New Study Submission and Internal Scientific Review Process

Effective Sept. 1, 2017

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:

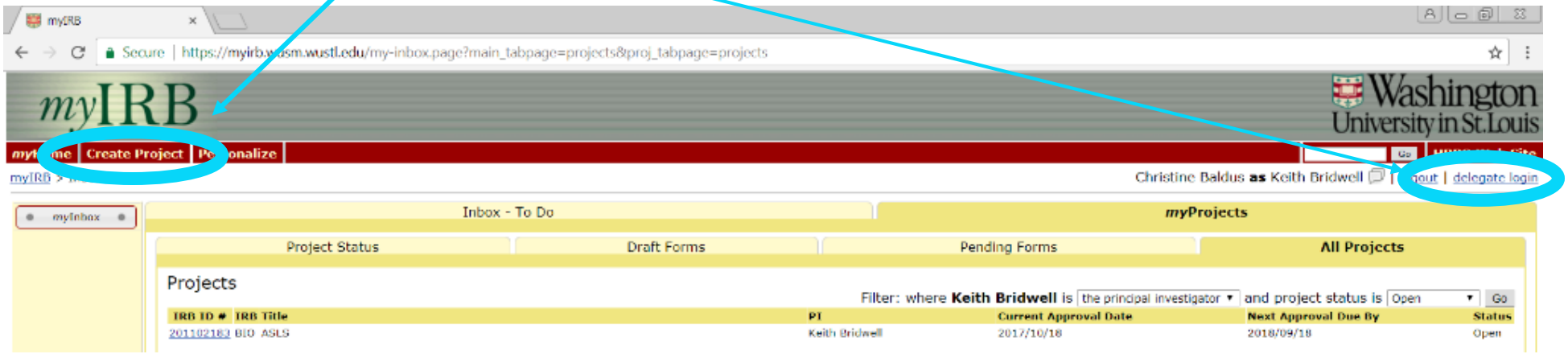
a. Experimental design of the study (e.g., single-blind, double-blind)
b. Study population general description
    a) Inclusion/Exclusion criteria
c. Number of participants needed
d. Sample size determination and power analyses
e. Study outcomes/endpoints

Statistical Methods:

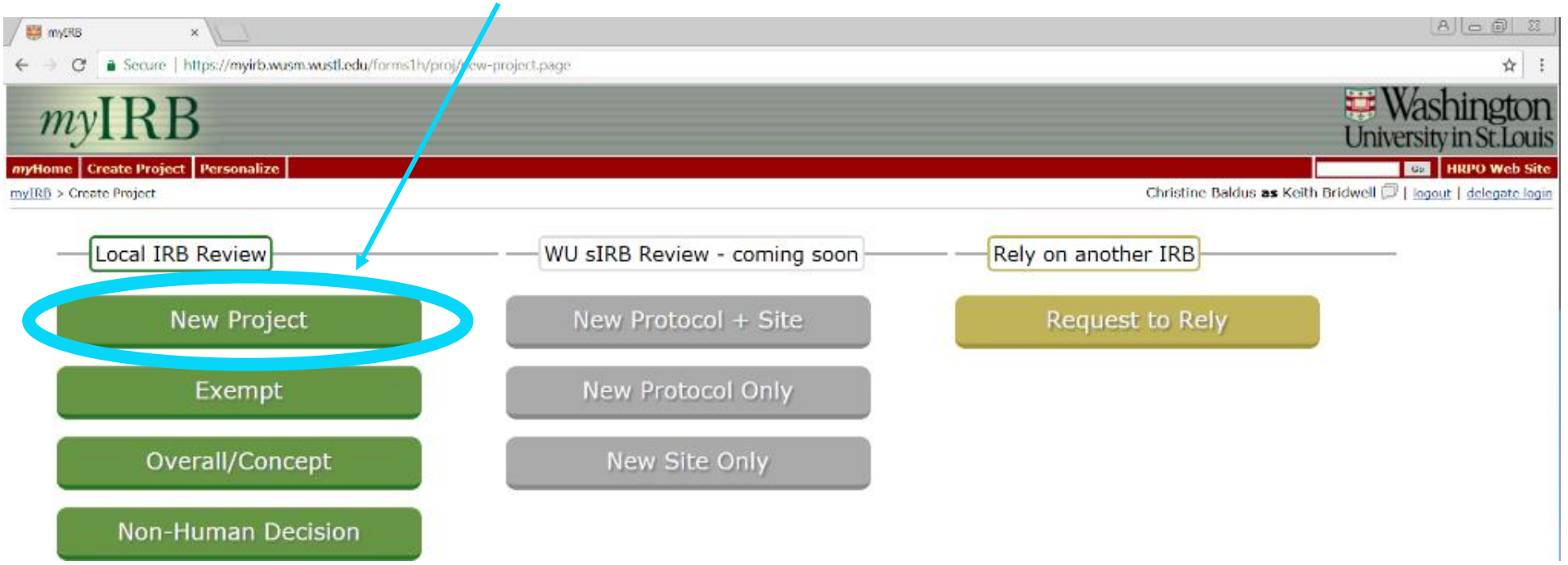
Describe statistical analysis methods as appropriate. For example, will intention-to-treat methodology be used in the analysis? Will there be any sample stratification?

