



## **JOB DESCRIPTION**

TITLE: Clinical Research Associate  
GRADE: Salary, Exempt  
LOCATION: Columbia, MD  
SHIFT: First Shift / Days (Full-Time)  
SUPERVISOR: Clinical Affairs Manager  
DEPARTMENT: Clinical Affairs

### **OBJECTIVE**

ACell, Inc., a leading company in the field of regenerative medicine, is focused on the development and commercialization of medical devices fabricated from porcine-derived extracellular matrix for the reparation and remodeling of damaged tissues and organs. ACell, Inc. is currently seeking an experienced Clinical Research Associate to join the Clinical Affairs Division.

The Clinical Research Associate will assist in the development, monitoring, and completion of multiple, high quality, medical device clinical trials at all phases of development. This position will involve primary contact with medical professionals, core laboratories, consultants, and CROs involved with the clinical studies. Prior work experience should demonstrate dependability, flexibility, and maturity. Candidate must be positive, even tempered, and effective in building interpersonal working relationships with various clinical personnel.

This position requires travel up to 25% of the time.

### **PRINCIPAL RESPONSIBILITIES**

- Written document development, including SOPs, clinical research study protocols, informed consent forms, clinical research forms, and IRB/IEC submissions and renewals.
- Assist in the development and distribution of training materials and study notebooks.
- Assist in the development and management of study-related agreements and budgets.
- Conduct site visits and investigator meetings.
- Monitor and visit clinical trial sites to ensure conformance with study protocol.
- Provide support to clinical investigators and study coordinators to resolve site related issues.
- Manage device accountability and distribution to clinical trial centers.
- Track, collect, and review clinical documentation.
- Review and report adverse events in conformance with FDA regulations.
- Coordinate with clinical investigators in the timely completion, submission, and review of CRFs and verify report data against protocol and patient files.
- Assist in collection and compilation of data for statistical analysis.
- Familiarity with development of clinical protocols and statistical analysis and report writing a plus.
- Working knowledge of GCP and 21 CFR 812 a plus.
- Assist with additional tasks as assigned by the Clinical Affairs Manager.



## REQUIRED SKILLS & KNOWLEDGE

The Clinical Research Associate position requires a BA/BS degree in the science/health care field or nursing degree or equivalent combined education and a minimum of 4 years clinical/scientific research experience or relevant work in the medical device industry. Strong organization, documentation, and interpersonal skills are a plus. Proficiency in Microsoft Office Suite (Word, Excel, and PowerPoint) required.