

New Study Submission and Internal Scientific Review Process

Effective Sept. 1, 2017

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Things you will need before you request Orthopedic Internal Review:

- Protocol (template provided below)
- Assurance document signed by Wash U faculty
- myIRB draft printed out/scanned
- Orthopedic Internal

Protocol Shell/Template:

Project Title/PI:

Background/Study Rationale:

Describe the basis for the proposed research, including a presentation of the problem to be studied and a review of current literature. Describe how this proposal will enhance this medical knowledge.

Objective/Purpose/Aims:

Describe the purpose of the study, including identification of specific primary objectives/hypotheses. Secondary objectives/hypotheses should be described as necessary.

Study Design:

- a. Experimental design of the study (e.g., single-blind, double-blind)
- b. Study population general description
 - a) Inclusion/Exclusion criteria
- c. Number of participants needed
- d. Sample size determination and power analyses
- e. Study outcomes/endpoints

Statistical Methods:

Describe statistical analysis methods as appropriate. For example, will intention-to-treat methodology be used in the analysis? Will there be any sample stratification?

myIRB New Project Submission:

1. Go to <https://myirb.wusm.wustl.edu/>
2. Login with *your* WUSTL key
3. Login as Delegate for PI on the project.
4. Go to Create a Project

The screenshot shows the myIRB dashboard for a user named Keith Bridwell. The navigation bar includes 'myHome', 'Create Project', and 'Personalize'. The 'Create Project' button is circled in blue. Below the navigation bar, there are tabs for 'Inbox - To Do' and 'myProjects'. The 'myProjects' tab is active, showing a table of projects. The table has columns for 'IRB ID', 'IRB Title', 'PI', 'Current Approval Date', 'Next Approval Due By', and 'Status'. A single project is listed with ID 201102181, title BIO ASLS, PI Keith Bridwell, and a status of 'Open'. A filter bar above the table allows filtering by PI (Keith Bridwell) and project status (Open). The 'delegate login' link in the top right is also circled in blue.

5. Select appropriate new study project. (Generally, New project)

The screenshot shows the 'Create Project' page in the myIRB system. The page is titled 'myIRB' and 'Washington University in St. Louis'. The navigation bar includes 'myHome', 'Create Project', and 'Personalize'. The 'Create Project' button is circled in blue. Below the navigation bar, there are three main categories of project types: 'Local IRB Review', 'WU sIRB Review - coming soon', and 'Rely on another IRB'. Under 'Local IRB Review', there are four buttons: 'New Project', 'Exempt', 'Overall/Concept', and 'Non-Human Decision'. The 'New Project' button is circled in blue. Under 'WU sIRB Review - coming soon', there are three buttons: 'New Protocol + Site', 'New Protocol Only', and 'New Site Only'. Under 'Rely on another IRB', there is one button: 'Request to Rely'. The user's name 'Christine Baldus as Keith Bridwell' and the 'HRPO Web Site' link are visible in the top right.

6. Enter study information.

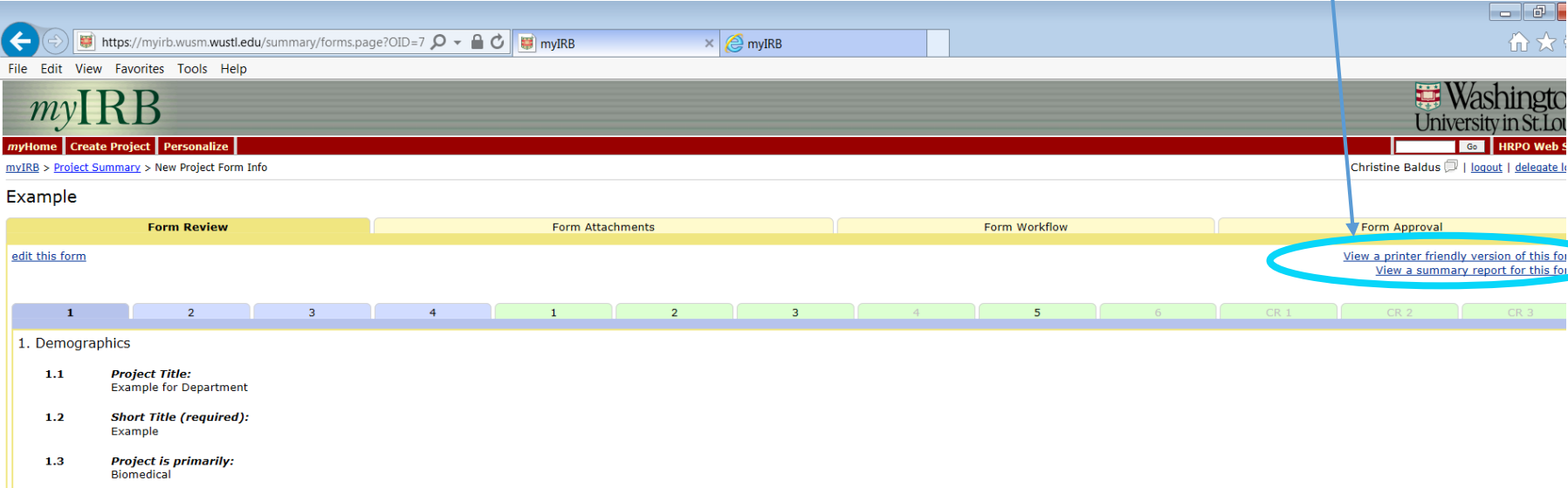
- Start with #1 (Demographics) and work through to #4 (Other Institutional Reviews).
- Then go to myIRB to complete remainder of HRPO submission draft.

