Study Title	Impact of the Revised Common Rule on Heartrate, Blood Pressure, and Anxiety
Researcher	Ace Student Researcher, Best Department
Supervisor	Ace Professor, PhD, Best Department

This application includes a "Key Information" box because it is more than 2 pages without it.

We're inviting you to participate in a research study. Participation is completely voluntary. If you agree to participate now, you can always change your mind later. There are no negative consequences, whatever you decide.

Key Information	
Summary	*The purpose is to evaluate changes in your anxiety, heart rate, and blood pressure before and after reading about the revised Common Rule. The study will be conducted over one, 45-minute session in our lab. You will complete an anxiety survey and we will measure your heart rate and blood pressure before and after reading a 10-page update to the Common Rule*
Reasonable, Foreseeable Risks or Discomforts	*Risks are minimal. It is likely you will experience a mild increase in anxiety, blood pressure, and heart rate after learning about the revisions to the Common Rule. It is less likely that those changes will be significant or endure beyond the study. Rare but serious risks include no longer wanting to conduct research.*
Reasonable, Expected Benefits	*There will be no direct benefit to you from participating in the study. However, this study will help IRB Chairs learn more about how the campus community responds to major changes in federal regulations.*
Alternatives, If Any	*There are no alternatives for faculty participants. If you are a student and decide not to participate in this research, your other choices include: completing a "Research Alternative" through SONA* or *taking part in another study.*

What Is the Purpose of This Study?

We want to evaluate changes in your heart rate, blood pressure, and perceptions of anxiety before and after reading about revisions to the common rule, in general, and changes to the consent form, in particular.

What Will I Do?

In our lab:

- You'll complete a 20-item survey about your feelings of anxiety (5 minutes)
- We will measure your heart rate and blood pressure (5 minutes)
- We will ask you to read approximately 10 pages of text about changes to the Common Rule, as well as review a new consent form required for Siena researchers (15 minutes)
- After you are done reading, we will ask you to complete the anxiety survey again (5 minutes) and measure your heart rate and blood pressure (5 minutes)

Risks

Possible Risks	***How We're Minimizing These Risks***
Some questions may be personal or upsetting	You can skip any questions you don't want to answer.
You may feel mild physical discomfort (increase in heart rate and/or blood pressure) when reading about the common rule changes	You may take a break or discontinue your participation at any time. (Unfortunately, you may not opt out of the common rule revisions.)
You may experience some mild anxiety after reading about the common rule changes that may last after the study concludes	You will be provided training in diaphragmatic breathing after you take the last survey. You will also be provided your IRB Chair's name and be encouraged to contact them if negative feelings persist.
Breach of confidentiality (your data being seen by someone who shouldn't have access to it)	• All identifying information is removed and replaced with a study ID. • We'll store all electronic data on a password-protected, encrypted computer. • We'll store all paper data in a locked filing cabinet in a locked office. • We'll keep your identifying information separate from your research data, but we'll be able to link it to you by using a study ID. We will destroy this link after we finish collecting and analyzing the data.

There may be risks we don't know about yet. Throughout the study, we'll tell you if we learn anything that might affect your decision to participate.

Other Study Information

Possible benefits	• There is no identified individual benefit to your participation this study • Your participation may help us understand more about people's reaction to federal regulation changes when provided short notice
Estimated number of participants	80 Siena faculty, 20 Siena Psyc100 students
How long will it take?	45 minutes
Costs	None
Compensation	None for faculty; 1.0 SONA credits for students
If I don't want to be in this study, are there other options?	• There are no alternatives for faculty • For students, Instead of participating, you can complete a different study or earn the same amount of SONA credit by completing a research alternative.

Future research	De-identified (all identifying information removed) data may be shared with other researchers. You won't be told specific details about these future research studies.
Removal from the study	If you threaten to stop the roll-out of the revised Common Rule by hacking into Processmaker and corrupting the files, we will have to take you out of the study. (Students will still receive SONA credit.)

Confidentiality and Data Security

For students, we'll collect the following personally identifying information for the research: your name, email, and Siena ID. This information is necessary so that you can receive SONA credit for your participation. For faculty, we will collect your name. This information is necessary as part of the consent process.

Where Will Data Be Stored?	• Signed consent forms and completed surveys, and hard copies of recordings of physiological data will be stored in a locked file cabinet in the supervisor's Siena office. • Responses will be stored in a password protected file on the Siena server.
How Long Will It Be Kept?	• Consent forms will be kept for 3 months after the semester ends • Completed surveys and data will be kept for 3 years.

Who Can See My Data?	***Why?***	***Type of data***
The researchers	To conduct the study and analyze the data	• Identifiable (consent forms) • De-identified (surveys, physiological responses)
Anyone (public)	If we share our findings in publications or presentations.	• Aggregate (grouped) data • De-identified (no names) • If we quote you, we'll use a pseudonym (fake name)

Who Do I Contact?

For questions about the research, complaints, problems	Ace Student Researcher	astudent@siena.edu /518-111-1111
	Ace Professor	aprof@siena.edu / 518-222-2222
For questions about your rights as a research participant, complaints, problems	Chair, Institutional Review Board (IRB; provides ethics oversight)	irb@siena.edu / (518) 782-6726

Signatures

If you have had all your questions answered and would like to participate in this study, sign on the lines below. Remember, your participation is completely voluntary, and you're free to withdraw from the study at any time. You must be 18 years or older to participate in this study.

_____

Name of Participant (print)

_____ _____

Signature of Participant Date