myIRB New Project Submission:

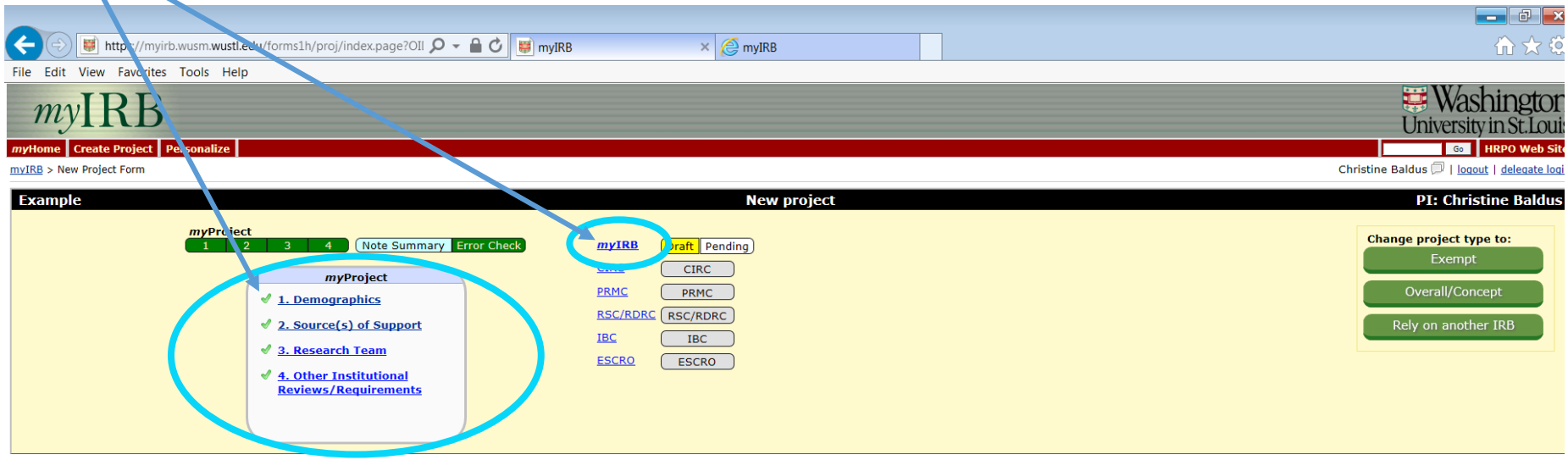
1. Go to https://myirb.wusm.wustl.edu/
2. Login with *your* WUSTL key
3. Login as Delegate for PI on the project.
4. Go to Create a Project



