





# PROGRAM BROCHURE

**UPDATED:** 12-01-2024

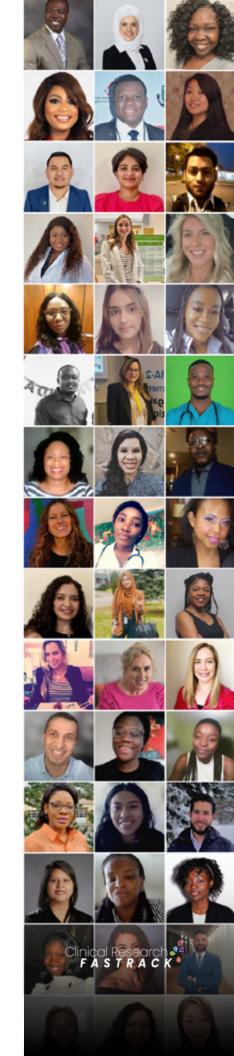
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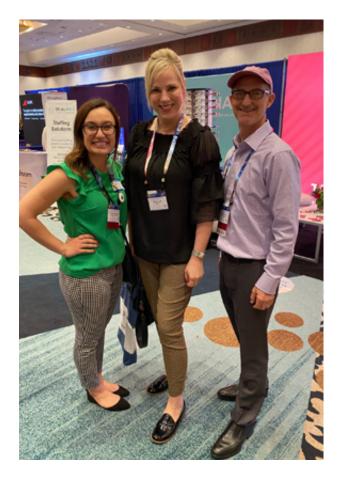
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The Clinical Research industry is dedicated to helping improve the quality of our lives and allowing us to live longer.



The race to find new cures, better medical devices, vaccines, and innovative biotechnology has created amazing new treatments in health care. The leading minds in science, business, and academia are pushing the edge of what is possible in the health sciences. To conduct this research and change our world, clinical research trials are being performed at increasing rates, and the need for trained staff to coordinate and run these studies has never been greater.

Clinical Research Fastrack (hereinafter referred to also as the "School") offers an intensive Bootcamp program to jumpstart the careers of individuals interested in entering the clinical trial industry. The program combines a comprehensive introduction to becoming a clinical research professional, followed by a two-week externship at a clinical trial provider. Our instructors are industry professionals who work for (or have worked for) the leading clinical trial providers to the pharmaceutical, medical device, and biotechnology industries.

### **Owners, Officers, and Administrators**

The School is owned by **Clinical Research Fastrack LLC of Arizona.** The officers of the School are David Silberman, MPH, CEO/Board Member, and Louis Silberman, Board Chair. Louis and David are equal partners, co-owners, and founders of the School. In addition to David and Louis Silberman who are the co-founders, officers, and administrators, Lauren Ballina Chang, MS, CCRP, Lauren Stockwell, BS, Genielle Brewer, BS, CCRC, Mone Brown, MS, Julia Martin, BSW, and Kiana Smalls, BS are our administrators and head up our graduate services department that supports the recruitment and placement of our students.

## **Faculty Members**

- Amy Raymond, PhD, PMP
- Andrew Adorboe, MS, BSN
- Angela Eyshou, MBA, BS
- Angelina Cooper, MS, CCRP
- Amber S. Roberts, MBA, CCRP
- Aryn Knight, BS, CCRP
- Catherine Gregor, MBA
- Charles Wright, BS
- Chizobam Obi, MSN, RN, CCRP
- Christina Chong, BSN, CCRC
- Elizabeth Weeks-Rowe, LVN, CCRA
- Genielle Brewer, BS, CCRC
- Gurpreet Brar, MD, MBA
- Jeannie Farnsworth, MS, BS, CCRP
- Jennifer Kocour, MPH, CCRC
- Julia Martin, BSW
- Kenyetta Sims, MA, CCRC
- Kimberly Kundert, BS, RN, CCRC

- Kristie Daly-Barnes, BS
- Lauren Ballina Chang, MS, CCRP
- Lauren Stockwell, BS
- Lisa Ince, BS, CCRC, CCRA
- Marie Clarkson Collins, MHA, CCRP
- Mary Sophy Yohannon, MBBS, CCRC
- Michelle McMahan Meek, BS
- Mitchell Hilbe, MS
- Mone Brown, MS
- Nancy Lizzul, BSc, RN
- Nichole Gallatti, M.S. Ed, CCRP
- Richie Kahn, MPH
- Sam Chimienti, BS, CCRC
- Tasia Long, MS, CCRP
- Terri Burghart, MBA
- Tiffany Drummond, MS
- William Jones, MS

## **Programs/Courses Offered**

160 HOURS

Clinical Research Fastrack Bootcamp & Externship

80 HOURS

Clinical Research Fastrack Bootcamp

80 HOURS

Fastrack Externship\*

40 HOURS

**WorkForce Training** 

1-1 COACHING

**Career Advancement** 

(\*must complete bootcamp to be eligible)

## **Bootcamp Training Program Course Outline**



## **Clinical Research Fastrack Bootcamp Training**

The Clinical Research Fastrack Bootcamp is an intensive course consisting of 80 hours of classroom instruction supplemented by 68 hours of asynchronous home study to reinforce the concepts learned in class. At the end of the course students will be prepared to jumpstart their career in the clinical trial industry. Students may also enroll in an additional course consisting of 80 hours of hands-on externship which provides real-world experience observing and participating in clinical trials at a research facility.

