

PREPARING TO GO ONLINE WITH WIRB: TRAINING & GUIDANCE

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AGENDA

- WIRB or RSRB?
- Submission via ROSS
- Submission via WIRBNet
- Documents to be Submitted
- Additional Points



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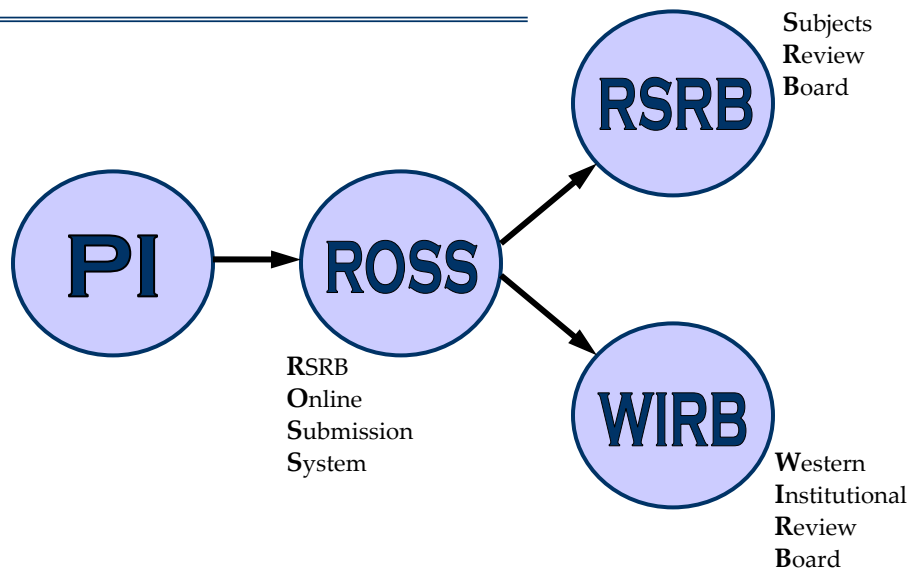
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THE BEST PRACTICE



WHAT REQUIRES WIRB REVIEW?

Is it...

- Industry sponsored or industry initiated study of drugs/devices?

AND

- Greater than minimal risk study?

OR

- Part of or a follow-up to a previously approved by WIRB study?

If YES, your study will be reviewed by WIRB



EXCEPTIONS

- If the sole intent is to give expanded access to drugs/devices for treatment use
- If the study involves gene transfer
- If the protocol was NOT developed by the industry sponsor

RSRB reviews your study



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SUBMITTING TO RSRB: VIA ROSS

I. Login to ROSS (<https://rsrb01.urmc.rochester.edu/rsrb>)



SUBMITTING TO RSRB: VIA ROSS (CONT.)

II. Create a New Application and complete Q. 1.1 - 1.8 as for any other RSRB submission

UNIVERSITY OF ROCHESTER
Research Subjects Review Board

Save | Print... **Continue >>**

1. Study Identification Information. Protocol & Measures

1.1 * **Study Working (short) Title:**
WIRB Submission
The "short" title will appear in your inbox to identify the study. The "full" title (the official study title) may include too many characters to use as an identifier.

1.2 * **Study Full Title:**
New WIRB Submission

1.3 * **Click Add to upload a Study Protocol. Important: If you're revising or replacing the previously uploaded document, use the Replace link next to the file name. Do not delete any document after the study has been submitted to the RSRB.**

name	Revision	Modified Date
<input type="checkbox"/> [Replace] Sponsor Protocol	0.01	2/7/2011 2:55 PM

IMPORTANT! Use the 'Add' button to upload new (i.e. previously not submitted) documents only. To make changes to a document that has already been submitted to the RSRB, use the 'Replace' link.
Example: If the study has been submitted and the RSRB sends the application back to your 'inbox' and

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SUBMITTING TO RSRB: VIA ROSS (CONT.)