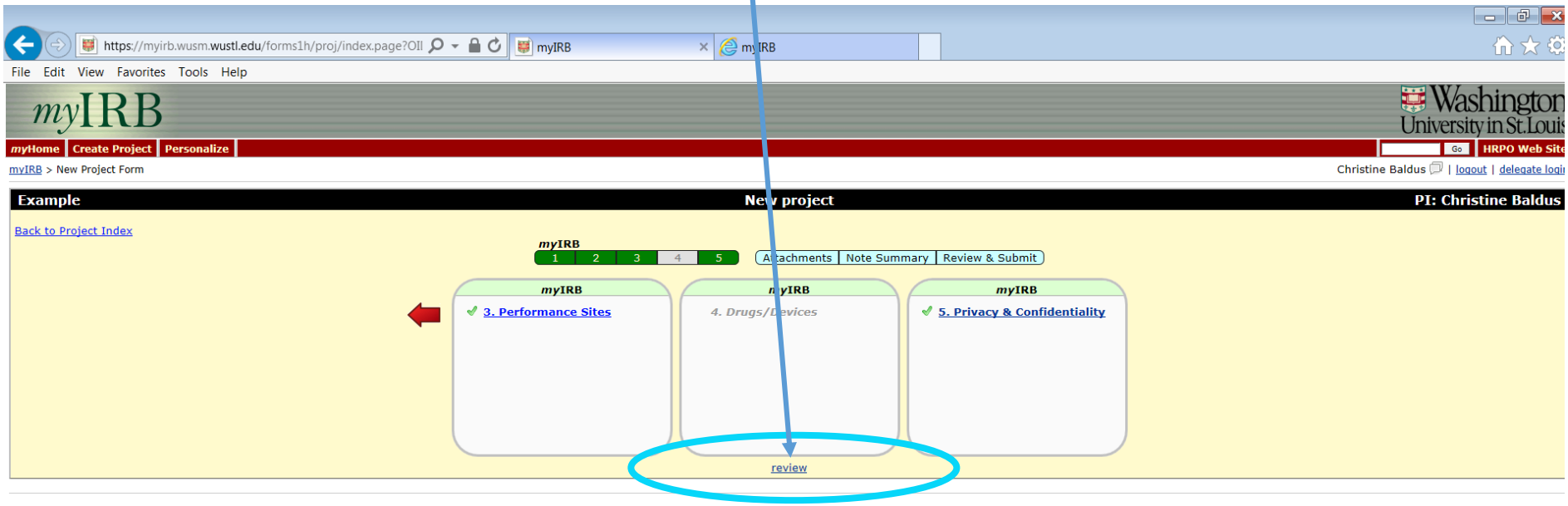
5. Select appropriate new study project. (Generally, New project)