**Total Classroom Bootcamp Units (hours):** 80 hours Subjects (numbered), skills to be learned, units (hours):

#### 1.1 Introduction to Research Concepts (5 hours of classroom instruction)

Introduction to Research Concepts will present the history of clinical research in human subjects, research design, phases of trials, key players, industry terminology and abbreviations associated with clinical trials. The ethical conduct of clinical research in human subjects has evolved over time. The understanding of historical events which led to Good Clinical Practices and Regulations is needed to ensure subject protection. Students will learn the previous misconduct of unethical research practices. An overview of research design, phases and concepts will be introduced in this section to provide a foundation for further discussion.

**OBJECTIVE:** At the end of this section, the student will have an understanding of historical events that led to Good Clinical Practices and current regulations. The students will be able to define a list of acronyms and terminology commonly used in research.

## 1.2 ICH GCP Guidelines and Protecting the Rights of the Patient (5 hours of classroom instruction)

The most important aspect of a Clinical Research Coordinator's role is to protect the rights and safety of the patient. This section will introduce this important concept and elaborate on the rights of a clinical research patient.

**OBJECTIVE:** Students will understand the protection of subjects through the Belmont Report, the role of the IRB, HIPAA laws and how to practice confidentiality through the de-identification of patient information.

#### 1.3 FDA Regulations (5 hours of classroom instruction)

This course will deliver key insights on how to follow and understand Title 21 of the Code of Federal Regulations under the FDA as it applies to Clinical Research Conduct. These regulations emphasize protecting the rights and safety of the patient and the ethical conduct of clinical research. The overview will cover the most relevant aspects of Title 21, including 21 CFR 56, 21 CFR 54, 21 CFR 50 and 21 CFR 11.

**OBJECTIVE:** At the end of this section, the student will be able to recall ICH/GCP Guidelines and FDA regulations which are required for knowledge in the conduct of human research.

#### 1.4 Regulatory Affairs (5 hours of classroom instruction)

Regulatory Affairs will provide information on essential regulatory documents and reporting requirements. Knowledge of regulatory documents is required for the initiation, ongoing maintenance and the conclusion of a clinical research trial.

**OBJECTIVE:** At the end of this section students will be able to complete regulatory documents and have a grasp of how essential items are retained and managed in a regulatory binder through a trial.

## 1.5 Dissection of a Protocol & Clinical Trial Budgeting (10 hours of classroom instruction)

Understanding the components of a research protocol and putting a protocol into practice is essential for the success of a clinical trial. Students will be provided with a sample protocol and discuss the elements of the study. Students will be able to locate endpoints, inclusionary and exclusionary criteria, visit procedures, reporting requirements, and other components of a protocol. Students will also learn the components of a site budget.

**OBJECTIVE:** By the end of this section, students will be able to answer questions on the conduct of the study through referencing the sample protocol.

#### 1.6 Good Documentation Practices (5 hours of classroom instruction)

Good Documentation Practice is a key element in clinical trial research. Documentation is the evidence that data was collected contemporaneously and accurately. Clinical Research Coordinators are typically involved in informed consent procedures, visit conduct, data collection, and are responsible for the accountability of investigational product.

**OBJECTIVE:** Students will complete this section of the course with an understanding of ALCOA-C and how to document within the standards of good clinical practice guidance.

#### 1.7 Data Management Systems (5 hours of classroom instruction)

Data Management Systems/Electronic Case Report Forms (eCRFs) are used to centralize data collected at protocol-defined visits. Source documents contain the original information whereby data points are transcribed into various electronic data management programs.

**OBJECTIVE:** At the end of this section, students will understand the importance of and the process of data entry in a clinical trial.

#### 1.8 Adverse Events and Protocol Deviations (5 hours of classroom instruction)

Adverse Events and Protocol Deviations require specific documentation and reporting procedures

**OBJECTIVE:** Students will understand how to properly identify and document adverse events and deviations within source documents, within eCRFs, to Sponsors, and when necessary, to IRBs

## 1.9 Recruitment and Retention of Clinical Research Subjects (5 hours of classroom instruction)

Enrolling qualified and reliable subjects into a research study will provide the data that a Sponsor needs to determine if their product is safe and efficacious. The tension between the business side of research that requires adequate enrollment and ethical considerations are discussed.

**OBJECTIVE:** This course will provide the student with skills to apply communication techniques and comply with regulations involved in ethically recruiting and speaking to potential research participants.

#### 1.10 Investigator Responsibilities (2 hours of classroom instruction)

Investigator Responsibilities is a section of the course that will deliver more in-depth information on the roles of the Principal Investigator and Sub-Investigators in a clinical trial. Content will include investigator assessment of safety of research subjects, managing treatment within a protocol and follow-up outside of research care with the subject's primary care physician, training of site staff delegated to conduct specific duties, and the limitations of a Clinical Research Coordinator.