The screenshot shows the 'New project' form in the myIRB system. The browser address bar is <https://myirb.wusm.wustl.edu/forms1h/proj/index.page?OI!>. The page header includes the myIRB logo and navigation links: [myHome](#), [Create Project](#), and [Personalize](#). The user is identified as PI: Christine Baldus. The form progress bar shows steps 1, 2, 3, and 4 as completed (green), with step 4 labeled 'Other Institutional Reviews/Requirements'. A 'myIRB' status box shows 'Draft' and 'Pending'. A list of project types is available: CIRC, PRMC, RSC/RDRC, IBC, and ESCRO. A 'Change project type to:' section offers buttons for 'Exempt', 'Overall/Concept', and 'Rely on another IRB'. A blue circle highlights the 'myIRB' status box, and a blue arrow points from step 4 to it.

7. When you have completed myIRB through #5, select review

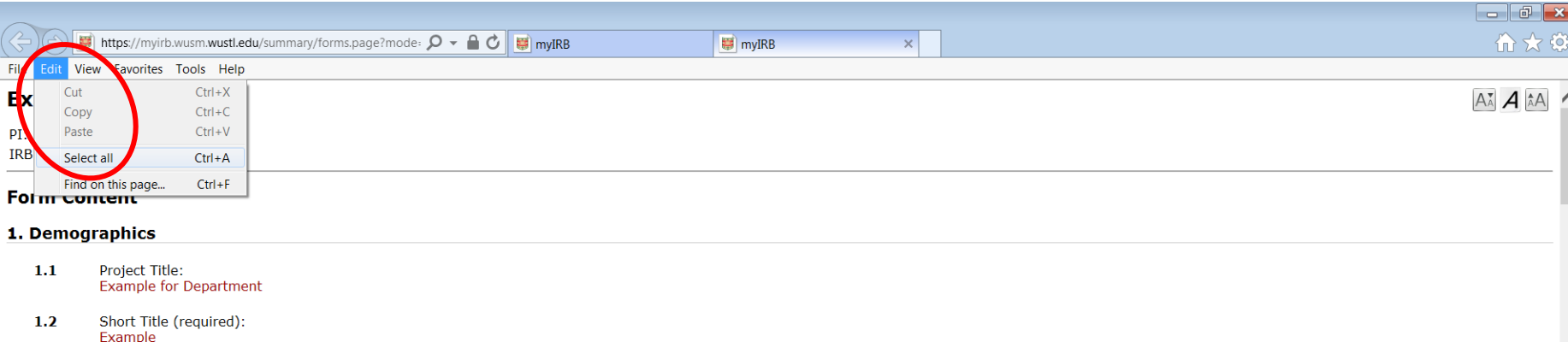
The screenshot shows the 'New project' form in the myIRB system. The browser address bar is <https://myirb.wusm.wustl.edu/forms1h/proj/index.page?OI!>. The page header includes the myIRB logo and navigation links: [myHome](#), [Create Project](#), and [Personalize](#). The user is identified as PI: Christine Baldus. The form progress bar shows steps 1, 2, 3, 4, and 5 as completed (green), with step 5 labeled 'Privacy & Confidentiality'. Three 'myIRB' status boxes are visible: '3. Performance Sites', '4. Drugs/Devices', and '5. Privacy & Confidentiality'. A red arrow points to the '3. Performance Sites' box. A blue circle highlights the 'review' button at the bottom of the form, and a blue arrow points from step 5 to it.

