

Revised Common Rule

The [Federal Policy for the Protection of Human Subjects](#), known as the Common Rule has undergone substantive revisions for the first time since its publication in 1991. **The effective date for the revised Common Rule is January 21, 2019.** While many changes will reduce the burden on researchers and institutional compliance areas, some of the new requirements come with additional responsibilities.

Several of the UNC IRB Policies & Procedures have been revised to reflect the Revised Common Rule. Once the procedural manual is up to date, you will find it marked “New!” under the IRB Guidance section below.

The IRB Members and Co-Chairs will be sharing information across campus. In addition, UNC affiliates will soon have access to specific Common Rule modules in CITI.

Major Areas of Change

<u>Topic</u>	<u>Description</u>	<u>Current Information</u>
Definition of Research	Projects focused on collection information from recognizable individuals that follow inquiry traditions from their field are now excluded from review by the IRB. Ex. Oral history, historical scholarship, journalism, biography, literary criticism, legal research and criminal justice inquiry for or by a CJ agency authorized by law or court order	Please contact ORSP if you are unsure about your project. We will also be working with the Graduate School to revise the Verification form for student thesis and dissertation research. More on that to come.
Informed Consent	“Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.”	We are currently working on a revised informed consent template that will incorporate the required elements of the “key information”. This will be posted as soon as it is available for investigators to begin utilizing.
Exempt Categories	New categories for exempt research have been added and some of the existing categories have been modified.	Benign behavior interventions and video recording of subjects may now qualify as exempt research.

Continuing Review	Continuing review will no longer be required for most research that qualifies for expedited review or for studies that were initially approved by the full board and are now in data analysis only.	Expedited studies will initially be approved for 3 years. We will implement a system of checking in at that mark to update the status of your project. Details will be forthcoming. **The IRB will communicate with a PI when continuing review is no longer necessary. Continue to submit renewal materials until instructed otherwise.
Broad Consent	There is an option for the use of broad consent from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens. This option requires an extensive tracking mechanism.	UNC has elected not to implement this option for biospecimens at this time.

Definitions Comparison Chart

Exempt Comparison Chart

Questions and suggestions should be directed to [Nicole Morse, Research Compliance Manager](#), [Dr. Maria Lahman, IRB Co-Chair](#), or [Dr. Megan Babkes Stellino, IRB Co-Chair](#)