**OBJECTIVE:** Students will gain an understanding of how to coordinate necessary time with a PI to discuss important updates within a trial and be able to outline the scope and limitations of a Coordinator's role with respect to the PI.

#### 1.11 Monitoring, Quality Assurance and Inspections (3 hours of classroom)

Oversight in Clinical Research stems from the history of unethical practices. Monitoring, Quality Assurance programs and Inspections are held to ensure that source data is accurate and the conduct of the trial is honest and reliable. Students will have an opportunity to review monitor letters, FDA 483s, warning letters, and to discuss how to best address discrepancies in data.

**OBJECTIVE:** By the end of this section, students will learn how to ensure that data is accurate and the trial is honest and reliable. The student will be able to describe and draft a corrective and preventative action plan related to a deviation within a research study

#### 1.12 Clinical Trial Operations (5 hours of classroom instruction)

Clinical Trial Operations will provide the student with a fundamental understanding of the operational aspects of a clinical trial from beginning to end. Students will become familiar with the feasibility process, preparing for and hosting pre-study selection visits from Sponsor representatives, investigator meetings, site initiation visits, monitoring visit expectations and final study close-out visits.

**OBJECTIVE:** Students will be able to describe the path from study award through the conduct of a trial until the IRB has closed out the study at the investigative site detailing the key phases of this process.

#### 1.13 The Informed Consent Process (5 hours of classroom instruction)

The informed consent process is arguably the most important component of clinical research practice. To properly consent, the Coordinator and Investigator must understand the elements of an informed consent, how to discuss the study, how to execute a consent properly, how to correct errors should they occur and to document the process as it occurs. Students will perform a mock consent and be able to answer questions about the study. Students will also be able to identify errors in the consent forms and facilitate or perform corrections to the document(s).

**OBJECTIVE:** By the end of this session students will be able to administer consent with a human subject.

## 1.14 Research Skills and Research Communications Training (5 hours of classroom instruction)

Research skills training will provide the student with basic knowledge of how to perform common procedures: height, weight, temperatures, blood pressures, ECGs, introduction on the process of phlebotomy and processing lab specimens.

**OBJECTIVE:** Students will be able to describe the purpose of each procedure and communicate clearly, confidently and affirmatively their understanding of clinical research practices.

#### 1.15 Tying it all Together (5 hours of classroom instruction)

After eight days of intensive training in the classroom, a participant in this program should now have the educational and historical framework to demonstrate their knowledge of how and why regulations in this industry have been developed and the critical importance of practicing GCP.

**OBJECTIVE:** At the end of this section, students will have taught one subject area from the syllabus to the rest of the class.

## 1.16 Clinical Research Communication and Career Opportunities (5 hours of classroom instruction)

The students will learn about additional positions beyond just the roles of RA, CRC, and CRA which include regulatory coordinators, data managers, enrollment specialists, and other positions that the student is now qualified to apply for with this training.

**OBJECTIVE:** At the end of this section, the student will be able to list a series of entry points into this field and will be prepared to apply for positions in the industry.

#### 1.17 Clinical Research Fastrack Individualized Career Coaching

Clinical Research Fastrack career coaches will provide guided tutoring sessions to review resumes, help students prepare for interviews, and teach networking skills. This professionalism coaching empowers graduates to rise above the competition when interviewing for jobs in the Clinical Research field, and secure useful industry connections. Our career coaching is one of the key differences between Clinical Research Fastrack and other learning programs. Our coaches work with students on an individual basis to help them strengthen their professional skills and excel in their new career.

**OBJECTIVE:** To understand a clear, proven, process designed to quickly move into job interviews.

#### 1.18 One-on-One Mentorship and Career Coaching

Clinical Research Fastrack pairs every trainee with a career mentor for additional coaching and support outside of the classroom. Mentorship and coaching consists of one-on-one interactions via email, phone and/or video conferencing. Career support specialists assist students with resume tailoring, preparing cover letters, and practicing for interviews. This preparation and support in the career search process empowers Clinical Research Fastrack students to find positions quickly and negotiate for the best offers.

**OBJECTIVE:** To become the best candidate possible in order to enter and advance quickly in a Clinical Research career.

## Clinical Research Fastrack Externship

The Clinical Research Fastrack Externship immerses the student in a real world clinical trial environment at clinical research facilities where they learn vital skills in an actual clinical setting. The concepts and skills learned in the initial bootcamp are applied and reinforced. Upon completion of the externship, the student will have practical first-hand experience to apply to a role as a clinical researcher in a clinical or academic setting. The subject matter of the externship, listed below, provides a comprehensive overview of skills required and protocols to follow during a research study.

The Clinical Research Fastrack Externship provides hands-on experience to our students at a clinical research site inside a clinical research facility working on clinical trials. Training while working in a clinical setting observing actual studies allows the student to gain valuable experience and apply the knowledge they have learned in a real-world setting. The school will arrange directly with the externship site and maintain supervision and control over all student activities at the site.

#### TOTAL EXTERNSHIP UNITS (HOURS) | 80 HOURS

Students complete their externship in a minimum of 60 hours up to 80 hours.



