TWD COURSE CATALOG

https://twd.ce.emorynursingexperience.com/dashboard/in-progress

Managing Your Career

"No one should care more about your career than you."

Translational Workforce Development (TWD)

Free Course Catalog

https://twd.ce.emorynursingexperience.com

SC CTSI Clinical and Translational Science Institute

Georgia CTSA Clinical & Translational Science Alliance

Accessing TWD Catalog

- One-time set up
- To log in:
  - Select a course - it will direct you to create an account
- After you complete the one-time set up you will have **unlimited access to all current & future courses!**

Georgia CTSA
Georgia Clinical & Translational Science Alliance

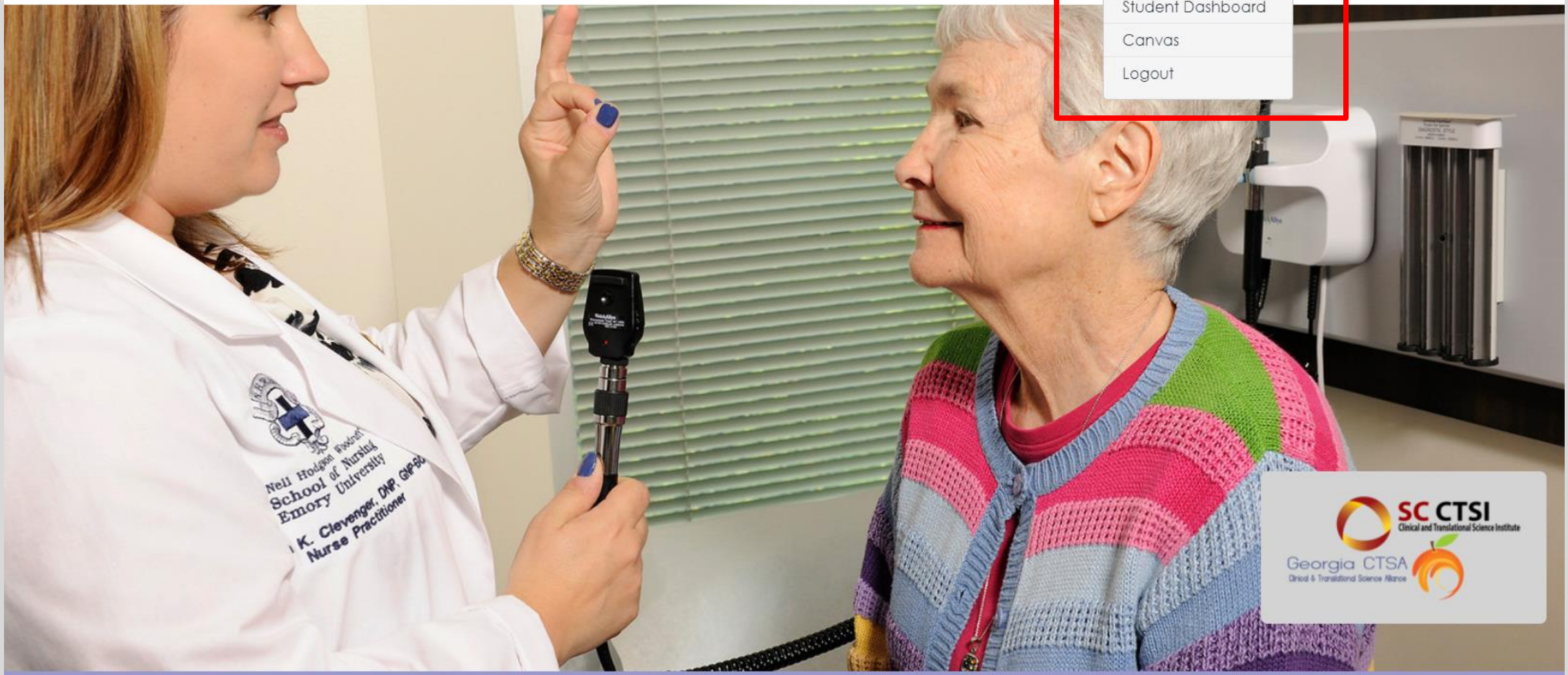
After one-time set up - log in → Login

Georgia CTSA
Georgia Clinical & Translational Science Alliance

Drop Down Features

Elaine Fisher ▲

- Admin
- Student Dashboard
- Canvas
- Logout



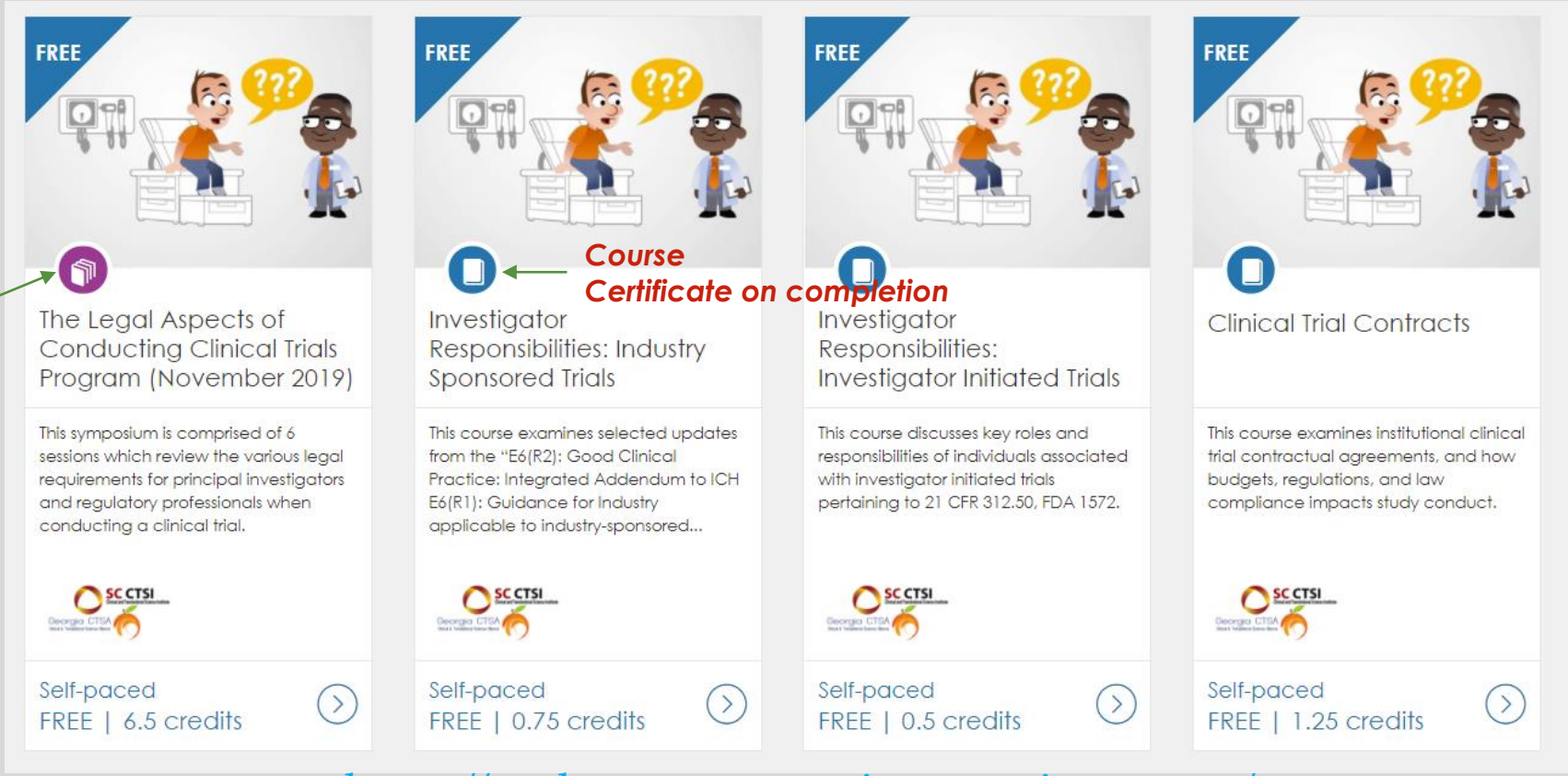
PROGRAMS & COURSES

Badges Awarded for Program Completion
Continuing Education/Contact Hours for Courses

