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| Electronic Informed Consent Management System |
| Project Vision Document | |
| **Version 0.3** | |
| 10/7/2014 | |

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# Introduction

Project Vision document describes scope of the project, stakeholder requirements, business opportunity and system features as well as project feasibility in high level details.

## Purpose

The purpose of Project Vision Document is to provide brief overview of the project, stakeholder requirements, business opportunity as well as the business case to prove project feasibility.

## Scope

The main scope is to build a web application that would implement all consent management workflows including obtaining consent and electronic signature, audit log and administrative interface for user management.

### In Scope

Application will include following features:

1. Patient management module;
2. Consent form template management module;
3. Informed Consent tracking module;
4. Search and reporting capabilities

As non-functional requirements, system will support:

* HTTP over SSL encryption;
* Password based authentication
* Role based security
* Audit log and tracking all changes in the database with capturing information of who made specific that change and when.

### Out of Scope

The system will not support integration with third party clinical trial management or electronic data capture software.

Patients/subjects do not have accounts in the system.

## Definitions, Acronyms, and Abbreviations

**CTMS** - clinical trial management system is a [software system](http://en.wikipedia.org/wiki/Software) used by [biotechnology](http://en.wikipedia.org/wiki/Biotechnology) and [pharmaceutical](http://en.wikipedia.org/wiki/Pharmaceutical) industries to manage [clinical trials](http://en.wikipedia.org/wiki/Clinical_trial) in [clinical research](http://en.wikipedia.org/wiki/Clinical_research). The system maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones.

**PHI** - protected health information.

**Consent management** is a system, process or set of policies for allowing consumers and patients to determine what health information they are willing to permit their various care providers to access. It enables patients and consumers to affirm their participation in e-health initiatives and to establish consent directives to determine who will have access to their protected health information (PHI), for what purpose and under what circumstances. Consent management supports the dynamic creation, management and enforcement of consumer, organizational and jurisdictional privacy policies.

**Informed consent** is aprocess for getting permission before conducting a healthcare intervention on a person. A health care provider may ask a patient to consent to receive therapy before providing it, or a clinical researcher may ask a research participant before enrolling that person into a clinical trial. Informed consent is collected according to guidelines from the fields of medical ethics and research ethics.

**Electronic Informed consent** - electronic way of capturing informed consents to enable indexing, to improve comprehension, search and retrieval of consent data, thus enhancing the ability to honor to patient intent and identify willing research participants.

**IRB** - institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB) or research ethics board (REB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be done.

**Full Signature**–is an electronic signature treated as though the signature were full electronic on paper. For example, a signature provided on a credit card scanning machine would be considered a full signature. Full signatures are typically not an option unless consent is conducted in-person at a facility with the required technological hardware and software.

OHRP allows full signatures as long as they are legally valid within the jurisdiction where the research is conducted, provided that the IRB considers the following:

* How the signature is created
* If the signature can be shown to be legitimate
* If the consent document can be produced in hard copy for review by the potential participant.

**OHRP** - Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.

**HIE** - Health information exchange is the mobilization of healthcare information electronically across organizations within a region, community or hospital system. In practice the term HIE may also refer to the organization that facilitates the exchange.

**Title 21 CFR Part 11** is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records (Title 21 CFR Part 11 Section 11.1 (a)). EMA and Health Canada have similar regulations in their jurisdictions.

**EMA** - The European Medicines Agency is a European Union agency for the evaluation of medicinal products. From 1995 to 2004, the European Medicines Agency was known as European Agency for the Evaluation of Medicinal Products.

## References

| Reference File Name | Version | Description |
| --- | --- | --- |
| N/A |  |  |
|  |  |  |

# Positioning

## Business Opportunity

Electronic Consent management is vital part of the patient enrolment process. Normally, most of modern Clinical Trial Management System have Electronic Consent Management feature as the part of the system. However, systems like that are intended to be used in regulated clinical trials which compliant with FDA CFR 21 Part 11 and it significantly increase the license cost and total cost of the ownership. That is why; non-commercial institutions such as university research teams who are conducting non-regulated trials and have limited budgets may not be able to afford those systems and have to use Microsoft Office or even pen and paper to handle clinical trial specific information.

This system is intended to fill that gap and provide robust cost effective solution to manage patients/subjects consents.

## Problem Statement

Electronic Informed Consent Management System aims to improve and organize the process of capturing, reasoning, integrating and sharing consent permissions provided by patients for reusing clinical data and samples for research.