#### Externship Subjects (numbered), skills to be learned, units (hours):

Instructional topics are presented in varying order depending on the flow of the trials taking place at the externship site and the time allotted for the externship.

#### 2.1 Introduction to Clinical Visit Flow

Students will shadow clinical visits throughout the day over various studies. Shadowing experience may include, but is not limited to, exposure to informed consent process, observing visit procedures, charting, and data entry.

#### 2.2 Recruitment

Students will be provided with protocols and observe the recruitment process.

#### 2.3 Clinical Skills Training

Students will train with site staff and practice competency on blood pressures and vital signs.

#### 2.4 Medical Terminology

Students will be provided with medical records and observe medical histories being taken.

#### 2.5 Laboratory Skills

Students will observe lab procedures, learn how a centrifuge works, observe sample processing and shipping lab samples.

#### 2.6 Administrative Assistance in Clinical Trial Coordinating

Students will review charts, letters, and other important study documents utilized by clinical research staff and gain an understanding of the filing and documentation systems.

#### 2.7 Quality Assurance

Students will be given actual subject charts to review. Students will read monitor letters and observe how visits are prepped for review. Students will observe an informed consent review on an entire trial.

#### 2.8 Clinical Trials Overview and Data management systems

Students will meet department heads in Business Development, Budgets and Contracts, Accounting, IT, Recruitment, Source Document Development, and Regulatory. Students will also view data management systems and learn to enter data and answer queries.

#### 2.9 Mock visits

As time permits, students will perform mock visits screening, interim and final visits to show competency in all areas of a clinic visit.

#### **Externship Objective:**

Upon completion of the externship the student will be able to assist in running a clinical trial and be prepared to work in the industry as a clinical research professional.

## **Admission Requirements**

The school does not discriminate based on race, color, sexual orientation, gender, religion, ethnic origin, or disability. Our student body includes professionals coming from a wide range of educational and career backgrounds from Associates Degrees to PhDs to International Medical Graduates and Nurses. All applicants should be detail oriented and personable in order to succeed in this industry. Applicants to our program must be at least 21 years of age and have completed at least two years of college credit or have an LVN or Medical Assistant diploma. The applicant must also complete a written application and participate in an admissions interview. This is the minimum requirement. Additional education and experience is desirable, but not required.

#### **Externship Screening and Eligibility Requirements**

The externship placement is at a clinical research site in a physician's practice that is performing clinical trials. The externship site is selected by Clinical Research Fastrack for the student at an affiliated clinical research facility. The student is "hosted" by the research site and is treated as a visiting fellow for the term of this segment of the bootcamp training. The student must have attended their in-classroom training hours and completed their exams with a passing grade of 75% to be eligible to begin their externship. While the primary goal of the externship is training and education, the student is screened as an employee, required to sign HIPAA confidentiality agreements, and allowed to review records that clinical research staff has access to. The student must conduct themselves professionally at all times and act according to the standards of conduct and work rules that all the employees of the host facility adhere to.

Like most medical facilities, the research centers embedded in clinical research facilities that are hosting the externships require background checks and drug screenings of all employees and interns at their facility. Students who test positive for illicit drugs, have a felony on their record, or have any conviction on their record related to drugs, violence or theft will be prohibited from participating in the externship. All background checks are performed in compliance with all federal and state statutes. The information obtained from the screening and background check process will only be used as part of the onboarding process of the externship and will be kept strictly confidential. Any potential student with any of the aforementioned excluding infractions may be withdrawn from the program.

## **PROGRAMS/COURSE COSTS**

	Tuition	Registration	Study Materials	Total Tuition/ Fees
Career Advancement	\$1,000			\$1,000
WorkForce	\$2,500			\$2,500
Fastrack Externship Only* (*must have completed Bootcamp)	\$2,900	\$100	\$50	\$3,000
Clinical Research Fastrack Bootcamp	\$9,800	\$100	\$50	\$9,950
Clinical Research Fastrack Bootcamp and Externship	\$12,800	\$100	\$50	\$12,950

#### PROGRAM/COURSE INFORMATION

#### **Equipment, Study Guides, Textbooks, and Technology Requirements**

All students are expected to have basic proficiencies in the use of computers and common software applications such as Microsoft Office, email applications, and other similar applications. Students must have access to a smartphone, tablet, or computer to complete the online homework portion of the course.

Study guides are provided to all students. Textbooks are available to students in our reference library. Textbooks may be purchased for an additional charge. The following textbooks will be referenced in class:

- Sather, S., Woodin, K.E. (2019). The CRCs Guide to Coordinating Clinical Research, Fourth Edition. ISBN-13: 978-1604301007
- Ballina-Chang, L.; Cundiff, J.; Silberman, D. (2019) The Clinical Research Fastrack Student Guide
- Various journal articles, magazines, and newspaper articles are provided to the students.
- Monthly Prescribing Reference
- Online additional training resource: CITI GCP, Basic Course

#### **Employment Opportunities and Graduate Services**

Clinical Research Fastrack prepares our students to jump into the growing field of clinical research. Pharmaceutical, Contract Research Organizations, Medical Device Companies, Biotechnology and Academic Institutions as well as Clinical Research Sites and Site Networks are actively hiring qualified clinical research professionals to assist with their trials. The size of the marketplace is very large in the United States and globally. Career opportunities abound for trained Clinical Research Professionals and our training will set our students on this career path.

