



New Informed Consent Templates: Human Subjects Research

The Human Subject’s Protection Program has revised their Informed Consent templates, for both Social/Behavioral/Educational and Biomedical research. The use of consent templates is strongly recommended to streamline IRB review and to make certain that federal regulatory requirements are met. Additionally, the IRB provides a template to include boilerplate language that meets institutional requirements “local context” and applied as relevant to each research study.

Consent templates serve as a guide to help researchers develop consent documents. The templates contain the information considered by the IRB to constitute the basic elements of informed consent such as descriptions of research procedures or activities and reasonably foreseeable risks and benefits associated with participation in a study. When using a template to build consent documents, you will need to tailor the template to your specific study, i.e., adding to areas that pertain to your research and deleting items that are not applicable to your study.

The new informed consent templates and guidance documents are located on the Human Subjects website, [Informed Consent](#) tab. If you have any suggestions on ways to improve the templates, please contact the IRB Office 251-460-6308 or email srobbins@southalabama.edu

IRBNet Board Action Documents

ATTENTION: IRB, IACUC, and IBC board action documents published in IRBNet must be carefully reviewed. Particularly, approval letters may provide additional details/instructions regarding compliance associated with protocol approval.

SPRING, 2018

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Contact us at:
Office of Research Compliance
AD 240
251-460-6625
dlayton@southalabama.edu

Healthcare Operations: Research vs. Quality Improvement

Quality improvement activities are an essential function carried out in hospital operations, as they allow for the measurement and improvement of quality of care for patients. Similar to research activities, quality improvement activities involve systematic investigations and can involve human subjects creating difficulty in distinguishing between the two. The following definitions should be considered when determining if a projects is research or quality improvement:

- ❖ **Research:** a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.
- ❖ **Quality improvement:** a systematic, data-guided activities designed to bring about immediate improvement in delivery of health in specific settings
- ❖ **Human subjects research:** any activity that meets the definition of “research” that involves human subjects as defined by FDA or the Office of Human Subjects Protections.

There are important distinctions between research and quality improvement that are systematic investigations involving human subjects. Quality improvement utilizes analytical tools and a hypothesis that is used in research, with the intent to investigate practices or procedures conducted in the course of routine medical care. However, research, is designed to develop, test, and evaluate practices and procedures that are outside of that which is conducted as routine medical care.

	Quality Improvement	Human Subjects Research
Purpose	Acquire knowledge, assess a process/program as judged by currently accepted standards/bests practices	Develop or contribute to generalizable knowledge
Risks	No increased risks to patients	May incur risks to subjects
Benefits	Directly benefits a process/program; may/may not benefit patients	May/may not benefit subjects, intended to benefit future patients
Analysis	Compare a program/process/system to established standards	Support/disprove hypothesis

It is encouraged that you contact the IRB Office if assistance is needed in determining if a quality improvement project involves human subject’s research. Please email irb@southalabama.edu or call 460-6308.

Federal Agencies Release: Updated Notice Further Delay of Common Rule

A new notice of proposed rulemaking was released on April 19th proposing to delay the general compliance date for the revised Federal Policy for the Protection of Human Subjects, or “Common Rule,” for an additional six months to January 21, 2019. Additionally, the notice also proposes to allow institutions to implement three “burden-reducing provisions” during the delay period, specifically:

1. use of the revised definition of “research,” which deems four categories of activities as not research
2. allowance for no annual continuing review for certain categories of research
3. elimination of the requirement for IRB review of grant applications for research

Currently, the federal agencies are seeking public comment on these proposals.

Export Controls Compliance: New Training

Export control laws covers a range of activities including research, international travel, collaborations with non-U.S. persons and entities, shipment of controlled items, or work with items such as source code, toxins, high performance computers, nanotechnology, or other high-end technology devices. Export control laws apply to academic, research and operational activities of the University community.

