



IRB Software Information

TITLE: Tennessee Department of Health-Institutional Review Board Hosted Software Services

The State of Tennessee, on behalf of **Tennessee Department of Health** requests a hosted software solution for the **Institutional Review Board for the Tennessee Department of Health**.

1.1 INTRODUCTION

1.2 1.1 Background

Tennessee Department of Health (TDH) desires to implement a packaged software solution for the Department of Health's Institutional Review Board (IRB). This software should allow the Department of Health to manage TDH's IRB business processes efficiently and provide for an ethical review of research in a timely manner while ensuring adherence to regulatory and ethical review requirements.

1.2 Summary

TDH is seeking a hosted software solution that must be easy to implement, have a single point of support, and meet TDH IRB requirements. This RFI will be used to acquire the software (if needed), implementation services, customer support, and any required hardware devices.

The primary function of this system is to provide an out-of-the-box solution that will enable TDH's IRB to manage its business processes efficiently. It should boost operational efficiencies for the IRB with reasonable cost. Further, it should meet today's guidelines and requirements for the safeguarding of sensitive Department of Health information, as well as any regulatory and ethical review requirements.

1.3 Requirements Overview

The software must not only provide an easy to use user interface for the IRB members, but also for all investigators who submit proposals. As part of the features, the software should have sufficient reports to view or analyze the IRB data. The solution must:

- Be a hosted solution with configuration and support originating from one source;
- Be easy and fast to install without placing a demand on TDH's resources;
- Have the capability to monitor and update compliance requirements, so that TDH does not have to notify vendor to change software when regulatory changes occur;

- Provide a central application gateway capable of handling IRB related proposals;
- Have a proven track record with institutions of as evidenced by number of years and/or clientele;
- Provide web-based usage, reporting, and management tools;
- Have a disaster recovery plan to minimize the chance of data loss, Tennessee Department of Health being the owner of the data;
- Be up-to-date with current technology, the user interface based on current Web technologies;
- Be able to track changes in protocols as they are revised, so that changes are highlighted or marked for reviewers;
- Describe the support model the vendor uses for fixing system-related issues and for answering questions by the users;
- Allow TDH to keep records for the length of time that meets federal standards, and provide the feature to allow old records to be maintained and/or archived;
- Provide easy access to protocols by investigators, committee chair, and committee members, with specific roles managed by the Department of Health's administrative staff;
- Allow Investigators to submit protocols online, and have the capability to allow users to attach supporting documents;
- Have features to easily manage the submitted documents, for example, by grouping information for each protocol together (such as including new application, amendments, revisions, unanticipated problems/adverse events, and renewals of approval);
- Specify the maximum/limit on the number of documents that investigator can upload into each application as required;
- Have an easy to use work flow that allows TDH's IRB members to view and comment on protocols that can be shared among members;
- Allow the IRB chair to view, assign reviewers, make comments, track protocol status, communicate with investigators and reviewers, and track application status;
- Should have features that allow the Committee chair to schedule meetings and maintain meeting minutes;
- Have the ability to search data and generate reports;
- Have the ability to track specific study features, such as vulnerable populations, type of review, levels of risk, or clinical trials;
- Meets professional standards and requirements for IRB compliance;
- Offers opportunities for ongoing training on new features and/or compliance updates;
- Requires minimal need for use of client software;

1.4 Projected Environment

TDH envisions an environment in which the IRB committee will be able to use this software to process all IRB proposals. The software must be capable of handling special cases, and allows the IRB administrators to make administrative adjustments when situations arise.