Our graduate support services are designed to help our students not only in entering externships with the lead clinical trial providers in the country, but more importantly we help our graduates secure jobs upon graduation. While assisting in a student's job search, we make no guarantee, expressed or implied, of future employment.

#### **Requirements for Graduates to Practice**

There is no minimum requirement for a person to work as a Clinical Research Assistant, Clinical Research Coordinator or a Clinical Research Associate. Federal law requires that all personnel working on a clinical trial are qualified to do so and the sponsor of each trial documents those qualifications. Clinical researchers must be delegated the authority to work on trials by their principal investigator. This delegation happens very quickly for Clinical Research Fastrack graduates.. The training they receive qualifies them to start working right away on the clinical trials.

#### **Enrollment**

Prospective students are expected to enroll three weeks prior to an upcoming training course. Due to the intensive, condensed nature of this program, late enrollments will be accepted only if deemed appropriate by a school official and no more than one day into the course. Classes will be held throughout the year and a late enrollee may attend a future course.

#### **Educational Delivery Systems**

Clinical Research Fastrack begins with classroom education which includes lecture, PowerPoint presentations, question and answers, reading, quizzes, small group projects, short videos and activities. Our classroom may be held on video conferencing platforms or in-person. The homework portion of the course, to be completed online, includes videos, slides, reading material, quizzes, research, and other interactive activities.

Our mentorship and coaching consists of one on one meetings on the phone and/or video conferencing with our career coaching staff and each student. This portion of the program involves updating resumes, preparing cover letters, and practicing for interviews.

After the classroom homework portion of the course is completed, those students who sign up and are eligible for externships have the opportunity to go to a research site for hands-on learning in a clinical setting. This portion of the course includes lecture, role plays, clinical work, and mock trials combined with work on actual subjects participating in active clinical trials.

#### **Payment Schedules**

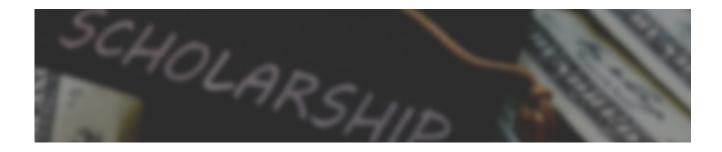
Clinical Research Fastrack has arranged for institutional financing plans for eligible students. Qualified students may, on their own or with the assistance of a co-signer, apply for payment plans to pay their tuition with an initial down payment and monthly payments over a period of one to five years.

Please contact the Clinical Research Fastrack Admissions Department for more information regarding financing and payment options.

#### **Tuition Scholarships Available**

Clinical Research Fastrack awards partial scholarships every year to enrich the economic diversity of our classroom demographics. The deadline for applying for a scholarship is three weeks prior to the first day of class for the session. Applications and additional scholarship information can be requested from the Clinical Research Fastrack Admissions Department. Completed applications may be turned in to the admissions office by website submission or by email.

Clinical Research Fastrack is committed to offering scholarships to low-income students, with earnings less than 50% of the mean income in their area and demonstrates academic and career promise. Scholarship applications are reviewed based on economic need. Clinical Research Fastrack believes that this policy will enhance the learning community



### **Cancellation and Refund Policy**

An applicant denied admission by the school is entitled to a refund of all monies paid.

#### Three-Day Cancellation:

An applicant who provides written notice of cancellation within three working business days (excluding Saturday, Sunday and federal and state holidays) of signing an enrollment agreement is entitled to a refund of all monies paid. The school shall provide the refund no later than 30 days of receiving the notice of cancellation.

#### Other Cancellations:

An applicant requesting cancellation more than three days after signing an enrollment agreement and making an initial payment, but prior to seven days of their in-class training, is entitled to a refund of all monies paid.

#### **Procedure for Withdrawal/Withdrawal Date:**

Refund after the commencement of classes:

- A student choosing to withdraw from the school after the commencement of classes is to provide written notice to the Director of the school. The notice is to indicate the expected last date of attendance and be signed and dated by the student.
- For a student who is on authorized Leave of Absence, the withdrawal date is the date the student was scheduled to return from the Leave and failed to do so.
- A student will be determined to be withdrawn from the institution if the student has not attended any class for 3 consecutive class days.
- All refunds will be issued within 30 days of the determination of the withdrawal date.

