

CERTIFICATION AND TRAINING REQUIREMENTS

All off-site employees must comply with the following and provide to the Human Resources Department, within the time required, all documents in section # 1, 2, 3 and 4.

1. On initial date of employment:
 - a. Proof of license or certification and drug test are due on or before date of employment before reporting to off-site

2. Within ten days of hire:
 - a. Must have Computer Security Access and email address on-site.
 - b. Immunizations screening titer status:
 - c. TB/PPD test (date, result)
 - d. Hepatitis B vaccine
 - e. Hepatitis B vaccine titers
 - f. Rubella and Varicella titers
 - g. Gain access to TRUE's website
 - h. Must comply with all site requirements

3. Within 30 days of hire:
 - a. Proof of off-site Orientation
 - b. Proof of Universal Precaution Training
 - c. Verification of Infection Control training
 - d. Verification of Fire, safety, HAZCOM training
 - e. Proof of CPR/BCLS training
 - f. Verification of full or interim security clearance

4. Annual Recurring Training
 - a. Within ten (10) days of the Birth Month Annual Review (BMAR), after the initial training, an annual recurring training on the employee's birth month is required. Documentation of the training must be submitted to the Human Resource Department within 7 days of completion.

TRUE shall maintain all original employee records to include training and shot records. Employee's file shall contain only information as needed to conduct business or as required by federal, state, or local law. Access to personnel files shall be controlled by the Human Resources Department or Chief Executive Officer and limited to Supervisors with a need-to-know. Copies of the training and shot records will be provided to off-site designates only by written request with approval given by the Human Resources Department as to where the files will be maintained. Personnel files on any employee will not be retained in the department where the employee has been assigned.

CERTIFIED CLINICAL RESEARCH COORDINATOR (CCRC) CERTIFICATION OF REGISTERED NURSES, LVNS, LPNS AND CLINICAL RESEARCH COORDINATORS:

It is a requirement, that Registered Nurses (RN's), LVN's, LPN's and Clinical Research Coordinators, who work directly on a research study, take and pass the Certified Clinical Research Coordinator (CCRC) examination in order to be eligible for continued employment with TRUE Research. This requirement may be waived if the employee is required to take courses or training through the work sites that are equivalent to the CCRC Examination. The employee must submit all completed training and a written summary of the content of the course and its relation to the CCRC exam to the Human Resources Department within the first year of eligibility. The CEO will make the final approval of course eligibility.

1. To be eligible to take the CCRC Exam, a candidate must have accumulated, by the date of the exam, a minimum of two (2) years full time (forty [40] hours or more per week) or four (4) years part time (twenty [20] hours or more per week) experience in enrolling subjects, conducting subject study visits and maintaining source documents. The Principle Investigator must attest to the candidate's work experience by completing the Verification Statement on the candidate's CCRC Exam application form.
2. Once the employee reaches eligibility to take the exam, he/she will have one year from the date of eligibility to take and pass the certification exam. Failure to pass the certification exam within the allotted time frame will result in termination.
3. In order to receive reimbursement for the a) cost of certification, and b) up front cost for one-time lodging, food and travel, the employee must adhere to the following requirements.
 - a. Complete the CCRC application listing TRUE Research's address on the application form.
 - b. Ensure that the certification is mailed directly to TRUE, and not to the employee's home address. TRUE's address **MUST** be listed on the application. Only certifications mailed directly to TRUE from the Association of Clinical Research Professionals will be reimbursed.
 - c. Although the employee is responsible for paying the initial examination fee, it is important that the application and request for up-front expenses be approved by the CEO in advance and prior to taking the examination.
4. When TRUE receives a copy of the successful certification of the employee, the employee will be reimbursed for the cost of certification, upon submission of an expense reimbursement report and all applicable receipts. The original certificate will be given to the employee and a copy of which will be kept in the

employee's file

5. If an eligible employee does not take, or fails to pass, the certification examination or submit equivalent training by the required date, the employee will be terminated unless the Principal Investigator chooses to assume responsibility for the eligible employee who did not pass the exam or submit equivalent training for an additional year. During this year, the employee must retake the examination or present training for approval.

RECERTIFICATION

1. CCRCs must be recertified every two years. Recertification requires the completion of 24 documented continuing education contact hours. Fifty percent of these hours must be in clinical research-oriented training courses, home study programs or symposia/conferences.
2. Notices from the Association of Clinical Research Professionals are sent to candidates three months prior to the expiration date of their current certification. Employees are ultimately responsible for maintaining their CCRC certification
3. Once an employee has been notified by the Association of Clinical Research Professionals that it is time for recertification, the employee must follow steps 3a, 3b, 3c, 4 and 5 above

EMPLOYMENT DOCUMENTATION

Each new employee is provided, by TRUE, a copy of TRUE's Personnel Policy, a job description, Conflict of Interest Statement, Credentialing Information, Employee Confidentiality Agreement, a Drug-Free Workplace Policy, and an Anti- Harassment Policy. Employer's Resource will provide the new employee with the following documents: Application for employment, W-4, Direct Deposit, I-9 form, and Health Benefit information. Employees working at a Military off-site are given an employee agreement of employment. Each employee must acknowledge in writing that she/he has received and signed each agreement. The statements and the employee's resume are maintained in the employee's personnel file.

ADDITIONAL DOCUMENTATION IN PERSONNEL FILES

TRUE will maintain an individual personnel file for each employee. Such files are kept confidential and used by authorized employees only. The Chief Executive Officer and Human Resource Department have authorized access to Personnel files. Employees have the right to inspect and review their personnel files upon request but may not remove any of the content, nor make copies of the contents. The personnel files are the property of TRUE Depending on the research off-site or DCI/CID; personnel files may also include the following documents:



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San Antonio, Texas 78217
Ph: (210) 829-1239
Fax: (210) 829-5513*

EMPLOYEE ACKNOWLEDGMENT

I acknowledge that I have received a copy of the Certification and Training requirements taken from the Policy #8 handbook. I understand that all conditions of this requirement must be fulfilled in order to obtain a security clearance. Additionally, I acknowledge that if my position requires a Certified Clinical Research Coordinator (CCRC) examination, I will complete this within the given timeframe.

Signature of Employee

Date

Print Name

Employee Social Security #