The Office of Research Compliance and Assurance provides a convenient way to gain a better understanding of Export Compliance through the [Collaborative Institutional Training Initiative](#) (CITI) program. If it is your first time entering the system, registration is required, make sure to select University of South Alabama as your organization affiliation. This web-based training series was initially launched in 2015 and currently provides 11 topic-specific modules. All are encouraged to complete the General Overview module; however, designated modules will be required for individuals carrying out specific roles and responsibilities, in particular researchers, research administrators, procurement, etc.

Angela Williams may be reached at aswilliams@southalabama.edu or 460-6863 to discuss any questions or concerns you have related to export and trade sanctions, or to discuss customized training session for your department.



REMINDER: National Science Foundation (NSF) Requirement: Responsible Conduct of Research Training

Responsible Conduct of Research (RCR) is defined as "the practice of scientific investigation with integrity." It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. National Science Foundation students and fellows conducting research directly supported from salary or stipends paid by NSF are required to take RCR training.

The Office of Research Compliance and Assurance reviews NSF Fastlane award documents to facilitate in identification of NSF awards that must comply with the RCR training requirement. All students and trainees receiving NSF funds must complete RCR training within one month (30 days) after participation in the project begins. Funding may be withheld for student payment if training is not complete within the allotted time frame.

Objectives of RCR training:

- Encourage best practices in the conduct of research and scientific investigations.
- Foster an ability to recognize an ethical choice and the ability to make a principled decision.
- Provide accessible educational opportunities and resources designed to help students and postdoctoral researchers meet the America COMPETES Act Responsible Conduct of Research training requirements.

Education and training in RCR is an essential component for individuals engaged in any field of research. Therefore, institutional policy on RCR training applies to **ALL** students and fellows involved in the conduct of research. Please review the [University's institutional policy on Research Conduct of Research Training for Students and Postdoctoral Fellows](#) for detailed information.

Items of Interest:

NSF Important Notice 144

On February 8, 2018, the National Science Foundation (NSF) issued “Important Notice No. 144” (see attached file) to the heads of universities and colleges and other NSF grantee organizations. This notice discusses a new award requirement that will require grantee organizations to report findings of sexual harassment or any other kind of harassment regarding a PI, co-PI, or any other grant personnel.

The American Statistical Association’s points of caution in interpreting p-values

Source: Retraction Watch

Potential FERPA violation in research conducted as a class project

Published March 8, 2018

Preparing for an Academic Career: The Significance of Mentoring

Gezzer Ortega, MD, Connor Smith, Margaret S. Pichardo, Alexander Ramirez, Maria Soto-Greene, MD, John P. Sánchez, MD

Published Date: March 5, 2018

A Curriculum to Teach Learners How to Develop and Present a Case Report

Gina Luciano, MD, Kathryn Jobbins, DO, Michael Rosenblum, MD

Published Date: March 16, 2018

Source: MedEd PORTAL

The Journal of Teaching and Learning Resources

Online Survey Tools: Ethical and Methodological Concerns of Human Research Ethics Committees

Buchanan, Elizabeth, and Hvizdak, Erin.

Published Date: June 2009

Source: Journal of Empirical Research on Human Research Ethics



Have a Question or a Comment?

Dusty Layton

Executive Director
460-6625
dlayton@southalabama.edu

Angela S. Williams

Assistant Director
460-6509
aswilliams@southalabama.edu

Stefanie White

Associate Director, Research Quality Assurance & Improvement
460-7573
swhite@southalabama.edu

Human Subjects Research**SuzAnne Robbins**

IRB Compliance Specialist
460-6308
irb@southalabama.edu

Animal Care & Use and Biosafety**Jennifer Chaplin**

Research Compliance Coordinator
460-6863
jchaplin@southalabama.edu

Reminder! IRB 101 for Students Educational Outreach

The Office of Research Compliance and Assurance and the IRB Office are available to provide class room presentations to students on information involving human subject's research and the IRB submission process.

Please email dlayton@southalabama.edu if you're interested in scheduling an educational session.