated. You may include one separate document as an attachment that lists a response to each question requiring an attached explanation.</li> </ul>