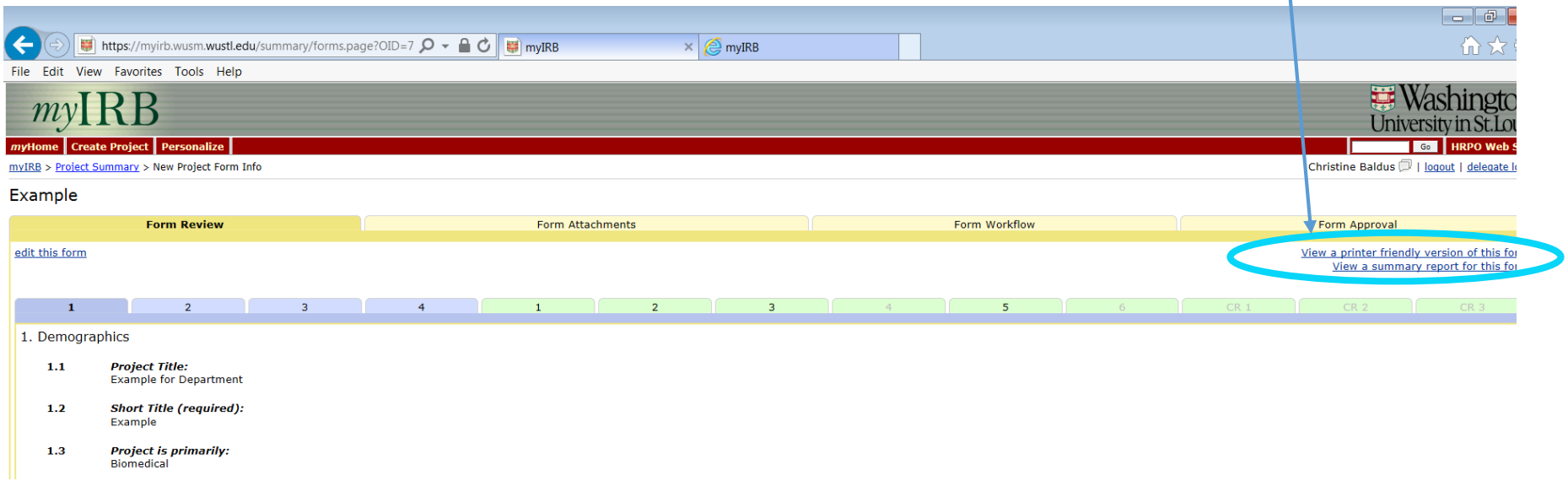
6. **Enter study information.**
   a. **Start with #1 (Demographics) and work through to #4 (Other Institutional Reviews).**
   b. **Then go to myIRB to complete remainder of HRPO submission draft.**



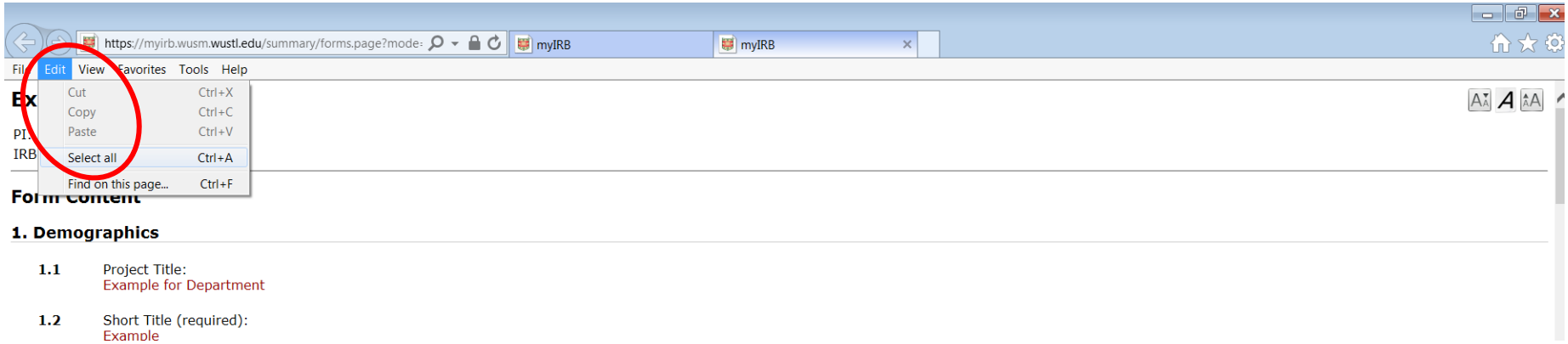
7. **When you have completed myIRB through #5, select review.**



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.