Translational Workforce Development (TWD) Course Catalog
Over 16 programs and 55 courses*

Program - Badge on completion

Course Certificate on completion



https://twd.ce.emorynursingexperience.com/

* Watch for new courses added!

4/13/2023

OPENING A COURSE

Description:

The first course in a 6-part series, examines selected updates from the "E6(R2): Good Clinical Practice: Integrated Addendum to ICH E6(R1): Guidance for Industry applicable to industry-sponsored trials" specific to industry-sponsored trials. Updated topics from the addendum include: resources, records and reports, quality management, trial management, data handling and recordkeeping.

Topics:

1. E6(R2): Good Clinical Practice: Integrated Addendum to ICH (International Council for Harmonisation) E6(R1): Guidance for Industry (https://www.fda.gov/media/93884/download)
    - INVESTIGATOR (4)
        - Adequate Resources (4.2)
        - Records and Reports (4.9)
    - SPONSORS (5)
        - Quality Management (5.0)
        - Trial Management, Data Handling, and Record Keeping (5.5)
        - Monitoring Plan (5.18)

Speaker:

Nancy Smerkanich, DRSc, MS, is an Assistant Professor, Department of Regulatory and Quality Sciences in the School of Pharmacy at the University of Southern California (USC). Dr. Smerkanich received her faculty appointment after successfully completing her Doctoral Dissertation on "Benefits Risk Frameworks –Implementation in Industry" in 2015. In addition to teaching in courses related to drug development and clinical trials, she continues to provide regulatory guidance to industry peers. Nancy brings many years of practical regulatory knowledge and experience to academia where she participated in all regulatory aspects of product development, having served as Regulatory Liaison, US Agent, and Global Regulatory Lead across all therapeutic areas. Known for her dedication to education and mentoring across industry, Nancy continues to be recognized for her ability to provide accurate, relevant and dynamic instruction on both the technical and strategic aspects of global regulatory affairs and for her service to professional organizations such as the Drug Information Association (DIA) and The Organization for Professionals in Regulatory Affairs (TOPRA). With over 30 years of experience, Dr. Smerkanich has participated in all regulatory aspects of drug development, having served as Regulatory Liaison, US Agent, and Global Regulatory Lead across all therapeutic areas. Prior to joining Octagon, Dr. Smerkanich held various Regulatory Affairs positions within industry, including nine years at Merck and seven years as an independent consultant. Dr. Smerkanich holds a Doctorate and Master's degree in Regulatory Science from USC and Bachelor of Science Degree in Microbiology and a Bachelor of Arts in Russian from the University of Connecticut. piresmer@usc.edu

Audience:

This session is designed for Clinical Research Associates or Clinical Research Coordinators in academia, clinics, hospitals, industry, or CRO with at least 3 years of clinical research experience. Individuals should be experienced with research study coordination, IRB submission process, budgeting, research compliance, recruiting, enrolling, financial management, data collection and analysis.

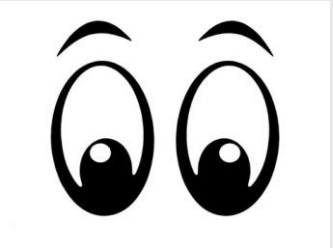
Learner Level: Intermediate

Contact Hours:

Emory Nursing Professional Development Center (ENPDC) is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Attendees to this CNE activity will be awarded 0.75 Continuing Nursing Education contact hours from ENPDC.