III. PI's Conflict of Interest (COI): Q. 2.1.1 - 2.2

2. Conflict of Interest

All individuals involved in the **design, conduct, or reporting of research** are to disclose financial interests, as stated below. Please note that this requirement is not just for the principal investigator but includes: sub-investigators, study coordinators who interact with subjects, persons obtaining consent, individuals analyzing adverse events, individuals collecting/analyzing data; etc.

For purposes of University of Rochester reporting policies, this includes at least those persons listed in Items 1.4, 1.5, 1.6, 1.7, 1.7.1, 66.2, 78.1, 78.2 and 85.1 of this application.

Principal Investigator Conflicts of Interest (Individual identified in section 1.4)

2.1.1 * Does the PI, the PI's spouse or the PI's dependent children receive or expect to receive income for licensing discoveries from the sponsor; or have an interest in a patent, copyright or licensing agreement whose value may be affected by this research? no	• Office of Technology Transfer
2.1.2 * Does the PI, the PI's spouse or the PI's dependent children have an ownership interest or serve in a management capacity or on the Board of Directors of the sponsor/company? no	
2.1.3 * Does the PI, the PI's spouse or the PI's dependent children hold or expect to hold stock, stock options, or similar financial instruments from any company which may be affected by the outcome of this research? no	Mutual funds that are not actively managed by the individual are not included.
2.1.4 * Does the PI, the PI's spouse or the PI's dependent children receive or expect to receive financial compensation from any company which may be affected by the outcome of this research (other than through a contract to the University to conduct this research)? no	

Upload PI's Management Plan:
Please ensure that the consent form and the protocol accurately reflect the requirements in the management plan.

- Consent form – Disclosure of the conflict
- Protocol – Changes in recruitment strategies, obtaining consent, oversight of the research, safety monitoring procedures, etc.

Please note that if a conflict of interest is identified, please contact your Dean's office to submit the appropriate disclosure form to determine if a Management Plan is needed.

- UR Conflict Disclosure Reporting Form
- Policy on Conflict of Interest

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SUBMITTING TO RSRB: VIA ROSS (CONT.)

IV. Study Personnel COI: Q. 2.3.1 - 2.3.4

Study Personnel Conflicts of Interest (Individuals identified in section 1.5, 1.6, 1.7, 1.7.1, 66.2, 78.1, 78.2, and 85.1)	
2.3.1	<p>* Do any study personnel involved in the design, conduct or reporting of the research, or their spouses or dependent children receive or expect to receive income for licensing discoveries from the sponsor; or have an interest in a patent, copyright or licensing agreement whose value may be affected by this research? no</p>
2.3.2	<p>* Do any study personnel involved in the design, conduct or reporting of the research, or their spouses or dependent children have an ownership interest or serve in a management capacity or on the Board of Directors of the sponsor/company? no</p>
2.3.3	<p>* Do any study personnel involved in the design, conduct or reporting of the research, or their spouses or dependent children hold or expect to hold stock, stock options, or similar financial instruments from any company which may be affected by the outcome of this research? no</p>
2.3.4	<p>* Do any study personnel involved in the design, conduct or reporting of the research, or their spouses or dependent children receive or expect to receive financial compensation from any company which may be affected by the outcome of this research (other than through a contract to the University to conduct this research)? no</p>
<p>If Yes to any of the above (2.3.1 through 2.3.4): Upload the management plan (or waiver) signed by your Dean, for each individual with a conflict. Possible conflicts of interest should be reviewed by your Department Chair first.</p>	
<p>Click Add to add the name of individual(s) with conflict and the management plan(s). Individual With COI Individual Management Plan There are no items to display.</p>	



SUBMITTING TO RSRB: VIA ROSS (CONT.)