#### **Tuition Charges/Refunds:**

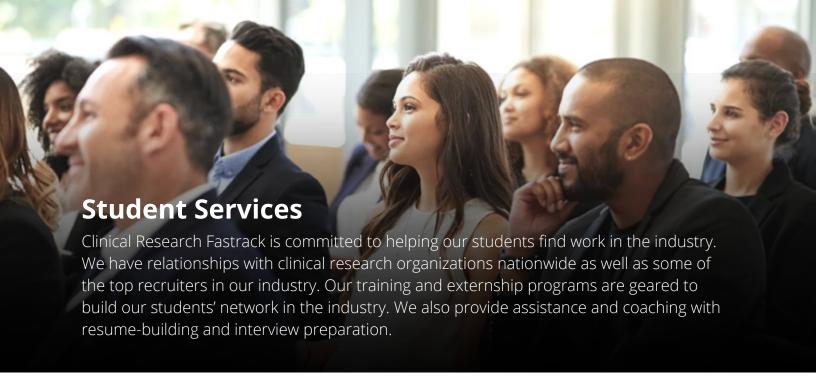
Refund after the commencement of classes:

- Before the beginning of classes, the student is entitled to a refund of 100% of the tuition.
- After the commencement of classes, the tuition refund amount shall be determined as follows:

% of the clock hours attempted (elapsed):	Tuition refund amount:
10% or less	90%
More than 10% and less than or equal to 20%	80%
More than 20% and less than or equal to 30%	70%
More than 30% and less than or equal to 40%	60%
More than 40% and less than or equal to 50%	50%
More than 50%	No Refund is required

The percentage of the clock hours attempted is determined by dividing the total number of clock hours elapsed from the student's start date to the student's last day of attendance, by the total number of clock hours in the program.

Refunds will be issued within 30 days of the date of student notification, or date of school determination (withdrawn due to absences or other criteria as specified in the school catalog), or in the case of a student not returning from an authorized Leave of Absence (LOA), within 30 days of the date the student was scheduled to return from the LOA and did not return.



### **Academic Policies:**

#### **Attendance Requirements**

Students are expected to arrive on time for class. If a student is 30 minutes late or more to a session, without prior written communication with a course Director, this will result in an official absence being recorded for that session. The course is divided into morning and afternoon sessions. If a student accumulates a total of 3 absences, they will be subject to termination from the remainder of the program.

Attendance is defined as being on camera and able to participate and engage in discussion. Driving a car, trying to be in class in a busy room or other distracting environment or being off camera does not qualify as "in attendance".

#### **Homework Pre & Post Study Requirement**

The homework component of the course reinforces and solidifies the learning that has taken place in the classroom. Completing the homework is mandatory and a student will not receive a final grade or diploma without finishing this portion of the course. We expect that a student completes this work within five (5) weeks from the first day of the class. If the course is not completed in five (5) weeks, the student will be given a grade of "incomplete". Students who have not completed the course within ten (10) weeks will be withdrawn from the program with a grade of W. Students with a grade of W will be required to re-enroll in the program and pay a fee of \$200, as long as they are within five (5) months of the commencement of the course. After five (5) months a student with a grade of W would have to retake the entire course and pay the tuition over again if they wish to complete the program.

#### **Postponement of Start Date**

Postponement of a starting date, whether at the request of the school or the student, requires a written agreement signed by the student and the school. The agreement must set forth:

- A. Whether the postponement is for the convenience of the school or the student, and;
- B. A deadline for the new start date, beyond which the start date will not be postponed.

If the course is not commenced, or the student fails to attend by the new start date set forth in the agreement, the student will be entitled to an appropriate refund of prepaid tuition and fees within 30 days of the deadline of the new start date set forth in the agreement, determined in accordance with the school's refund policy.

#### **Satisfactory Academic Progress**

Academic Progress is evaluated five times over the course of the program. Students must maintain a 75% grade or higher to be in good standing. Students must complete a minimum of 75% of their required homework assignments in addition to the attendance and exam requirements. Those who do not, will be placed on probation for one week. During the probation period students must raise their grade average to 75% or higher. The student will be terminated if they do not meet an average grade of at least 75% at the end of the probationary period.

Academic progress is evaluated as follows:

- after the midterm exam on the fourth day of class,
- after the second midterm exam on the final day in the classroom,
- after the first completed week of externship, (where applicable)
- after the second completed week of externship, (where applicable)
- and the final evaluation takes place after five weeks to assess that the final homework assignment has been completed.

To complete the program and receive a final grade a student must have completed at least 75% of their homework assignments with a passing grade of 75% or higher on both the midterm and the final.

If a student has not successfully achieved a passing score on their coursework within 10 weeks of completing the synchronous program they are subject to termination from the program with a failing grade.

Grading System	
90 - 100 = A	Excellent
80 - 89 = B	Above Average
75 – 79 = C	Average
Under 74 = U	Unsatisfactory
Grade W = W	Withdrawal

#### **Grade Reporting and Transcripts**

Students are notified upon completing the course if they pass or fail. Training diplomas are provided to each student upon completing the course and downloadable from the learning management system. Hard copies of the final diploma may be requested to be mailed to the student for a \$25 administrative fee.

Student transcripts are available to all students that request them. To request transcripts, the student must provide a written request along with a \$25 administrative fee and the transcripts will be mailed to them.

#### **Graduation Requirements**

In order to graduate from the Clinical Research Fastrack course, students must be in good standing (please see our probation policies for details on good standing status), meet or exceed their attendance requirements of the class, complete a minimum of 75% of their homework assignments (pre-study and post-study) with a passing grade, and pass each exam and all coursework with a grade of 75% or higher.