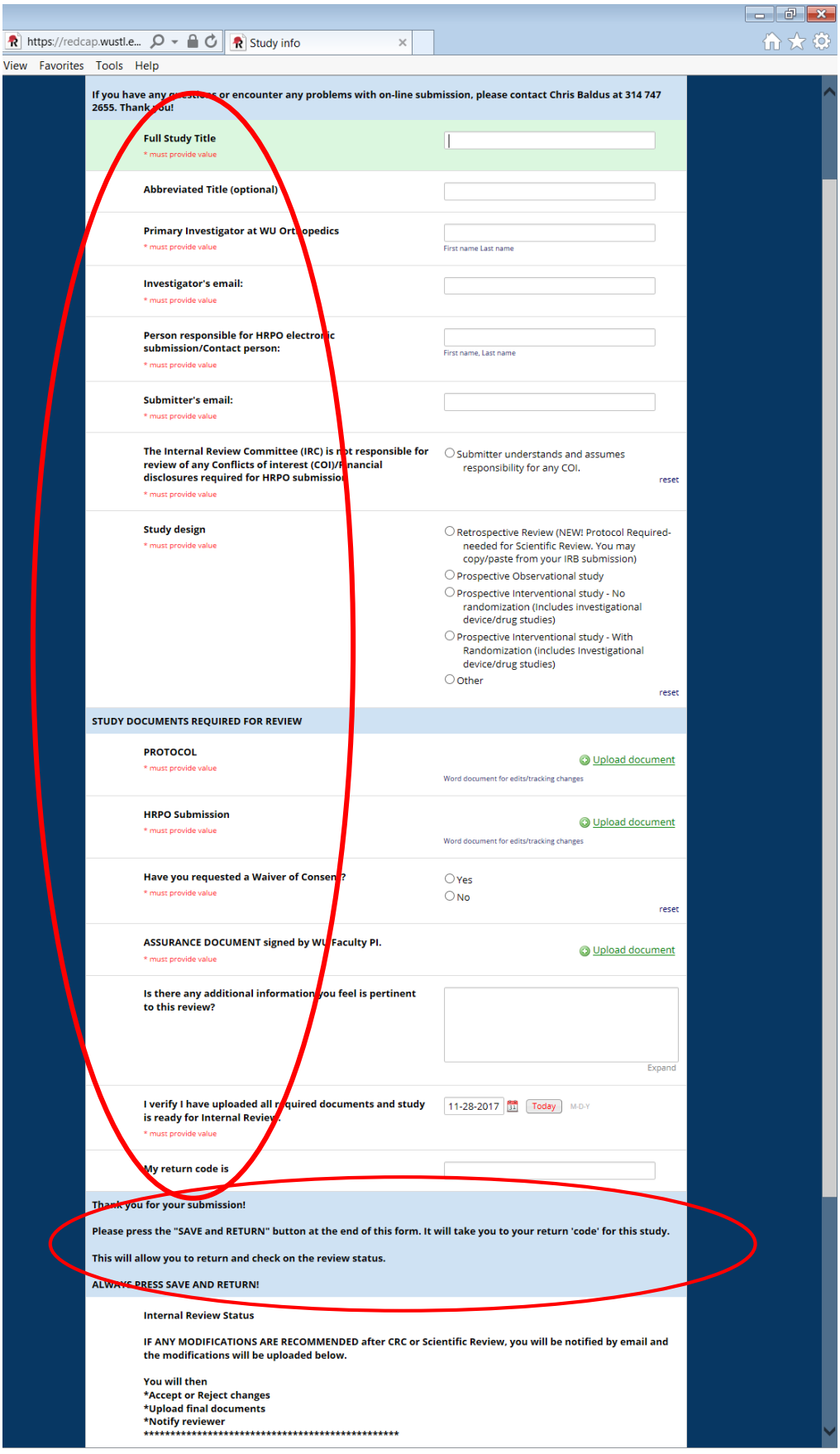
Information you will need to submit.