V. Select an appropriate sponsorship*

3. Source of Funding/Sponsorship (Grants and contracts must be submitted to the Office of Research and Projects Administration (ORPA).)	
3.1	<p>Please indicate Sponsor Type and Name:</p> <p><input checked="" type="checkbox"/> Industry Initiated Company Name: Biogen [Select...] [Reset] If other, please indicate: <input type="text"/></p> <p><input type="checkbox"/> Industry: PI-Initiated Company Name: [None] [Select...] If other, please indicate: <input type="text"/></p>

* Also described in slide No. 5



SUBMITTING TO RSRB: VIA ROSS (CONT.)

VI (a). Nature of Study (Part 1)

4. Nature of Study Part 1	
4.1	* Is this study part of an RSRB-approved 'umbrella' study? <input type="radio"/> Yes <input checked="" type="radio"/> No Clear
4.2	* Will Gene Transfer be used in the study? <input type="radio"/> Yes <input checked="" type="radio"/> No Clear
4.3	* Is this an expanded access or single patient treatment study only? <input type="radio"/> Yes <input checked="" type="radio"/> No Clear
4.4	This study is: <input type="radio"/> not a clinical trial, and does not need registration <input type="radio"/> a clinical trial that does not need registration <input checked="" type="radio"/> a clinical trial that needs registration - sponsor/ coordinating center has registered/will register <input type="radio"/> a clinical trial that needs registration - UR PI has registered/will register Clear



SUBMITTING TO RSRB: VIA ROSS (CONT.)

VI (b). Nature of Study (Part 2)

5. Nature of Study Part 2	
5.1	* Does the study <u>only</u> involve procedures that are minimal risk (i.e., equates to every day risks)? <input type="radio"/> Yes <input checked="" type="radio"/> No Clear
5.2	* Is this study part of, or a follow-on to, a study previously approved by WIRB? <input type="radio"/> Yes <input checked="" type="radio"/> No Clear



SUBMITTING TO RSRB: VIA ROSS (CONT.)

At this point you will be prompted to either RSRB or WIRB review based on:

- ✓ Provided answers in ROSS application

(slides No. 13, 14, 15)

- ✓ Main requirements (slide No. 5)

- ✓ Exceptions (slide No. 6)



SUBMITTING TO RSRB: VIA ROSS (CONT.)

VII. WIRB Application (ROSS version)

10. WIRB Application.	
10.1	At what site(s) will this study be conducted? [Check all that apply.] <input type="checkbox"/> University of Rochester Medical Center <input type="checkbox"/> URMFG (Medical Faculty Group) <input type="checkbox"/> Monroe Community Hospital <input type="checkbox"/> Eastman Dental Center <input type="checkbox"/> Clinton Crossings <input type="checkbox"/> Highland Hospital <input type="checkbox"/> The Highlands [Brighton or Pittsford] <input type="checkbox"/> Other University of Rochester facility: Specify: <input type="text"/> <input type="checkbox"/> Non-University of Rochester facility: Specify: <input type="text"/>
10.2	Has this study been submitted to ORPA? <input type="radio"/> Yes <input type="radio"/> No Clear
10.3	Will this study use the Cancer Center at the University of Rochester? <input type="radio"/> Yes <input type="radio"/> No Clear [If yes, this study must have CTO approval.]
10.4	Is this study part of an RSRB-approved 'umbrella' study? <input type="radio"/> Yes <input type="radio"/> No Clear



10.5	Is this study part of, or a follow-on to, a study previously approved by WIRB®? <input type="radio"/> Yes <input type="radio"/> No Clear
10.6	Has the scientific peer review signature been obtained? <input type="radio"/> Yes <input type="radio"/> No Clear
10.7	Does the consent form include the University-approved Compensation for Injury ^{1/} language ? <input type="radio"/> Yes <input type="radio"/> No Clear
10.8	Does the consent form include a telephone number for research-related injury? <input type="radio"/> Yes <input type="radio"/> No Clear <small>[Note: The pager number, 275-2222 may not be included. The number must reach the investigator or someone who has specific knowledge of this research study.]</small>
10.9	List (a) the 'research' procedures and (b) who is billed. <input type="text"/>
10.10	List (a) the 'standard of care' procedures and (b) who is billed. <input type="text"/>
* Is this Application completely filled out? <input checked="" type="radio"/> Yes <input type="radio"/> No Clear	

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SUBMITTING TO RSRB: VIA ROSS (CONT.)

