**IRB Steps for Investigators Before Conducting Human Subjects Research**

**Principal Investigators / Student Investigators**

**Steps for Submitting a New IRB Application**

**Step 1: Complete the Required Human Subject Protection Training**

Principal Investigators and their co-investigators/study staff are required to take a human subjects protection training. To begin your training, request the [Required Human Subject Training course](#) information/instructions from the IRB Compliance Officer.

**Step 1.b.: Students must fill out and have signed the “Student Research Approval Form” by a faculty mentor as the Principal Investigator.**

**Step 2: Determine Which Application to Submit and Request Forms from the IRB Compliance Officer at: lderment@rvu.edu**

Projects that involve human subjects’ research may undergo one of three types of review:

- Exempt Review
- Expedited Review
- Full Board Review

The type of review depends on the risk level of the research and if the research falls into one of the expedited or exempt categories as defined by the federal regulations.

For assistance in determining which application should be completed for your study, please refer to the IRB’s guidance: [IRB Levels of Research Review](#) at: [www.rvu.edu/academics/research](http://www.rvu.edu/academics/research)

Once the application is received by the Compliance Officer, the IRB Chair will make the final determination on the type of review.

*What happens if you send in the wrong application?*  
The IRB may be able to obtain the necessary information from the application that was initially submitted. If additional information is needed, the IRB will let you know. In some cases, the IRB will ask that you complete the correct application for your study type.

**Step 3: Obtain Appropriate Signatures & Approvals**

There are several signatures required on the IRB application. The IRB accepts original, scanned, faxed, or copied versions of the signature page. If you do not have access to a scanner, you can digitally sign a .pdf copy of the signature page and send it to the Compliance Officer.

**For Student Investigators:**

- Be sure to include the Student Research Approval form signed by your faculty mentor and the Director of Research.
- Your signature is required on the IRB review application.
- Your faculty mentor/advisor must also sign the application and be listed as a co-investigator.
- RVU has an IRB pre-review process and IRB applications must first be reviewed by the IRB.
For Faculty Investigators:

- Your signature is required on the application
- You are asked to be accountable for ensuring the student investigator(s) conduct ethical and compliant human subjects research.

Step 4: Assemble Study-Related Documents for IRB Review

The IRB reviews most study-related documents. The following documents should be included with your submission, as applicable:

- Appropriate Request for IRB Review Form
  - Exempt – 1001
  - Expedited – 1002
  - Full Review – 1003
- Declaration of Conflicts of Interest Form – 1006
- Informed Consent Template (filled in with study information)
- Outside IRB Authorization Agreement (if applicable)
- Completion of CITI Human Subjects Research Training Certificate
- Recruitment materials, website or email text
- Questionnaires/Surveys/Data Use Agreements (if being used in the research)
- Grant application (intramural or external) (if applicable)
- A device approval/description/manual (if applicable)
- FDA, DHHS letters related to sponsorship (if applicable)
- Drug label information/package insert, Investigator Brochure etc. (if applicable)
- Data and Safety Monitoring Board (DSMB) Memo (if applicable)

If the project is federally funded and RVU is the prime awardee, submit a full copy of the grant application. If RVU receives a subcontract, submit relevant sections of the grant application and/or the scope of work. Additional steps are required if the project is related to grant funding.

Step 5: Email Application to the Compliance Officer

Prior to sending in your application, ensure that:

1. You and your study staff/co-investigators have taken the required human subjects protection training
2. You have completed the appropriate IRB application
3. You have obtained all of the proper signatures
4. You have assembled all study-related documents

After you complete the above steps, you may email your completed application and relevant documents to the Compliance Officer at: lvement@rvu.edu.

Exempt and Expedited submissions are reviewed on a rolling basis. If the study qualifies for Full Board review, it will be reviewed at the next Full Board meeting. Full Board meetings occur four times per year in March, June, September, and December or more often as determined.

PLEASE DO NOT CONDUCT HUMAN SUBJECTS RESEARCH WITHOUT IRB APPROVAL!!!