Purpose of the CLRA Practicum experience:
The practicum provides an opportunity for applying and integrating in a clinical research setting, the knowledge and skills acquired throughout the M.S. degree program in Clinical Research Administration and for further development of key professional competencies ("Practicum"). The Practicum experience is in alignment with the student’s academic and professional goals. It proceeds under the supervision of a Walden Faculty Member and can occur at a clinical site where a research study is being conducted or with a research sponsor where a study is being planned or facilitated ("Agency"). Supervision by an on-site preceptor ("Preceptor") involved in the planning or conduct of a clinical research study is a critical component of the Practicum. Students start their 120-hour Practicum with participation in an accompanying online seminar course and begin development of a professional portfolio based on assigned professional development activities, which include a journal of interactions/interviews with clinical research administrators, an assessment of the research culture, and the identification of key management challenges in research administration. Ongoing monitoring and evaluation of student performance is provided by the Preceptor and the course instructor.

The Practicum is a capstone experience designed to provide students who have finished their course work with the opportunity to (1) synthesize knowledge, (2) develop competence in professional practice in the foundation areas identified by the Walden Faculty Member, (3) apply knowledge to the solution related to the development of products and protocols used in health care, and (4) develop a respect for and commitment to continued professional knowledge. The field instruction experience that each student receives through the practicum is a critical educational component of the CLRA program.

Walden University views the field placement experience as a joint sharing of responsibility among the student, the Preceptor, and a Walden Faculty Member (i.e., the seminar instructor). Two additional staff members at Walden, the Practicum Coordinator and Field Education Coordinator will oversee the administrative aspects and the quality of the experience from beginning to end.

Competencies that the student should expect to gain from the Practicum experience must reflect application of the Core Clinical Research Administration competencies. Examples of appropriate tasks may include the following but are not limited to:

- Discuss how the objectives, assignments and products (if any) identified in your Practicum Learning Plan support and advance your career goals
- Complete the NIH on-line training course: Protecting Human Research Participants (NIH Office of Extramural Research)
- Discuss how protective measures identified in the NIH training are implemented in the organization’s IRB approval process
- Discuss specific subject enrollment procedures available to researchers
- Describe key features of an informed consent agreement
• Identify the relevant regulatory requirements governing the use and storage of a drug, device or therapy under investigation
• Summarize key components of clinical data management system
• Discuss how compliance with relevant regulations is publicly documented
• Describe internal procedures at the site or sponsor used to ensure and promote adherence to the study protocol
• Describe how subject enrollment is maintained at appropriate levels in a research study
• Identify how and why an original study protocol can be amended and the potential consequences of such action
• Identify how adverse events and serious adverse events are distinguished, monitored and reported
• Discuss standard procedures for a planned and unplanned closure of a research study
• Describe the circumstances which might justify the premature closure of a clinical research study

Agency and Preceptor Expectations:
Jointly supervising a student taking field instruction is an important undertaking. Walden University would like to thank you for your interest in providing field instruction for our students. The following are the expectations and responsibilities that the Agency and the Preceptor need to consider.

• The student and the Preceptor should discuss learning and teaching styles and expectations, methods for facilitating learning, and methods for evaluating progress.
• The Preceptor must provide the student with an orientation to the Agency, including safety, policies, and procedures within which the student is to operate.
• The Preceptor should clearly identify tools and learning opportunities, provide frequent constructive feedback, and provide ongoing evaluation of the student.
• The Preceptor should be available to the student as needed, and provide close coordination of any additional persons that will work with the student.
• The Preceptor must provide at least one (1) hour of direct supervision to the student for every fifteen (15) hours worked. This may not be delegated.
• The Agency must provide the student an appropriate work space and a private space for student evaluation.
• The Preceptor must sign off on all time sheets to certify that the student worked the hours indicated. This may not be delegated.
• The practicum requires a minimum of 120 hours.
• At least one (1) mid-term conference call is required to take place during each term. The conference call is between the student, the Preceptor, and a Walden Faculty Member. Additional calls may be requested by any party.
• A student evaluation at the end of the experience is a very important aspect of the practicum. The Preceptor is expected to fill out and return the evaluation form that will be provided towards the end of the practicum. The evaluation will be used by the Walden Faculty Member in providing the student assessment.

Agency Benefits:
The Agency is gaining an individual who has successfully completed all requirements for a M.S. degree with the exception of the practicum experience. The student is a productive asset capable of assuming responsibility and fulfilling tasks. The Practicum
assignment may also provide the Agency with an opportunity to observe the student as a prospective employee.

CONFIDENTIALITY
Confidentiality is essential in the Practicum. Students will be instructed to not discuss or make known information from the Agency regarding participants in the clinical trials or products and protocols with which they are working during the Practicum. Confidentiality shall extend to other students, other staff at the Agency and personal relationships. Students may communicate with a Walden Faculty Member but discretion should be used and students should communicate only what is necessary to have a scholarly discussion.

Required Agency Documents:
The student will be providing the Agency with information and several documents that will need to be signed and returned to Walden before the student begins the Practicum. The student will provide the Agency with a schedule of Practicum deadlines.

Preceptor Resume/Curriculum Vitae:
Please note that persons providing direct supervision of students within the CLRA program must have, at minimum, a Master’s degree and at least two (2) years of relevant experience post degree. The resume or curriculum vitae (CV) of the proposed Preceptor is required as proof of educational background and clinical research experience, and must reflect employment by and correct contact information for the Agency. The student must email the Preceptor resume or CV along with the Practicum Application to the Walden Field Education Coordinator. Upon approval of the Preceptor, the Field Education Coordinator will send a notification email to the student.

Field Site Affiliation Agreement:
This legal document addresses the responsibilities of the Agency and Walden University. Both the Agency administrator and Walden University Practicum Coordinator sign this document. This document is located on the Walden website.

The Agency may wish to use its own agreement. If so, the student shall provide the Agency with Walden contact information so the approval process can begin. The student shall direct the Agency to email an electronic copy of the agreement in Word format to clrafieldtraining@waldenu.edu. It may take up to 6-8 weeks for approval.

Learning Agreement:
The Learning Agreement must be filled out jointly by the approved Preceptor and the student. The Learning Agreement form is available on the Walden website. The Practicum Coordinator will review the Learning Agreement and the student will be notified of approval. Upon approval, the student and Preceptor will sign the Learning Agreement and send to clrafieldtraining@waldenu.edu. If changes are needed, the student will be notified and must submit a revised version of the Learning Agreement.

Walden University’s Policy on Electronic Signatures
Walden University manages the Practicum Application processes in a nearly paperless environment, which requires reliance on verifiable electronic signatures, as regulated by the Uniform Electronic Transactions Act. Legally, an electronic signature can be the person’s typed name, email address, or any other identifying marker. An electronic signature is just as valid as a written signature as long as both parties have agreed to
conduct the transaction electronically. Walden Staff will verify any electronic signatures that do not originate from a password-protected source (i.e., an email address officially on file with Walden University).

Please direct questions to:
Field Education Coordinator
College of Health Sciences
800-925-3368
clrafieldtraining@waldenu.edu