VIII. When ROSS Application is complete, hit Finish.

IX. Print-out a hardcopy of the completed ROSS Application, by clicking the Print Application button.

X. The Department Chair / Designee must sign the Certification of Scientific Review

Certification of Scientific Review

IMPORTANT: Department Chairs, note that the submission and sign-off pages have been reformatted and now require checking the box before submitting.

CERTIFICATION OF SCIENTIFIC REVIEW

The department chair/chief, authorized delegate, or appointed peer review committee of the Principal Investigator's department/college is responsible for scientific review of the research protocol. Faculty Advisors are responsible for reviewing student research projects. Department / Faculty Advisor approval signifies that the proposal has been given scientific review and is endorsed by the department/advisor, and is therefore recommended for approval by the WIRB.

Confirm, by checking the box below, that departmental review has made the following determinations:
The investigator has:

1. the necessary qualifications, knowledge and experience;
2. sufficient time to conduct and complete the research;
3. access to a population that would allow recruitment, retention and follow-up of the required number of subjects;
4. adequate numbers of qualified staff and adequate facilities;
5. a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties;
6. availability of medical or psychological resources that participants might require as a consequence of the research; and
7. complied with the University's policy on conflict of interest.

* Confirm check here:

X

Print Name

Position/Title

Date

Department Chair's or designee's signature here



SUBMITTING TO RSRB: VIA ROSS (CONT.)

XI. Submit ROSS Application to RSRB

Current State <input type="radio"/> Pre Submission	WIRB Submission Description: New WIRB Submission PI: Training PI Coordinator: No Coordinator RSRB Case Number: RSRB00034061 Date Submitted: Not Submitted Yet Date Created: 2/7/2011 3:05 PM Online Dept Review?: yes Ready to Submit: yes
View <input type="button" value="Application Forms"/> <input type="button" value="Print Application"/>	Instructions: <ul style="list-style-type: none">• This application has not yet been submitted to the RSRB office.• Click on the 'Submit Application' link on the left hand side of this page to submit the application.• During submission, the system will check to make sure all required fields are filled in.• To edit the form, click on the 'Application Forms' button. <p><i>Please Note: Only the PI can "Submit" this application</i></p>
My Activities <input type="button" value="Submit Application"/> <input type="button" value="Withdraw"/> <input type="button" value="Edit Guest List"/>	



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WHAT IS CHANGING?

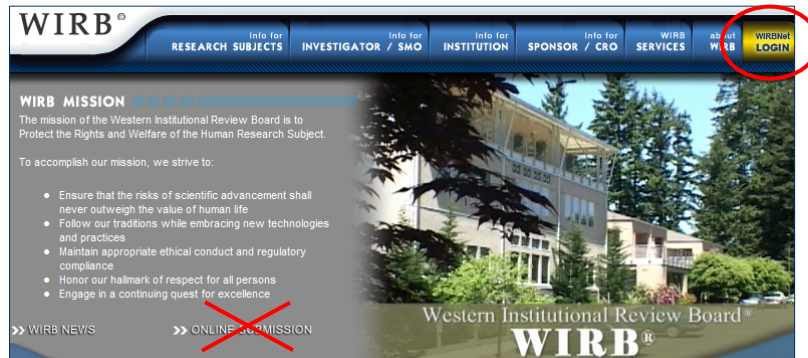
Effective March 1st, 2011

- WIRB Submission Form must be completed **online** via WIRBNet (use the SmartForm)
- All the documents must be submitted **electronically** via CD to RSRB, including:
 - I. Signed and scanned **ROSS application form**
 - II. Signed and scanned **WIRB submission form**



SUBMITTING TO WIRB : VIA WIRBNET

I. Login on WIRBNet (www.wirb.com)



DON'T use the online submission option



SUBMITTING TO WIRB : VIA WIRBNET (CONT.)