Need Help with Registration? Please contact us at ene@emory.edu or 404-727-9208.

Program Information: This is the first course in a six session program. To complete the entire program and earn badge Click Here.



LOOK INSIDE

- DESCRIPTION
- TOPIC
- SPEAKER WITH CONTACT INFO
- LEARNER LEVEL
- CONTACT HOURS
- HELP!
- IS THIS COURSE PART OF A PROGRAM?

VIDEO

Click to view lecture

Resources:

SLIDES

- Presentation Slides
- **Before proceeding to the quiz**, review Subparts C & D of the CFR-Code of Federal Regulations Title 21 .

RESOURCES

At the end of the presentation:

- Availability of slides
- References to additional materials

QUIZ

3 STRIKES & YOUR OUT! – DON'T MISS GETTING A CERTIFICATE ON COURSE COMPLETION

ANSWERS WITH RATIONALE

Lecture, Slides, Resources, Quiz

Click below to view the lecture in a new window. When you have finished viewing the lecture, complete the End-of-Course Quiz (button below) and the Course Evaluation to receive your CE certificate.

Click to view lecture

Resources:

- Presentation Slides
- **Before proceeding to the quiz**, review Subparts C & D of the CFR-Code of Federal Regulations Title 21 .

End-of-Course Quiz

CFR - Code of Federal Regulations Title 21

FDA Home › Medical Devices › Databases

The information on this page is current as of April 1 2020.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).

New Search

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER D - DRUGS FOR HUMAN USE

PART 312 INVESTIGATIONAL NEW DRUG APPLICATION

Subpart A - General Provisions

§ 312.1 - Scope.
§ 312.2 - Applicability.
§ 312.3 - Definitions and interpretations.
§ 312.6 - Labeling of an investigational new drug.
§ 312.7 - Promotion of investigational drugs.
§ 312.8 - Charging for investigational drugs under an IND.
§ 312.10 - Waivers.

Subpart B - Investigational New Drug Application (IND)

