

REQUEST FOR PROPOSAL (RFP)

Contracted Good Clinical Practice (GCP) External Auditor

Issued by: Hennepin Healthcare Research Institute

Date Issued: February 20, 2026

RFP Submission Deadline: March 13, 2026, 5:00 PM Central

1. Introduction

Hennepin Healthcare Research Institute (HHRI) is a non-profit research organization supporting human research conducted in a safety-net hospital in downtown Minneapolis. We are seeking proposals from qualified external auditors to perform independent GCP audits of our ongoing clinical studies.

2. Project Overview

The contracted GCP auditor will provide an independent review during an annual audit of a clinical trial selected by HHRI. These efforts are to provide routine review and ensure that our clinical trials meet regulatory requirements, ethical standards, and internal quality procedures.

Key Deliverables:

- Risk-based audit planning and scheduling
- Audit of HHRI site-specific clinical trial activities
- Audit reports with findings, observations, and recommendations

3. Scope of Work

The selected auditor will:

- Conduct on-site GCP audits as per agreed audit plan
- Review essential documents, informed consent processes, and data integrity
- Assess compliance with applicable federal regulations and institutional guidelines. May include ICH E6(R2) and/or ICH E6(R3) as adopted by FDA, FDA 21 CFR Parts 11, 50, 54, 56, 312, 812 and GCP guidelines
- Provide detailed audit reports within 10 business days of audit completion
- Maintain confidentiality and impartiality at all times

4. Proposal Requirements

Proposals must include:

- Company or consultant profile, including years of GCP auditing experience
- List of any relevant certifications
- Summary of past GCP audit projects (without disclosing confidential client details)
- Proposed audit methodology and tools used
- Availability and estimated turnaround times
- Detailed fee structure (hourly/daily rates, travel costs, etc.)
- References from at least two recent clients

5. Evaluation Criteria

Proposals will be evaluated based on:

- Relevant GCP auditing experience (30%)
- Regulatory knowledge and certifications (25%)
- Quality and clarity of proposed methodology (20%)
- Cost competitiveness (15%)
- References and client feedback (10%)

6. Submission Guidelines

- **Deadline:** March 13, 2026, 5:00 PM Central
- **Submission Method:** Email proposals in PDF format to EQ@hhrinstitute.org
- **Contact Person:** Bonnie Crissman, Director, Office for Education and Quality in Clinical Research | bcrissman@hhrinstitute.org

7. Terms & Conditions

Hennepin Healthcare Research Institute reserves the right to accept or reject any proposal, negotiate terms, and award the contract to the vendor deemed most suitable. All submitted materials will remain confidential.