- 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
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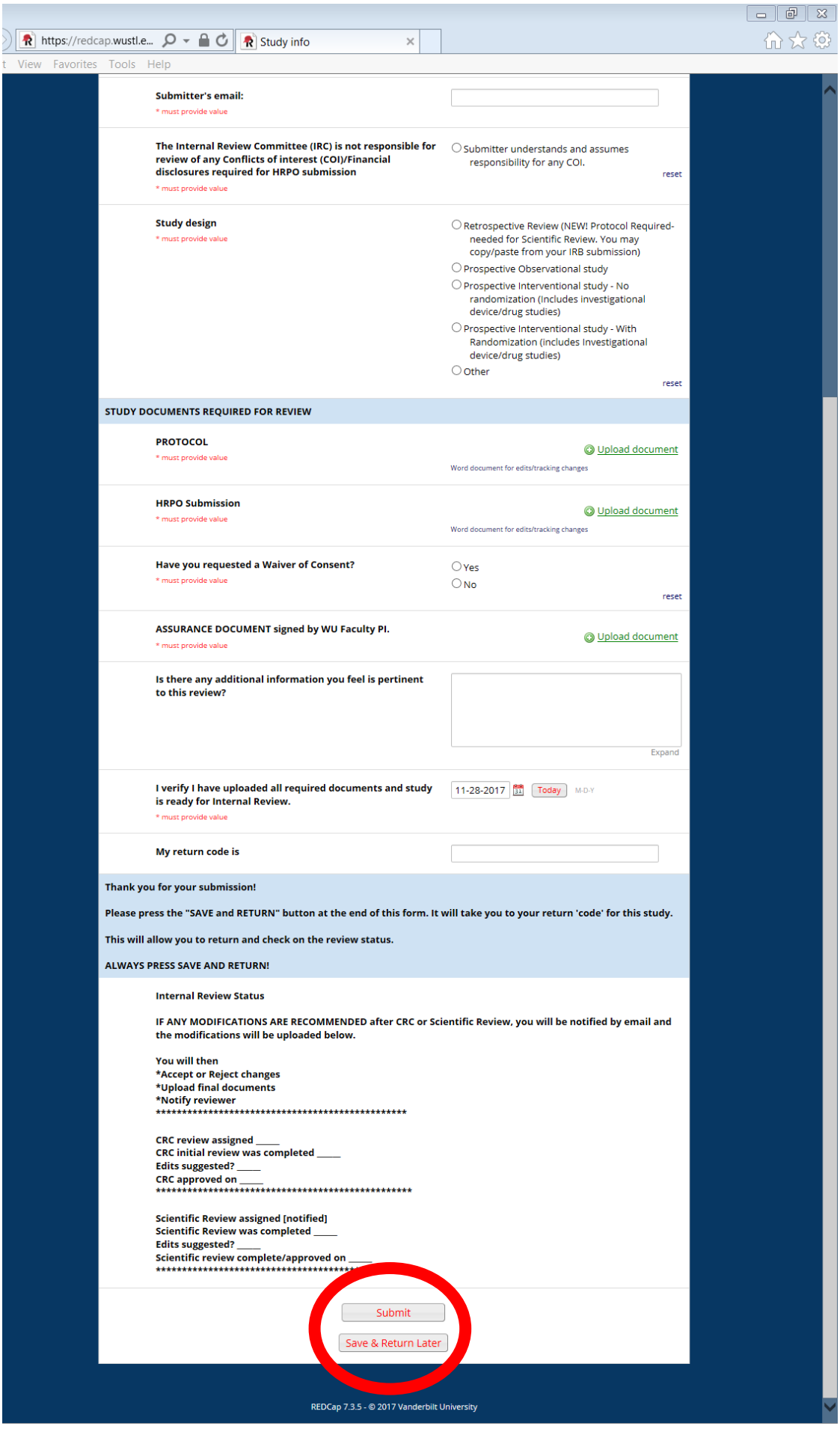
Word document for edits/tracking changes
Have you requested a Waiver of Consent?
* must provide value
Yes
No
reset
ASSURANCE DOCUMENT signed by WU Faculty PI.
* must provide value
Upload document
Is there any additional information you feel is pertinent to this review?
Expand
I verify I have uploaded 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
t View Favorites Tools Help
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
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Submitter understands and assumes responsibility for any COI.