II. Select **Online Submission using a SmartForm** option



SUBMITTING TO WIRB: VIA WIRBNET

(CONT.)

III. For initial submissions select **New Research** option



The screenshot shows the WIRB website interface. At the top, there is a navigation bar with the WIRB logo and several menu items: 'Info for RESEARCH SUBJECTS', 'Info for INVESTIGATOR / SMO', and 'Info for INSTITUTION'. Below the navigation bar, there is a section titled 'Online Submissions using Smart Forms'. Under this section, there is a heading 'Create a new Submission' and a list of options: 'New Research', 'Change in Research', 'Unanticipated Problems that ARE Adverse Events', 'Unanticipated Problems that ARE NOT Adverse Events', 'Study Closure', 'Partial Waiver of Authorization for Recruitment', and 'Request for Full Waiver of Authorization'. The 'New Research' option is circled in red. At the bottom of the list, there is a link: 'Submissions already sent to WIRB (click here)'.



SUBMITTING TO WIRB: VIA WIRBNET

(CONT.)

IV. Follow WIRBNet instructions and complete the WIRB Submission Form.

DON'T submit it!

V. Print-out a hardcopy of the WIRB Submission Form

VI. Sign, date and scan it



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REQUIRED DOCUMENTATION: PREPARATION FOR "NO PAPER" PROCESS

*These items **MUST** be submitted to RSRB
via CD:*

1. Signed and scanned ROSS Application Form
2. Signed and scanned WIRB Submission Form
3. Sponsor's Protocol
4. Subject Consent Form(s)



REQUIRED DOCUMENTATION (CONT.)

5. Investigator's Brochure (for drug studies)
6. IDE Documentation (for device studies)
7. Signed FDA Form 1572
8. Study recruitment materials
9. PI's current Medical License
10. PI's, Co-PI's and Sub-Investigator's current CV's
11. Departmental Letterhead



END OF ADMINISTRATIVE REVIEW

Once the RSRB administrative review is done:

- ✓ WIRB liaisons at RSRB will submit your documents to WIRB electronically
- ✓ You will receive an email confirmation when this process is completed



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POINTS TO CONSIDER

- **DO NOT** submit your study documents **directly** to WIRB
 - ✓ RSRB administrative review is required for all **initial** submissions to ensure compliance with UR policies (i.e. compensation for injury, conflict of interest, etc.)

* RSRB administrative review fee is \$1000 for each study



COMPENSATION FOR INJURY

The following standard language should be included in consent forms for industry-sponsored studies:

“If you are directly injured by the drugs [or devices] that are being studied, or by clinical procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will be reimbursed for the reasonable and necessary medical expenses for such treatment. You will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for treating study-related injuries from your health insurer or the study sponsor.”



POINTS TO CONSIDER:

PI'S RESPONSIBILITIES

- Disclosure of Conflict of Interest (COI) in ROSS Application, WIRB Submission Form and Consent Forms (matched to COI Management Plan)
- Disclosure of any new COI, after the study has been approved by WIRB
- Modification of Consent Forms to be applicable to our site



POINTS TO CONSIDER:

AMENDMENTS, CONTINUING REVIEWS (CRs) AND REPORTABLE EVENTS (RES)

- Amendments, CRs and REs should be submitted directly to WIRB via WIRBNet
 - ✓ No RSRB review required
- As of **March 1st, 2011** the RSRB will stop mailing services to WIRB



UoFR NOT ENGAGED IN RESEARCH

If research conducted NOT on behalf of the University and UR site is NOT engaged in research:

- RSRB review is not required;
- You may submit your study directly to WIRB or any other commercial IRB.



COMING SOON...

WIRB is going **GREEN**.
RSRB will provide appropriate
training.



THANK YOU!

QUESTIONS?

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