8. Review your entries. If there are not edits to be made, select "View a printer friendly version of this form".



9. Create copy of HRPO submission for upload to REDCap for internal review.

- a. Word document (preferred method for editing purposes).
 - i. Go to Edit. Select all. Right click & select Copy.
 - ii. Open a new Word document. Right click and Paste. Save to your computer to upload into REDCap.



Orthopedic Internal Scientific Review:

Please do not upload partial information. Upload only when you have all required documents available and ready for review.

Information you will need to submit.

- Study design
 - Retrospective
 - Prospective
 - Observational
 - Interventional/Investigational, no Randomization
 - Interventional/Investigational, with Randomization
- Protocol – Word document (required for all studies. See template on page 2)
- HRPO submission copy – Word document
- Informed consent – Word document
- Assurance document signed by WU Faculty – PDF

Process:

- Go to https://redcap.wustl.edu/redcap/srvrs/prod_v3_1_0_001/redcap/surveys/?s=WDDLKK38PE
- Complete/upload document for all required fields. (See page 7. All required fields are designated by “*must provide value”)
- Verify date REDCap submission was completed.
- Click on ‘Save and Return’ at bottom of form. (See page 8)
- Copy ‘Return Code’ – save for you records
- Press ‘Continue Survey Now’
- Paste your return code into ‘My return code’. By doing so, your return code will be included automatically in emails generated & referencing the study.
- Study goes through review.
 - Research Coordinator reviews HRPO submission information.
 - If edits are suggested submitter will be notified by email. See page 9.
 - Dr. Wright (or designee) will review protocol for Scientific Review. If edits are suggested submitter will be notified by email.
- You can monitor review progress by accessing your Study Info page through the return website: https://redcap.wustl.edu/redcap/srvrs/prod_v3_1_0_001/redcap/surveys/?s=WDDLKK38PE&_return=1 and entering your return code. See next page.
- Study is approved. You will be notified by email and signed Assurance document will be attached.
- Go to your draft project in myIRB. Upload signed Assurance Document. Submit for HRPO review.

https://redcap.wustl.e... Study info

View Favorites Tools Help

If you have any questions or encounter any problems with on-line submission, please contact Chris Baldus at 314 747 2655. Thank you!

Full Study Title
* must provide value

Abbreviated Title (optional)

Primary Investigator at WU Orthopedics
* must provide value
First name Last name

Investigator's email:
* must provide value

Person responsible for HRPO electronic submission/Contact person:
* must provide value
First name, Last name

Submitter's email:
* must provide value

The Internal Review Committee (IRC) is not responsible for review of any Conflicts of interest (COI)/financial disclosures required for HRPO submission.
* must provide value
 Submitter understands and assumes responsibility for any COI. reset

Study design
* must provide value
 Retrospective Review (NEW! Protocol Required- needed for Scientific Review. You may copy/paste from your IRB submission)
 Prospective Observational study
 Prospective Interventional study - No randomization (Includes investigational device/drug studies)
 Prospective Interventional study - With Randomization (Includes Investigational device/drug studies)
 Other reset

STUDY DOCUMENTS REQUIRED FOR REVIEW

PROTOCOL
* must provide value [Upload document](#)
Word document for edits/tracking changes

HRPO Submission
* must provide value [Upload document](#)
Word document for edits/tracking changes

Have you requested a Waiver of Consent?
* must provide value
 Yes
 No reset

ASSURANCE DOCUMENT signed by WU Faculty PI.
* must provide value [Upload document](#)

Is there any additional information you feel is pertinent to this review?

Expand

I verify I have uploaded all required documents and study is ready for Internal Review.
* must provide value
11-28-2017 Today M-D-Y

My return code is

Thank you for your submission!

Please press the "SAVE and RETURN" button at the end of this form. It will take you to your return 'code' for this study.

This will allow you to return and check on the review status.

ALWAYS PRESS SAVE AND RETURN!

Internal Review Status

IF ANY MODIFICATIONS ARE RECOMMENDED after CRC or Scientific Review, you will be notified by email and the modifications will be uploaded below.