The following problems will be resolved:

1. Patient demographic information management;
2. Consent form management;
3. Fast and secure access to patient and consent information through search and reporting capabilities.

|  |  |
| --- | --- |
| The Problem of | Informed Consent Management as:   1. Patient/Subjects Management 2. Consent Form Management 3. Fast and secure access to patient and consent information through search and reporting capabilities |
| affects | * Project Sponsor, * Study Director, * Clinical Research Coordinator |
| the impact of which is | Slow and cumbersome paper based Consent Management |
| a successful solution would be | Web based semi-automated Informed Consent Management System will reduce manual work to obtain Informed Consent from the patient and dramatically reduce time to get list of patients who are eligible to participate in the specific clinical trial or group of trials |

## Product Position Statement

The main category of users who will use the Electronic Informed Consent Management System is Clinical Research Coordinators who enroll prospective patients for specific clinical research trial or study. The product name is ConMan(Consent Management).This product will be targeted as cost effective solution for academic sector and research teams who conducts non-commercial non-regulated clinical trials and cannot afford large commercial FDA CRF 21 Part 11 compliant regulated CTMS systems and solutions.

|  |  |
| --- | --- |
| For | Clinical Research Coordinators |
| Who | Obtain signed informed Consent forms from patients/subjects, provide list of patients who signed specific consent form and therefore eligible to participate in the specific study |
| The Electronic Informed Consent Management | is an semi-automated solution |
| That | Is fast, easy, cost effective |
| Unlike | The current paper based process |
| Our product | * Reduce time to obtain signed informed consent, * reduces paper handling and storage costs, * improvespatients/subjects satisfaction, * improve workflow efficiency, * improve transparency, * enable faster decision making using list of patients who are eligible to participate in the specific study because they are already signed required consent forms and provide greater information security |

# Stakeholder and User Descriptions

## Stakeholder Summary

| Stakeholder Name | Represents | Role |
| --- | --- | --- |
| Clinical Research Coordinator (Internal Stakeholder) | Clinical Research Coordinator is the key user of the system. | Clinical Research Coordinator is responsible for:   * Add, update and remove patient demographic information; * Verify patient’s identity * Obtain evidence of granted or revoked consent |
| System Administrator (Internal Stakeholder) | System Administrator is the user with administrative privileges in the system | System Administrator is responsible for:   * user accounts management * consent form management |
| Study Director (Internal Stakeholder) | Study Director does not have account in the system nor use it directly but he is directly interested in the outcomes. | Study director is responsible for:   * clinical trial management * patient/subject enrollment * data management process organization |
| Project Sponsor (Internal Stakeholder)  NatalliaIsayenka  Anna Poluektova | Project Sponsor if the key Manager or employee who demonstrates interest in the outcome of the project. He is a decision-maker for the project. | * Project Sponsor is responsible for securing spending authority and resources for the project. * Legitimizes the project’s goals and objectives * The Project Sponsor will lead project initiation. * He will participate in project planning * The Project Sponsor will assists with major issues, problems, and policy conflicts. |
| Project Team (Internal Stakeholder)  NatalliaIsayenka  Anna Poluektova | Project Team is a group responsible for planning and executing the project. | * Responsible for ensuring that the Project is completed and solution meets the stakeholder requirements. * Develops the Project Plan * Executing tasks and producing  deliverables as outlined in the  Project Plan * Secure acceptance and  approval of deliverables from the Project Sponsor and Stakeholders * Responsible for communication * Ensures the project is delivered  in budget |

Table 3 Stakeholder Summary

## User Summary

| User Name | Description | Responsibilities | Stakeholder |
| --- | --- | --- | --- |
| Clinical Research Coordinator | Clinical Research Coordinator obtains content, enrolls patient and manages Consent Forms | * Add, update and remove patient demographic information; * Verify patient’s identity * Obtain evidence of granted or revoked consent | Study Director |
| System Administrator | System Administrator is the user with administrative privileges in the system | System Administrator is responsible for user accounts management and consent form management | Study Director |

Table 4 User Summary

# Stakeholder Requirements

Notes:

