

WIRB®

WESTERN INSTITUTIONAL REVIEW BOARD®
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Cover Letter/Checklist For Transfer of IRB Oversight to WIRB

Date: _____
Principal Investigator: _____
Protocol No.: _____
Title: _____

**Name and Address of
Previous IRB:** _____

Indicate the documents that are being submitted for review:

- WIRB Initial Review Submission Form (required)
- Most recent version of protocol if one is not on file at WIRB (dated: _____)
- Amendments (dates of those included: _____), if not incorporated in protocol (required)
- Complete grant application, if submitted to a Federal agency
- Most recent IRB approved version of the consent form
- Advertisements presently being used for recruitment
- Investigator's Brochure, if applicable and if one is not already on file at WIRB (dated: _____)
- Signed FDA Form 1572, if applicable, with WIRB listed as the IRB
- Curriculum vitae for principal investigator and all sub-investigators (required)
- Professional license for principal investigator (required)
- Medical licenses for all sub-investigators (if applicable)
- Radiation safety committee approval (if applicable)

Reason for Transfer to WIRB:

Date of initial approval by the previous IRB: _____

Date approval expires: _____

Summary of Study Activity Prior to Transfer

At your site:

1. Has the study begun? Yes No
2. Total subjects enrolled (signed consent form): _____
3. Do you intend to enroll any more subjects? Yes No
4. Are subjects coming in for scheduled visits? Yes No
5. Are any subjects still on active treatment? Yes No
Comments:

6. Is the study completed, but not yet closed out by the sponsor? (Have all subjects at your site completed their final visit?) Yes No
7. Has any new risk or benefit information become available that was not reported to the previous IRB? Yes* No

*If yes, submit the new risk or benefit information for review.

8. Have there been any unanticipated problems¹ (other than new risk information described in response to question 7 above) related to this research? Yes* No

*If yes, describe the problem and actions taken, if any, as a result of the unanticipated problem (attach a separate page if necessary) and submit **any IRB correspondence related to the unanticipated problem**.

9. Have there been any subject complaints related to this research? Yes* No

*If yes, describe the complaint and actions taken, if any, as a result of the complaint, and submit any IRB correspondence related to the complaint (attach a separate page if necessary).

¹ Unanticipated problems include any incident, experience, or outcome that meets **all** of the following criteria:
(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 (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved 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.

10. Did the previous IRB ever suspend or terminate this research at your site? ... Yes* No

*If yes, provide information on the reason for the Board action, the steps taken to resume the research and copies of any IRB correspondence related to the suspension (attach a separate page if necessary).

Prepared and sent to WIRB by:

Printed Name / Title

Date