You will then
*Accept or Reject changes
*Upload final documents
*Notify reviewer

https://redcap.wustl.e... Study info

Submitter's email:

* must provide value

The Internal Review Committee (IRC) is not responsible for review of any Conflicts of Interest (COI)/Financial disclosures required for HRPO submission Submitter understands and assumes responsibility for any COI. reset

* must provide value

Study design Retrospective Review (NEW! Protocol Required- needed for Scientific Review. You may copy/paste from your IRB submission)

* must provide value

Prospective Observational study

Prospective Interventional study - No randomization (Includes investigational device/drug studies)

Prospective Interventional study - With Randomization (Includes Investigational device/drug studies)

Other reset

STUDY DOCUMENTS REQUIRED FOR REVIEW

PROTOCOL Upload document

* must provide value

Word document for edits/tracking changes

HRPO Submission Upload document

* must provide value

Word document for edits/tracking changes

Have you requested a Waiver of Consent? Yes No reset

* must provide value

ASSURANCE DOCUMENT signed by WU Faculty PI. Upload document

* must provide value

Is there any additional information you feel is pertinent to this review?

Expand

I verify I have uploaded all required documents and study is ready for Internal Review. 11-28-2017 Today M-D-Y

* must provide value

My return code is

Thank you for your submission!

Please press the "SAVE and RETURN" button at the end of this form. It will take you to your return 'code' for this study.

This will allow you to return and check on the review status.

ALWAYS PRESS SAVE AND RETURN!

Internal Review Status

IF ANY MODIFICATIONS ARE RECOMMENDED after CRC or Scientific Review, you will be notified by email and the modifications will be uploaded below.

You will then

- *Accept or Reject changes
- *Upload final documents
- *Notify reviewer

CRC review assigned ____

CRC initial review was completed ____

Edits suggested? ____

CRC approved on ____

Scientific Review assigned [notified]

Scientific Review was completed ____

Edits suggested? ____

Scientific review complete/approved on ____

REDCap 7.3.5 - © 2017 Vanderbilt University

Edits were Suggested and Made. What to do now?

If edits were suggested after CRC &/or Scientific review, the study PI must review and accept or reject modifications. Any documents affected by the review should be updated with changes tracked and re-uploaded.

For this example, CRC review recommended changes to the HRPO submission. CRC would have uploaded document with changes tracked at the bottom of this form.

Study info Resize font

Please provide the following information regarding your new IRB submission.

All required fields must be answered and appropriate files uploaded for the review process. You can SAVE and RETURN to this form at a later date if necessary.

If you have any questions or encounter any problems with on-line submission, please contact Chris Baldus at 314 747 2655. Thank you!

After CRC review, are you replacing any study documents due to revisions? Mark all that apply

Yes, PROTOCOL has been revised and uploaded w/changes tracked.
 Yes, HRPO submission has been revised and uploaded w/changes tracked.
 Yes, ICD has been revised and uploaded w/changes tracked.
 No, the PI felt changes were not warranted.

The Email below was copied/paste/sent to Chris Baldus on: 08-30-2017 Today M D Y
 Chris Baldus, Charles Brown, the PI for Study #3 has reviewed your comments. Any revised study documents have been re-uploaded to the study page and are ready for 2nd review. Thanks!
 Abby Turner

Full Study Title * must provide value

Abbreviated Title (optional)

Primary Investigator at WU Orthopedics * must provide value
First name Last name

Investigator's email: * must provide value

Person responsible for HRPO electronic submission/Contact person: * must provide value
First name, Last name

Submitter's email: * must provide value

The Internal Review Committee (IRC) is not responsible for review of any Conflicts of Interest (COI)/Financial disclosures required for HRPO submission * must provide value

Submitter understands and assumes responsibility for any COI.

Study design * must provide value

Retrospective Review (Protocol Upload Optional)
 Prospective Observational study
 Prospective Interventional study - No randomization (Includes investigational device/drug studies)
 Prospective Interventional study - With Randomization (Includes Investigational device/drug studies)
 Other

STUDY DOCUMENTS REQUIRED FOR REVIEW

PROTOCOL Word document for edit/tracking changes

HRPO Submission [myIRB Draft.doc \(0.13 MB\)](#) * must provide value
Word document for edit/tracking changes

Have you requested a Waiver of Consent? Yes No * must provide value

ASSURANCE DOCUMENT signed by WU Faculty PI. [AssuranceDocument_OrthoIRC.pdf \(0.06 MB\)](#) * must provide value

Is there any additional information you feel is pertinent to this review?
Expand

I verify I have uploaded all required documents and study is ready for Internal Review. 08-28-2017 Today M D Y * must provide value

My return code is

Study staff would:

1. Reviewed and modify HRPO form (changes still tracked)
2. Answer this question
3. Remove original HRPO submission
4. Upload new HRPO submission
5. Email CRC review is complete.

CRC will re-review and approve study.

Study will move onto Scientific Review.

If there are any modifications suggested at Scientific review, the process is similar. You will be emailed, you will go to your Study Info page and access/download the Scientific review. PI will review and make appropriate modifications.