Checklist for Submitting a New Project to an Internal AU IRB

If you have trouble using this checklist or issues in IRBNet or CITI, please contact the IRB Office at 706.721.3110 or irb@augusta.edu

1. **Getting Started**
   Clicking on the blue links will open additional links to instructions that may help you.

CITI Completion	IRBNet Account	Update User Profile
☐ Each research team member must complete the applicable CITI learner group (www.citiprogram.org	☐ Each research team member must create an IRBNet Account and affiliate with Augusta University at www.irbnet.org	☐ Each research team member must link their CITI to their IRBNet Account. ☐ Each research team member must upload a current, **dated** CV/resume.
For additional guidance on CITI, creating an IRBNet Account or Submitting your CV/Resume please navigate to the main Augusta University web page, click Research, click Tools for Researchers (lime green tab) and search using key words.		

2. **New Study Checklist**
   *Please review the Exempt and Expedited Policies. Policies are located on the Augusta University website under Tools for Researchers. If your research does not fit within one of the above policies, you should choose Full Review on the Core Data form.

3. **Click Create New Project**

4. **Ensure the following required documents are uploaded in your package on the Designer page:**

Please note: Due to the revised regulations implemented on 1/21/19 you will notice that some templates and supplemental forms have '2018 Regulations (New Regulations)' and others have 'Pre-2018 Regulations. (Old Regulations).'
   - **The 2018 Regulations (New Regulations) documents should be used for new studies or response/follow-up packages to new studies submitted on or after 1/11/19 that are not FDA regulated or Department of Justice (DOJ) supported.**
   - **The Pre-2018 Regulations (Old Regulations) should be used for studies approved prior to 1/21/19, FDA regulated or DOJ supported studies.**

Basic requirements for EVERY STUDY:

☐ Core Data Form (Location: IRBNet, click Create New Project, under Designer tab, select Start a Wizard)

☐ Template: Protocol (Location: IRBNet, under Forms and Templates) Please ensure you put a version date in the footer of this document.

☐ Data collection form (this document should be created by the study team and can be questionnaires, surveys, Excel spreadsheet, interview script, etc) – Please ensure you put a version date in the footer of this document.

☐ Attestation: Research Data Storage (Location: IRBNet, under Forms and Templates)

☐ Attestation: Conflict of Interest Form (Location: IRBNet, under Forms and Templates)

☐ Applicable Supplemental Forms as indicated on the last page of the Core Data Form (Location: IRBNet, under Forms & Templates)

Additional Requirements that must be uploaded PRIOR to initial IRB Review, if applicable:

☐ Informed Consent Document/Parental Consent/Children's Assent Document (Templates located in IRBNet, under Forms & Templates)

☐ Advertisements (Template located in IRBNet, under Forms & Templates) Please ensure you put a version date in the footer of this document.

☐ Sponsor's Protocol or Grant

☐ Drug/Device information (i.e. Investigator's Brochure, Device Information Sheet, etc)

5. **Additional Institutional Approvals required if your research involves the any of the following:**

☐ **Radiation Safety Committee Approval**, for studies involving radiation outside of standard of care (for more information email radiationsafetyoffice @augusta.edu)	☐ **Stem Cell Committee Approval**, for studies involving stem cells for research purposes (evaluated on a case-by-case basis at this time)	☐ **Biosafety Committee Approval**, for studies involving any of the following: Introduction/Exposure to Biological Materials, Gene Transfer. Stem Cells, and/or Select Agents and Toxins (for more information email BIOSAFETY@augusta.edu)	☐ **PRMC Approval** for Oncology studies (excluding Chart Review studies) (for more information navigate to this website https://www.augusta.edu/cancer/research/grant-support-services/toolbox/prmc/submit.php)	☐ **Education Research Review Approval** for studies involving use of MCG students or their data for research purposes (for more information or to see if your study requires this type of approval navigate to this website https://www.augusta.edu/mcg/coffice/evaluation-services/edresearch.php)

6. **Share** the package with all research team members listed on the Core Data Form and the Department Approver (a list of Department Approvers can be found in Forms and Templates Library). (Click Share this Package, click blue word Share, Click Select Organization, Search for User, Grant needed access)

7. **Link the Training and Credentials** of all research team members listed on the Core Data Form (Please find Link/Un-Link Training Records link (see screenshot below) by clicking the Designer tab) Each study must have a CV/Resume linked and a valid CITI.

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

8. **Obtain Required Signatures** (Click Sign This Package, select role from dropdown, click Sign, enter IRBNet Username and password)

☐ Principal Investigator

☐ Department Chair

☐ Advisor (required if the Principal Investigator is a resident, fellow or student)

9. **Click** **Submit This Package**

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