



**University of Kentucky
Office of Research Integrity
BRAAN2 Electronic IRB Implementation Plan**

ORI Adopts Plan to Upgrade IRB Software

In the summer of 2003, the Office of Research Integrity started planning an upgrade the current IRB tracking system to provide web-based functionality that could both service the research community and the IRB committees and, thereby, improving the quality of protocol review and improving turn-around time from protocol submission to approval. An e-IRB Discovery Team was formed to identify and evaluate available software. A timeline of the pre-selection activities appears below.

Pre-Project Activities

June, 2003	e-IRB Discovery Team Formed
July, 2003	Team Site Visit to Baylor College of Medicine for BRAAN Demo
July, 2003	Team Site Visit to University of California San Diego for internally-developed system demo
November, 2003	UK Key Solutions Demo
November, 2003	BRAAN2 Enhancement Update Meeting
January, 2004	Team Site Visit to Texas Tech for IMedRIS Demo
January, 2004	Team Site Visit to Johns Hopkins for Click Commerce (formerly WebBridge) Demo
March, 2004	Contracted with TrinSoft, LLC to conduct feasibility study of converting in-house IRB system to web-base, workflow system
August – Dec., 2004	Preparing RFP
February, 2005	RFP Issued
March, 2005	Proposals Reviewed
November, 2005	Contract Negotiations with API (BRAAN2) begins
February, 2006	Contract with API finalized
March, 2006	Purchase Order to API Issued

**Anticipated BRAAN2 Implementation Phases / Milestones: Under Development
Implementation Start Date: To Be Determined**

	Phase	Goal	Estimated Timeframe
1.	Analysis and Design Phase	Determine the exact specifications required by BRAAN2 to meet UK's unique business requirements.	The average length of this phase is around 1 man month or 160 hours. However, several factors can affect the length of this phase including but not limited to: <ul style="list-style-type: none"> • Availability and dedication of client resources • Client personnel turn-over • Complexity / Non-standard client processes • Concurrent accreditation processes

2.	Development / Configuration Phase	Develop all new functional requirements into the system that were identified as necessary in the Gap Analysis Report in the previous phase. All other configurations are also performed at this stage to build UK's specific BRAAN2 installation.	This phase of the project could last from 1 to 4 months depending on the complexity of your business processes and how much they differ from the base BRAAN2 product.
3.	Testing Phase	Exercise all system functionality and verify the system does what it is designed to do. The project team identifies and fixes all system bugs prior to the Installation and Production phases.	This phase of the project could last from 2 weeks to 2 months depending on the amount of client resources dedicated to this phase and the amount of time spent each day testing. Factors that could adversely affect this phase are: <ul style="list-style-type: none"> • Other daily responsibilities of the client testing team • Client personnel turn-over
4.	Pre-Installation Phase	Determine the specific hardware and software needs for UK's specific installations.	This phase of the project will only last from 1 to 3 days for gathering required data and for API to recommend the exact hardware specifications from your desired vendor.
5.	Installation Phase	Acquire and install the required test and production hardware and software in a secured data center at the client site.	This phase of the project will only last from 3 to 5 days to ensure that all hardware and software is properly installed and configured.
6.	Data Conversion Phase	Analyze, convert and import existing IRB data to BRAAN1.	This phase could take anywhere from 1 to 3 months depending on the complexity of the conversion algorithms.
7.	Training Phase	In this phase of the project API's mission is to train-the-trainer. API will provide the client trainer with the appropriate documentation, system knowledge and hands-on classes to ensure that he/she can adequately train all system users in their respective roles within the system.	The initial Training Phase can last from 1 to 2 months depending on end-user availability, holiday and vacation schedules, amount of training requested, etc.
8.	Production Phase	"Go Live" with the BRAAN2 application eliminating the need for the paper submission and processing of protocols. Although, this phase is indicated by "going live" the Production phase lasts for the life cycle of your BRAAN2 application. This	This last phase of the BRAAN2 project is an on-going phase for the life of UK's BRAAN2 installation.

		consists of support requests and product enhancements. During this time all effected end-users are actively using the system.	
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Summary

The BRAAN2 implementation project is estimated to take approximately one year, minimum, from the start of the project, to be ready for production roll-out, assuming full-time resources are dedicated to the project. Meetings between UK staff and API to discuss and determine a reasonable project start date are scheduled. A determination on how to best fit the BRAAN2 project into the currently on-going AAHRPP accreditation project is also being discussed.

4/11/06