REGIS UNIVERSITY

**Human Subjects CITI Human Subjects Training Requirements**

For Human Subjects Research submitted after January 15, 2019

A total of 11 CITI modules must be taken for biomedical (8 required and 3 electives) and social-behavioral researchers (9 required and 2 electives).

-**Biomedical Researchers** must take all eight of the required modules (highlighted in yellow) in List A. Three additional elective modules must be taken. At least one of the modules should be an informed consent elective module from List B, and at least two of the remaining elective modules from List C.

-**Social-Behavioral Researchers** must take all nine of the required modules in (highlighted in blue) in List A. Two additional elective modules must be taken. At least one of the modules should be an informed consent.

N**OTE:** Regis offers additional courses through CITI, including the Responsible Conduct of Research (RCR) course which has other topics pertinent to researchers such as conflict of interest, plagiarism, and reproducibility of research results.

| **Required Modules** | **Biomedical Research Requirements (8 required)** | **Social-Behavioral Research Requirements (9 required)** |
|---|---|---|
| List A | Informed Consent | Informed Consent |
| | Conflicts of Interest in Human Subjects Research | Conflicts of Interest in Human Subjects Research |
| | Populations in Research Requiring Additional Considerations and/or Protections | Populations in Research Requiring Additional Considerations and/or Protections |
| | Records-Based Research | Assessing Risk |
| | Research and HIPAA Privacy Protections | Privacy & Confidentiality |
| | History & Ethics of Human Subjects Research | History & Ethical Principles |
| | Basic Institutional Review Board Regulations& Review Process | The Federal Regulations |
| | Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research | Unanticipated Problems and Reporting Requirements in Social & Behavioral Research |
| | At least one elective from List B (Informed Consent) AND at least two electives from List C (Types of Research) | Defining Research with Human Subjects |
| | | At least one elective from List B (Informed Consent) AND at least one elective from List C. |

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**Informed Consent Elective Module Selections**

- **Biomedical Researchers** must select at least one informed consent module from the options highlighted in yellow as one of their three electives.

- **Social-Behavioral Researchers** must select at least one informed consent module from the options highlighted in blue as one of their two electives.

| **Elective Modules: Informed Consent** | After requirements in List A, **Biomedical researchers** must select at least one module from these selections in List B and at least two modules from List C. | After completing modules from List A, **Social-Behavioral researchers** must select at least one module from List B and one module from List C. |
|---|---|---|
| **List B** | Consent and Biobanks and Associated Databases | Consent and Cultural Competence |
| | Consent and Cultural Competence | |
| | Consent and Subject Recruitment Challenges: Remuneration | Consent and Subject Recruitment Challenges: Remuneration |
| | Consent and Subject Recruitment Challenges: Therapeutic Misconception | Consent and Subject Recruitment Challenges: Therapeutic Misconception |
| | Consent in the 21st Century | Consent in the 21st Century |
| | Consent Tools Used by Researchers | Consent Tools Used by Researchers |
| | Consent with Subjects who do not speak English | Consent with Subjects who do not speak English |
| | Informed Consent and Confidentiality in Public Health Research | Informed Consent and Confidentiality in Public Health Research |
| | Informed Consent and Incidental Findings in Research with Human Subjects | Informed Consent and Incidental Findings in Research with Human Subjects |

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**Type of Research Elective Modules**

- **Biomedical researchers** must select at least two modules from the Type of Research options highlighted in yellow in List C.
- **Social-Behavioral researchers** must select at least one module from the Type of Research options highlighted in blue in List C.

