**New IRB Submission Checklist**

**All New Protocol Submissions**

**Preliminary Preparation:**

* **IRB Training**
  + CITI IRB Training - Available Online ([www.citiprogram.org](http://www.citiprogram.org))
  + IRB CITI Training Requirements
    - Course requirements differ for Faculty/Staff and Students (depending on risk level of student projects – see <https://www.radford.edu/content/research-compliance/home/irb/irb-training.html> for more information).
* Training Certificates from CITI (If user is affiliated with Radford University, CITI certificates do not have to be uploaded into IRBManager.) The user may affiliate his/her CITI account with Radford University within CITI for the Radford University IRB Office to confirm completion of training.
  + Training Certificates from other sources (or CITI but not affiliated with Radford University) MUST be uploaded to IRBManager (e.g., NIH IRB training, university-created training).
* **Create xForm in IRBManager** (Student MAY NOT be PI)
  + Create an account if a new user in IRBManager – All students/faculty/staff employed after July 2015.
* **Prepare/Assemble Documents for Project**
  + Download needed forms from the Radford IRB website, including, but not limited to:
    - [*Investigator Agreement Form*](http://www.radford.edu/content/dam/departments/administrative/Research%20Compliance/IRB/Resources/Investigator_Agreement_Form.docx) *(also see* [*Investigator Agreement form Instructions*](http://www.radford.edu/content/dam/departments/administrative/Research%20Compliance/IRB/Resources/Investigator_Agreement_Form_Instructions.docx)*)* ONLY External researchers are required to complete the Investigator Agreement form.
  + Download other needed templates from Radford IRB website including, but not limited to:
    - [Informed Consent Templates](https://www.radford.edu/content/research-compliance/home/irb/Consent_Tips/Templates.html)
    - Other Sample Documents and Guidelines

**Exempt, Expedited, and Full Board Submissions**

**Universal Submission Package Content:**

* **Initial Application xForm located in IRBManager**
* **Training Certification, if Not Accessible in CITI**
* **Investigator Agreement (IA) Forms**
  + ONLY **External** PI’s, Co-PI’s, Student Investigators
* **Recent CV/Resume**
  + Required for each member of the research team involved in the research.
* **IRBManager Submission Personnel**
  + The Faculty Mentor or other PI must be included with every submission by listing them as the PI on the protocol.
  + Students cannot be the PI on submission; instead they must specify the faculty mentor as PI in IRBManager.

**Project-Specific Package Content:**

* **Informed Consent/Assent Documents on Letterhead with Official Radford University Letterhead**
  + Exception: Online survey consent forms do not have to be on Letterhead but must have Radford University Logo
* **Surveys/Questionnaires/Other Research Tools Provided to Participants**
* **Recruitment and Other Supporting Documents to be Attached, as Appropriate** 
  + Study Advertisements, Initial Contact/Recruitment Scripts, Debriefing Forms, etc.
  + Letters of Support or Cooperation from external study sites
  + Grant/Award/ Funding Letters and Research Proposals
  + HIPPA Forms

**FINAL STEPS of INITIAL SUBMISSION PROCESS:**

* **Protocol must first be “Completed” in IRBManager**
* **Protocol Submission** 
  + The PI must sign-off on the application, uploading his/her CV. Select “Next” to go to the next page. Select “Submit” in order to submit your protocol to the RU IRB Office.
  + If you do not click on “Submit,” your protocol will not be submitted.

**WHAT COMES NEXT:**

* **IRB Office Pre-Review**
  + Your project/package will be reviewed by the IRB Office for completeness.
  + You will be notified if anything is missing and asked to revise your submission accordingly.
* **IRB Review**
  + The complete IRB submission will be forwarded to the appropriate IRB reviewer(s).
  + The reviewer may require further revisions/modifications required before approval is granted.

**WHEN CAN YOU START YOUR RESEARCH?**

* You may begin your research when you have **received your Approval Letter and stamped Informed Consent documents**, as applicable if any were submitted with the application.
  + You MUST use the STAMPED versions of the consent documentation (except for internet-based research) provided to you by the IRB Office.
  + You may NOT use expired versions of stamped consent forms when conducting research.