#### **Conduct Policy**

All students are expected to act maturely, professionally and are required to respect other students and faculty members. Possession of weapons, illegal drugs, and alcohol of any kind are not allowed at any time on school property. Use of profane language, or inappropriate behavior towards other students, staff or individuals related to Clinical Research Fastrack is not tolerated. Any proven violation of school conduct policies will result in permanent dismissal from school.

All Clinical Research Fastrack students are also expected to conduct themselves professionally while participating in their externship when applicable. We expect the following positive behavior from all students:

- Honesty and integrity in everything we do. All data and communication must be accurately and honestly portrayed.
- Accountability each of us is accountable for our actions.
- Teamwork All students are part of the same team. Work together with your team members and/or co-works towards the common goal to positively change the nature of clinical studies.
- A professional, calm, even-toned communication style and use of business appropriate language. Swearing, cussing and/or yelling is unacceptable.
- Respect for other students, teachers, co-workers, subordinates, managers, participants, investigators, clinic staff and sponsors, as shown in all communication and behavior.
- Appropriate problem resolution.
- Confidentiality of participant data and confidential information.

Our program adheres to the Code of Ethics developed by the Association of Clinical Research Professionals (ACRP) and commonly adopted by our industry. Unprofessional and unethical behavior is unacceptable and will be addressed by management. Any proven violation of school conduct policies will result in disciplinary measures and may lead to permanent dismissal from school and/or externship.

If a situation arises where it is difficult to determine the proper course of action or if you have any questions or concerns surrounding the Codes of Conduct, please contact your externship supervisor or a school official.

#### **Communication Policy**

Clinical Research Fastrack trains our students to be successful professionals in the clinical research industry. Successful professionals practice timely, responsive communication. We expect our students to adhere to a high standard of responsiveness during their studies and while pursuing employment in the field. The communication practices we follow are commonly followed expectations of the industry. Specifically, we expect response to our executives and team members regarding their potential employment and studies as follows:

- Email is the standard, professional and preferred means of communication
- Emails are responded to within 48 hours but ideally within 24 hours.
- Text messages are responded to within 24 hours but ideally within 3 hours
- Phone messages and calls should be followed up with an email.
- Communication in clinical research and as part of our program must be documented in a file or recorded by email or text.

## **Warnings and Probation**

**Attendance:** When a student has an unexcused absence for a total of 10 class hours of the course s/he will be emailed an attendance warning. The warning will remind the student that an additional absence or tardy will result in termination from the program. **Academic:** A student who fails an exam will be issued an academic warning stating that they must retake the exam and meet the graduation requirements to pass the course. Exams are returned to the student for 24 hours to review.

**Conduct:** A student who is warned about their behavior in class will go on immediate probation. An email will be sent to them documenting their probation. They will not be eligible to continue in class or enter an externship if they do not remedy the conduct violation.

#### **Student Reinstatement**

A student wishing to withdraw is requested to have an exit interview with a School Director where s/he will file a withdrawal form that will be put in his/her student file. A student who has been withdrawn from the institution, must wait 180 days before re-enrolling again and pay a re-entry fee of \$200.

#### **Probation**

A student on conduct probation will be suspended immediately from class and/or externship and will not be eligible to begin or complete their schooling and/or externship until the probation has been lifted. A student on academic probation will not be eligible to begin or complete their externship or receive career assistance until the probation has been lifted. A student will be put on probation for either academic reasons, behavioral misconduct or financial probation for failure to remain current on tuition payments due. A student will be put on academic probation if they fail a midterm or final or fail to complete 75% of their assigned homework. A student will be put on general probation for misconduct or failure to pay tuition. Probation will remain in effect until the student has returned to good academic standing per the Satisfactory Academic Progress Policy, or has remedied the misconduct to the satisfaction of the School Director and the tuition account balance is current. Exam retakes are administered on scheduled make-up exam dates. An assigned school Director will work with the student in order to share the available exam dates each month and coordinate the retake of these exams.

If a student is placed on probation because of behavioral misconduct, the student will not be allowed to begin or complete their schooling or externship until proven actions that resulted in probation will not happen again. If a student commits an action considered behavioral misconduct a second time, the student will be dismissed from the school immediately pursuant to dismissal procedures set forth below.

Any student placed on probation for any reason will not be given career support until probation is lifted.

#### **Dismissal**

Any student may be dismissed for violations of rules and regulations of the school, as set forth in school publications. A student also may be withdrawn from classes if he or she does not conduct him/herself appropriately, prepare sufficiently, neglects assignments, or makes unsatisfactory progress in the classroom or externship. The Director, after consultation with all parties involved in these violations, makes the final decision.

Any student who fails to satisfactorily complete the homework post-study component of the program within 10 weeks of commencing the course will be withdrawn from the course. Re-admittance will be at the discretion of the Director and a re-registration fee of \$200 will be charged to the student prior to re-admittance.

A school official may temporarily or permanently suspend students whose conduct is disruptive or unacceptable to the academic setting. After appropriate counseling, students who demonstrate a genuine desire to learn and conform to school standards of conduct may be allowed to resume attendance. The Director will review each case and decide upon re-admittance.