| **Elective Modules: Type of Research** | **Biomedical researchers must** select at least two modules from List C. | **Social-Behavioral researchers must** choose at least one module **from List C.** |
|---|---|---|
| **List C** | Avoiding Group Harms (International Research Perspective) | Avoiding Group Harms (International Research Perspective) |
| | Avoiding Group Harms (US Research Perspective) | Avoiding Group Harms (US Research Perspective) |
| | Belmont Report and Its Principles | Belmont Report and Its Principles |
| | Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites | |
| | Cultural Competence in Research | Cultural Competence in Research |
| | Data and Safety Monitoring in Human Subjects Research | |
| | Disaster and Conflict Research, Part 1: PI Responsibilities | Disaster and Conflict Research, Part 1: PI Responsibilities |
| | Disaster and Conflict Research, Part 2: Best Practices and Recommendations` | Disaster and Conflict Research, Part 2: Best Practices and Recommendations |
| | Ethical and Practical Considerations in Community-Engaged Research (CEnR) | Ethical and Practical Considerations in Community-Engaged Research (CEnR) |
| | Ethical Issues in Public Research | Ethical and Appropriate Uses of Administrative Data for Research and Evaluation |
| | External IRB Review | External IRB Review |
| | FDA-Regulated Research | FERPA: An Introduction |
| | | FERPA for Researchers |
| | | FERPA for Institutional Review Boards |
| | Gender and Sexuality Diversity (GSD) in Human Research | Gender and Sexuality Diversity (GSD) in Human Research |
| | Human Subjects Considerations and Big Data Research | Human Subjects Considerations and Big Data Research |

Revised: June 2, 2021

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|---|---|---|
| | Humanitarian Use Devices (HUDs) | Illegal Activities or Undocumented Status in Human Research |
| | Illegal Activities or Undocumented Status in Human Research | |
| | International Studies | International Studies |
| | | International Research – SBE |
| | | Internet-Based Research – SBE |
| | Introduction to Community-Based Participatory Research (CBPR) | Introduction to Community-Based Participatory Research (CBPR) |
| | Introduction to Community-Engaged Research (CEnR) | Introduction to Community-Engaged Research (CEnR) |
| | Introduction to Public Health Research | Introduction to Public Health Research |
| | Mobile Apps and Human Subjects Research | Mobile Apps and Human Subjects Research |
| | Overview of the Clinical Trial Agreement (CTA) | Research and HIPAA Privacy Protections |
| | Phase I Research: Protecting Phase I Subjects | Public Health and Public Health Practice |
| | Phase I Research: Understanding Phase I Research | |
| | Public Health and Public Health Practice | Research in Public Elementary and Secondary Schools – SBE |
| | Research Involving Subjects at the End-of-Life | Research with Children – SBE |
| | Research Involving Pregnant Women, Fetuses, and Neonates | Research with Critically Ill Subjects |
| | Research Involving Prisoners | Research with Prisoners - SBE |
| | Research with Critically Ill Subjects | Research with Decisionally Impaired Subjects |
| | Research with Decisionally Impaired Subjects | |
| | Research with Older Adults | Research with Older Adults |
| | Research with Persons who are Socially or Economically Disadvantaged | Research with Persons who are Socially or Economically Disadvantaged |
| | Research with Subjects with Physical Disabilities & Impairments | Research with Subjects with Physical Disabilities & Impairments |
| | Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA) | Single IRB (sIRB) Use and Administration: Authorization Agreements |
| | Single IRB (sIRB) Use and Administration: Authorization Agreements | |
| | Single IRB (sIRB) Use and Administration When Relying on an IRB | Single IRB (sIRB) Use and Administration When Relying on an IRB |
| | Single IRB (sIRB) Use and Administration When Serving as an IRB of Record | Single IRB (sIRB) Use and Administration When Serving as an IRB of Record |

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|---|---|---|
| | Social and Behavioral Research (SBR) for Biomedical Researchers | |
| | Stem Cell Research Oversight (Part I) | |
| | Stem Cell Research Oversight (Part II) | |
| | Students in Research | Students in Research |
| | Understanding the Terms of the Clinical Trial Agreement (CTA) | |
| | Vulnerable Subjects – Research Involving Workers/Employees | Vulnerable Subjects – Research Involving Workers/Employees |

| **Optional Modules** | Modules in this list **do not count** towards Biomedical course completion, but may be required by your advisor or be otherwise beneficial | Modules in the list below **do not count** towards Social-Behavioral course completion, but may be required by your advisor or be otherwise beneficial |
|---|---|---|
| **List D** | Are You Thinking about being in a Research Study | Are You Thinking about being in a Research Study |
| | Hot Topics | Hot Topics |
| | I Have Agreed to be an IRB Community Member: Now What | I Have Agreed to be an IRB Community Member: Now What |
| | The IRB Administrator's Responsibilities | The IRB Administrator's Responsibilities |
| | The IRB Member Module – "What Every New IRB Member Needs to Know" | The IRB Member Module – "What Every New IRB Member Needs to Know" |