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Study design
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*Accept or Reject changes
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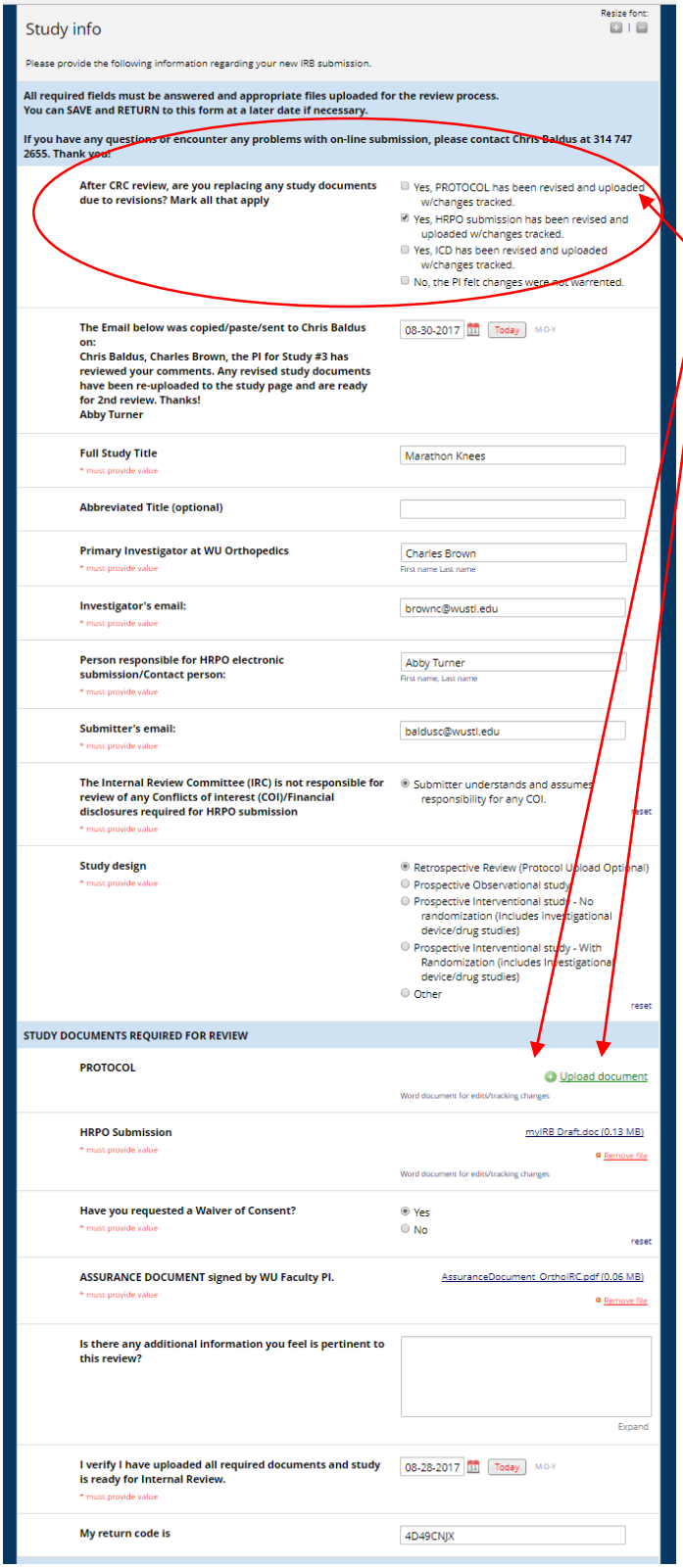
*Notify reviewer
****
CRC review assigned ____
CRC initial review was completed ____
Edits suggested? ____
CRC approved on ____
****
Scientific Review assigned [notified]
Scientific Review was completed ____
Edits suggested? ____
Scientific review complete/approved on ____
Submit
Save & Return Later
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 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.