#### Leave of Absence

A leave of absence is strongly discouraged. Due to the short nature of the course, a student who wishes a leave of absence for more than two days of the classroom portion of the course will be required to withdraw from the program and re-enroll in a future session. The student will only be able to re-enroll in a future session based on the availability of space.

Students who are unable to continue classes for medical reasons or severe personal problems will be required to take a leave of absence and re-enroll in a future program.

#### Withdrawal

A student must provide written notice to the administration to withdraw from the program. Please see our refund policy for details regarding withdrawal and refunds.

#### **Transferring Credits**

Clinical Research Fastrack does not guarantee transferability of our credits to another institution unless there is a written agreement with another institution.

#### **Student Records**

All student academic and financial records are maintained and filed in a secure and safe manner in perpetuity. Students are allowed to view their records, but the records must not leave the school. Students may request their official transcripts via email or by letter to our administrative offices. Should the institution cease operation, whether voluntarily or involuntarily, all educational records or legible true copies shall be filed with the Arizona State Board for Private Postsecondary Education within 15 days of ceasing educational operations.

#### **Transferring Credits**

Program or Course Cancellation Policy

In the unlikely event that a course is cancelled, it will be rescheduled for a later date. If the student is not able to attend, their tuition for that course will be refunded.





#### **Step 1: Instructor or Staff Member**

The student is recommended to directly communicate with the instructor or staff member involved in the grievance within 14 days (it is encouraged to address the problem right away, within a day or two). Most grievances can be resolved informally and this is always the recommended first step.

#### **Step 2: School Administrator**

In cases where the problem is not resolved through direct communication with the instructor or staff person involved, the student will submit the grievance in writing with supporting evidence, to the office of the school administrator within 14 calendar days of the communication with the faculty or staff member. The school administrator or designee will review the grievance.

Within 14 calendar days of receiving the written complaint, the school administrator or their designee will objectively investigate the grievance, consult and share appropriate information with all involved parties, consider relevant evidence, and render a decision in writing to the student and the administrative office.

#### Step 3: Appeal to President's Office

The student may appeal the decision in Step 2 if proper procedures were not followed or there is relevant evidence that was not available during Step 2. An appeal must be made within 14 calendar days of the decision from the administrator and made to the office of the President. The student must submit written justification for further review and provide evidence that there are grounds for the appeal. The President or a designated member of Clinical Research Fastrack will investigate how the grievance process was conducted in Step 2, consult with all involved parties, consider relevant evidence that was not available or not considered during Step 2, and render a decision in writing. The decision will be final and any further appeals shall be made to the Arizona State Board for Private Postsecondary Education as described in the section below detailing the students right to appeal.

#### Reporting, Recording, and Maintaining Records

When the grievance is concluded, all documentation shall be forwarded to the school administrator, who will maintain them in accordance with the state archival policies.

Students Right to Appeal to Arizona State Board for Private Postsecondary Education

"If the complaint cannot be resolved after exhausting the institution's grievance procedure, the student may file a complaint with the Arizona State Board for Private Postsecondary Education. The student must contact the State Board for further details. The State Board address is 1740 W. Adams St., Suite 3008, Phoenix, AZ 85007, phone # 602-542-5709, website address: <a href="https://ppse.az.gov">https://ppse.az.gov</a>

Grievance Procedure Published in Following Locations:

- Student Catalog
- Clinical Research Fastrack Website

#### **Class Schedule**

Class begins at 7:45 am each day. Classes not held in-person will be on a video conferencing platform and adjusted to a specific United States time zone. Students are notified of the exact time zone of each course well in advance of enrolling. Classes are held over the course of the year and are completed within 70 days. The online pre-study will be delivered one week in advance of the first day of synchronous classroom training. Externships are scheduled for each student individually. The precise dates of the externship following the classroom portion of the course are provided to the student once they have enrolled in the course. Please contact our admissions department regarding exact dates and times of upcoming courses.

When an unexpected closure occurs due to extraordinary conditions such as inclement weather, students will be notified as soon as possible by phone. Classes are not held on the following holidays:

- 1. New Year's Eve
- 2. New Year's Day
- 3. Memorial Day
- 4. Independence Day

- 5. Labor Day
- 6. Thanksgiving Day & the Friday following
- 7. Christmas Eve
- 8. Christmas Day

#### **Facilities**

The school is located at 16601 N 90th St, Suite 100, Scottsdale, AZ 85260. Our classrooms are furnished with modern equipment. Our facility has a lounge area for breaks and all the amenities needed for classroom education.

Our externship locations are provided in partnership with leading clinical trial providers and are set in clinical research facilities and have all the required staff, equipment and supplies to train our students and perform the studies. Our current clinical trial sites are located around the country with multiple locations in the Greater Phoenix area.

#### **Acknowledgments**

Catalogs are available to students and prospective students. Within 10 days from the date of a catalog revision, the revised catalog shall be submitted to the State Board.

The 2025 catalog shall be available to all students and prospective students in either written or electronic format.





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