

## Siena University Institutional Review Board

### Additional Required CITI Training When Working with Vulnerable Populations

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*Vulnerable subjects are defined as persons who “have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity...or situational circumstances...or because they are especially at risk for exploitation.” This includes (and is not limited to):*

<ul style="list-style-type: none"><li>• Prisoners</li><li>• Children</li><li>• Individuals with cognitive impairments</li><li>• Non-English-speaking participants</li><li>• Employees (vulnerability due to social hierarchy)</li></ul>	<ul style="list-style-type: none"><li>• Terminally ill or very sick patients</li><li>• Economically disadvantaged or socially marginalized individuals</li><li>• Institutionalized persons (e.g., nursing homes, hospitals, mental health facilities, prison)</li></ul>
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✓ **Policy:** Effective 10/1/19, Siena college students (and their supervisors), faculty, and staff must submit documentation of additional required CITI training if recruiting participants from vulnerable populations. This training will be valid at Siena for 5 years. (The Basic Course is valid for 3 years.)

✓ **Rationale:** Participants from vulnerable populations require additional consideration and/or protections that are not discussed in the basic IRB training.

✓ **What Training Should You Complete?** All PIs (and supervisors of student PIs) who are working with vulnerable populations will complete:

- A. The CITI module entitled, *“Populations in Research Requiring Additional Considerations”* and
- B. Additional relevant modules specific to the setting and/or target population (next page)

Examples:

If conducting research in 3rd grade classrooms, a PI would complete the training for *“Any Vulnerable Population,” “Minors,”* & *“Research in Public Elementary and Secondary Schools.”*

A PI doing research in a facility serving individuals with dementia would complete the training for *“Any Vulnerable Population,” “Individuals with Impaired Decision-Making Capacity,”* & *“Older Adults.”*

Contact the IRB at [IRB@siena.edu](mailto:IRB@siena.edu) if you have any questions about required training for your project.

✓ **What Documentation Is Needed?** In the IRB application there will be a request to provide verification of additional training. In CITI (accessed from the IRB [website](#)) under “REQUIRED MODULES” there is a “VIEW-PRINT-SHARE RECORD” button. Click and “COPY LINK.” You will be asked to include this link in the “Subject Population” section of your application.

*Note: This process is separate from Basic Course CITI training verification at the end of the application. (For that, you will need to download the PDF of the certificate.)*

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Complete all relevant training to your target population and/or setting.

If You Are Working With...	Then Complete This Module
<b>Any Vulnerable Population (EVERYONE COMPLETES)</b>	Populations in Research Requiring Additional Considerations and/or Protections (ID 16680)
<b>Prisoners</b>	Research Involving Prisoners (ID 8) <u>and</u> Research With Prisoners - SBE (ID 506)
<b>Minors</b>	Research Involving Children (ID 9) <u>and</u> Research With Children - SBE (ID 507)
Students in <b>Public Schools</b>	Research In Public Elementary And Secondary Schools - SBE (ID: 508)
Individuals With <b>Impaired Decision-Making Capacity</b>	Research With Decisionally Impaired Subjects (ID: 16610)
<b>Socially or Economically Disadvantaged</b> Individuals	Research With Persons Who Are Socially Or Economically Disadvantaged (ID 16539)
Subjects at the <b>End-of-Life</b>	Research Involving Subjects At the End-of-Life (ID 16658)
<b>Critically Ill</b> Individuals	Research With Critically Ill Subjects (ID 16592)
<b>Older Adults</b>	Research With Older Adults (ID 16502)
<b>Non English-Speaking</b>	Consent With Subjects Who Do Not Speak English (ID 17260)
Workplace <b>Employees</b>	Vulnerable Subjects - Research Involving Workers/Employees (ID 483)

**DIRECTIONS**

**IMPORTANT:** You can only access the elective modules **after** completing the basic required CITI training (Human Subjects Research – Basic Course) for all PIs.

1. Access CITI through the IRB [website](#) (“Online Certification Training”).
2. Under “COMPLETED COURSES”, find “FACULTY OR STUDENT STAGE 1 – BASIC COURSE.”
3. Click on “REVIEW COURSE.”
4. A listing of previously completed “Required Modules” appears, first. Scroll down to “ELECTIVE MODULES.”
5. Choose the elective module you want to complete and click “START.”
6. Follow this procedure for all supplemental required training.