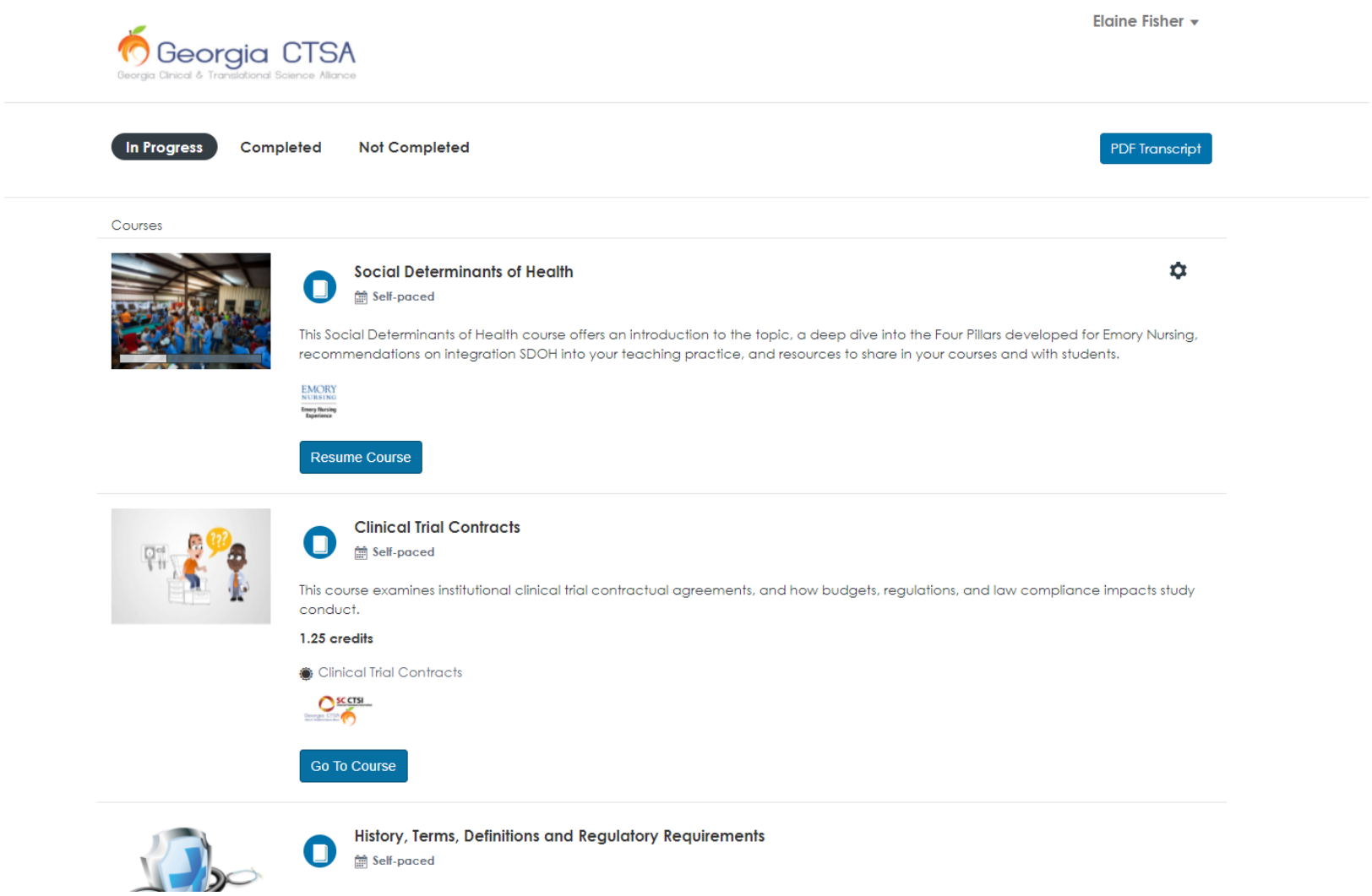
§ 312.20 - Requirement for an IND.
§ 312.21 - Phases of an investigation.
§ 312.22 - General principles of the IND submission.
§ 312.23 - IND content and format.
§ 312.30 - Protocol amendments.
§ 312.31 - Information amendments.

Quick Links to Resources

Download and save for future reference

DASHBOARD FEATURES

IN PROGRESS – COMPLETED – NOT COMPLETED



What's in my cart and what do I have **in progress**?

Courses can be added to the dashboard

Quick link back to courses

Sometimes you change your mind about taking a course….. Don't want it on your Dashboard?
Drop it!

