**CARTI Clinical/Translational Research Training Track Didactic Coursework**

The didactic training will include synchronous (live) and asynchronous (recorded) lectures combined with presentations from CARTI scholars as they develop their research project. The major topics to be covered are listed below.

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| **Didactic Lectures** |
| Program Overview |
| Developing a clinical research question and hypothesis (including writing a project summary) |
| Scholar Presentation: research question and hypothesis |
| Study design: case reports, case series, ecologic, cross sectional |
| Study design: case control and study biases |
| Study design: cohort, population definitions |
| Study design: clinical trials |
| Scholar Presentation: project presentation focused on study design |
| Choosing study subjects, sampling, and recruitment strategies |
| Identifying study measurements and data collection methods |
| Implementing a clinical research study |
| Scholar Presentation: study subjects, sampling, recruitment, study measurements, and data collection |
| Introduction to biases and confounding |
| Principles of sample size estimation |
| Data management |
| Scholar Presentation: data collection, data management plan, and case report forms |
| Responsible conduct of research & informed consent |
| Small group discussion of case studies |
| Developing a CICERO application |
| IRB Approval |
| Scholar Presentation: criteria for IRB approval and regulatory binder |
| Effectively presenting your research |
| Critically reviewing a scientific manuscript |
| Small group discussion of scientific manuscript |
| Writing & publishing a research manuscript |
| Developing an elevator pitch |
| Funding your research & grant writing |
| Communicating your research with broad audiences |
| Writing an abstract/project summary |
| Scholar Presentation: abstract/project summary |
| Writing specific aims |
| Small group discussion of specific aims examples or drafts |
| Writing an NIH biosketch |
| Scholar Presentation: NIH biosketch |

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| **Optional Specialty Lectures** |
| Secondary data sources & analysis |
| Use of biomarker data in clinical studies |
| Bioinformatics to identify genetic variation in disease states |
| Campus resources for conducting a clinical study |
| Rigor, reproducibility, and transparency |
| Confidentiality in clinical research |
| How to use RedCap |
| Data safety monitoring plans |
| Foundations of developing IND application |
| Working with vulnerable populations |
| Study design: clinical trials First-in-Human and Phase 1 |
| Study design: clinical trials Phase 2 |
| Study design: clinical trials Phase 3 |
| Study design: Post-marketing trials |
| Regulatory: Communicating with FDA |
| Regulatory: Dealing with serious adverse events |
| Publish don’t perish |
| Post-submission of your manuscript: peer review, dealing with feedback, and responding to reviewers |
| Negotiating for research needs as a clinical investigator |