New Faculty - Research Compliance Onboarding Checklist - Human Subjects Research (IRB)

The following information is provided to help new Auburn investigators become familiar with the Office of Research Compliance - Human Subjects Research (IRB). As you review the sections, please contact us if you have questions or need additional information.

Human Subjects Research (IRB)

The Auburn University IRB adheres to federal, state, and institutional guidelines and regulations to protect participants enrolled in human subjects' research. A goal of the AU IRB is to facilitate research while following the mandate to protect participants. The Office of the IRB and the AU Human Research Protection Program welcome questions and comments. Online guidance is an ongoing process, with revisions required as events affect human subjects research (first time revisions of the Common Rule and safety precautions related to the COVID-19 pandemic for face to face activities, for example). We encourage a review of the website prior to submissions, to ensure the most recent version of forms and guidance.

Human Subjects Research Contact

irbadmin@auburn.edu

334-844-5966

Area	Applies To	Description	Complete
Update CITI Affiliation to Auburn University or register	Auburn personnel with a primary CITI affiliation	Please update your existing CITI account to <u>affiliate with Auburn</u> <u>University</u> . Designate your @auburn.edu email as the Primary CITI	
for a CITI account	with another institution	email address.	
	or those who do not have a CITI account.	If you do not have a CITI account, please create one <u>following these</u> <u>steps.</u> Designate your @auburn.edu email as the Primary CITI email	
		address.	

Area	Description	Complete
REVIEW PROCESS	As a single PDF, completed, signed submissions are submitted for review via irbsubmit@auburn.edu . Regardless of the level of review (convened IRB, via the expedited process, exempt from some federal regulations, or a determination of not human subjects research (NHSR)), the IRB Specialists assigns the submission to an experienced reviewer.	
	 CONVENED/FULL BOARD - Protocols requiring review by the convened IRB are reviewed by the IRB Chair, a primary and secondary reviewer, and the Board as a whole. Meetings for all three of the AU IRBs (biomedical, social/behavioral, and prisoner) are held monthly. The dates for documentation submission deadlines and meetings is available online at auburn.edu/irb, then the Submissions page. For protocols requiring review by the convened IRB, the IRB recommends submitting materials 6 – 8 weeks prior to the expected study start date, to allow sufficient time for Board review and review of any required revisions. EXPEDITED - Protocols reviewed via the expedited process are reviewed on an ongoing basis by two IRB Chairs and an experienced Board member. EXEMPT and NHSR - Exempt protocols and requests for a not human subjects research determination are reviewed by the Human Research Protection Program (HRPP) Manager on an 	
Submissions	ongoing basis. The expectation for all submissions is the same.	
	 All items in the applications must be completed, including signatures, which may be handwritten or electronic. For faculty, this means the signatures of the Principal Investigator and Department Head/Supervisor. For Student Investigators, signatures of the Student Investigator, Faculty Advisor Investigator, and Department Head are required before approval can be issued. If a protocol requires revisions, on the clean copy of the revised application updated signatures and dates are required – no approval can be issued without required signatures. Copies of recruitment materials, consent documents, training documentation, and agreements/approvals from other entities are required. All key personnel (decision chart for what makes key personnel is available online) are required to complete human subjects training and include training with every submission. Training guidance is available online at auburn.edu/irb, then Training page. 	

Area	Description	Complete
THE IRB WEBSITE	The IRB website is broken down in categories designed to provide useful, concise information to the	
(auburn.edu/irb):	research community. The pages of the website include:	
	 Overview (a brief description of what is an IRB); 	
	 What's New (a resource to find the latest AU IRB guidance); 	
	COVID – 19 Guidance (safety precautions associated with the pandemic and requirements	
	for face to face interaction for research purposes);	
	 Guidance (detailed information for completing your submission); 	
	 IRB Submissions (levels of research and submission requirements): 	
	 Policies and Procedures (AU IRB policies and procedures); 	
	 Regulations and Ethical Guidelines (Federal guidelines); 	
	 Required Training (requirements and access to CITI program for training materials); 	
	Sample (to submit after completing).	