Investigator Responsibilities: Industry Sponsored Trials

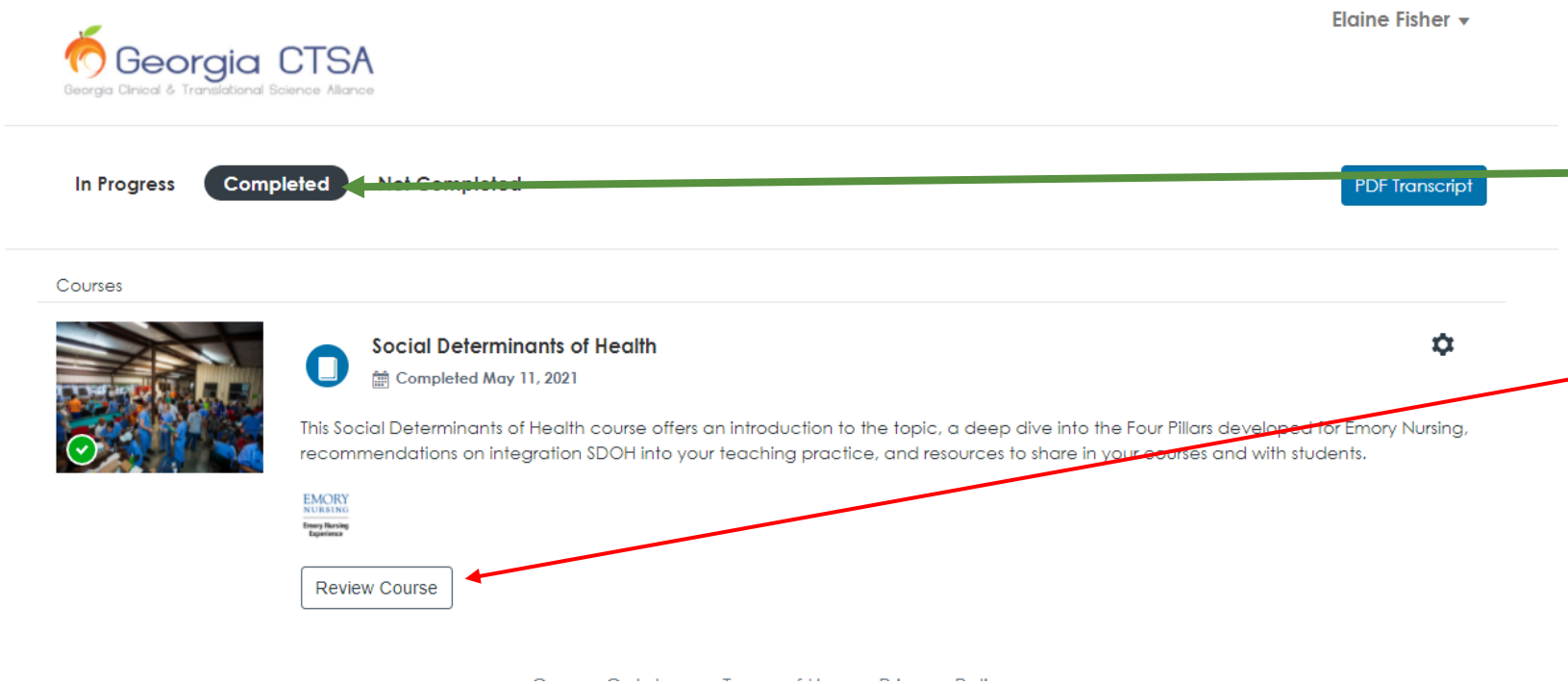
Self-paced

Drop Course

This course examines selected updates from the "E6(R2): Good Clinical Practice: Integrated Addendum to ICH E6(R1): Guidance for Industry applicable to industry-sponsored trials" specific to industry-sponsored trials.

0.75 credits

Investigators Responsibilities: Industry Sponsored Trials



Completed Courses

Courses Completed

Link back to course for review & future reference

Learner Transcript

Elaine Fisher

Enrolled	Completed	In Progress	Not Completed	Credit Earned	Credit Available
10	1	9	0	0	10.25

Completed

ENROLLED	COMPLETED	COURSE/PROGRAM	EARNED CREDITS
No Date Set	2021/05/11	Social Determinants of Health	

In Progress

ENROLLED	COURSE/PROGRAM	AVAILABLE CREDITS
No Date Set	Clinical Trial Contracts	1.25
No Date Set	History, Terms, Definitions and Regulatory Requirements	2
No Date Set	IRB Reviews on Medical Device Trials	0.75
No Date Set	Investigator Responsibilities: Industry Sponsored Trials	0.75
No Date Set	Investigator Responsibilities: Investigator Initiated Trials	0.5
No Date Set	Legal Considerations of Compassionate Use	1.5
No Date Set	Liability and Indemnification	1
No Date Set	Privacy and HIPAA: Concerns in Global Clinical Trials	1.5
No Date Set	Quality at the Data Level	1

Not Completed

No enrollments to display

Learner Transcript

Able to identify:

- Courses completed by date
- Courses in Progress
- Contact Hours earned
- Download and connect to your annual evaluation
- Attach to your resume

QUESTIONS

Please contact us at ene@emory.edu or 404-727-9208