In a requirement statement, must means that the requirement is mandatory

In a requirement statement, shall means the requirement is optional

| ID | Requirement | Stakeholder |
| --- | --- | --- |
| 1\_REQ\_01 | System must have password based authentication | System Administrator |
| 2\_REQ\_01 | System must have role based security | System Administrator,  Study Director |
| 3\_REQ\_01 | System must have audit log that reflects all changes in the database and capture who made this change and when | Study Director,  Project Sponsor |
| 4\_REQ\_01 | System must be accessible trough secure HTTP over SSL connection | Project Sponsor |
| 5\_REQ\_01 | System must provide patient registry capabilities | Clinical Research Coordinator,  Project Sponsor |
| 5\_REQ\_02 | System must capture patient demographic data | Clinical Research Coordinator,  Project Sponsor |
| 5\_REQ\_03 | System must allow to update patient data | Clinical Research Coordinator,  Project Sponsor |
| 5\_REQ\_04 | System must allow removing patient. | Clinical Research Coordinator,  Project Sponsor |
| 6\_REQ\_01 | System must provide consent form registry capabilities | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 6\_REQ\_02 | Each consent form template must have unique name and version ID | Clinical Research Coordinator,  Study Director,  System Administrator  Project Sponsor |
| 6\_REQ\_03 | System must allow adding new consent form template. | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 6\_REQ\_04 | System must allow updating consent form template.  Each consent form modification must be marked as new version of specific consent form template. | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 6\_REQ\_05 | Consent form template versioning must be automatic and incremental.  Nobody can modify consent form template version ID. This is accessible in read-only mode for all type of users. | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 6\_REQ\_06 | Consent template can be deleted only if there are no single patients/subjects who signed off this specific version of the consent template.  Otherwise consent template cannot be removed to preserve data integrity and audit trial. | Clinical Research Coordinator,  Study Director  Project Sponsor,  System Administrator |
| 7\_REQ\_01 | System must provide Consent tracking capabilities | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 7\_REQ\_02 | System must be able to capture full electronic signature of Clinical Research Coordinator using mouse, touch screen or other type of cursor manipulator supported by browser or client device host operation system | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 7\_REQ\_03 | System must be able to capture full electronic signature of patient/subject using mouse, touch screen or other type of cursor manipulator supported by browser or client device host operation system | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 7\_REQ\_04 | System must be able to capture current date and time i.e. timestamp when patient full electronic signature captured. | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 7\_REQ\_05 | Timestamp, signatures and context of signed consent form cannot be modified after patient/subject signoff.  If those changes are required, another consent must be taken from patient/subject. | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 7\_REQ\_06 | Patient must be able to revoke any previously signed specific consent or all consents at one time. Consent revoke form must be available as a part of consent form registry and must be versioned as other consent form templates | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 8\_REQ\_01 | System must provide search capabilities for search patients/subjects and Consent Form Templates | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 8\_REQ\_02 | Patients/subject must be searchable by:   1. First name, 2. Last name, 3. Home address, 4. Data of birth | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 8\_REQ\_03 | Consent form templates must be searchable by:   1. consent form name 2. consent form version   Full text search by consent form content is optional. | Clinical Research Coordinator,  Study Director  Project Sponsor |
| 8\_REQ\_04 | System must allow choice more than one consent form and show list of patients who signed those forms grouped by consent form, version number and sign-off date.  System must allow exporting search result into Microsoft Office Excel format or CSV. | Clinical Research Coordinator,  Study Director,  Project Sponsor |

Table 5 Stakeholder Requirements

# System Features

| ID | Feature | Stakeholder Requirement ID |
| --- | --- | --- |
| 1\_FR\_01 | System must have online form for password-based authentication. It shall have at least following UI components:   1. User name; 2. User password 3. Log in button | System Administrator,  Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 1\_FR\_02 | User password text field control shall mask entered symbols on the fly. | System Administrator,  Study Director,  Project Sponsor |
| 2\_FR\_01 | System shall have role based security feature and maintain at lest two roles:   1. Clinical Research Coordinator 2. System Administrator | System Administrator,  Study Director,  Project Sponsor |
| 3\_FR\_01 | System shall have audit log feature | Study Director,  Project Sponsor |
| 3\_FR\_02 | Audit log shall reflects all changes in the database | Study Director,  Project Sponsor |
| 3\_FR\_03 | Audit log must be maintained in the database | Study Director,  Project Sponsor |
| 3\_FR\_04 | Audit log entity record shall retain at lest following information:   1. Entity or table name 2. User name who made this change 3. Old value if available 4. New value 5. Time stamp(date and time) | Study Director,  Project Sponsor |
| 4\_FR\_01 | System shall have encryption feature. All interactions between users and application server shall go trough secure HTTP over SSL connection. | System Administrator,  Study Director,  Project Sponsor |
| 5\_FR\_01 | System shall have patient registry feature | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 5\_FR\_02 | System shall have at least two forms:   1. Patient/subject grid; 2. Patient Add/Edit patient details form | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 5\_FR\_03 | Patient/subject grid feature shall allow users to filter patients by:   1. First Name 2. Last Name 3. Address 4. City 5. Province/State 6. Postal/Zip Code 7. Country 8. Primary Subject ID 9. Secondary Subject ID 10. Sex 11. Age 12. Race | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 5\_FR\_04 | System shall have patient delete feature. There must be possible to check more than one patient and perform delete operation on all checked patients at once.  There must be confirmation pop-up before actual patient removal.  This removal must not delete physically patient record from the system to preserve integrity. This must be “soft-delete”, user must not be visible for search and modification once deleted but all historical information including audit log must be retained in the database. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 5\_FR\_05 | Patient grid must have check all button or checkbox to allow user to check all patients | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 5\_FR\_06 | System must allow Clinical Research Coordinator to perform following actions for specific subject/patient from patient/subject grid from:   1. Add subject/patient 2. Update subject/patient 3. Add consent 4. Revoke consent | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 5\_FR\_07 | Patient Add/Edit patient details form shall capture and store following patient information:   1. First Name 2. Last Name 3. Address 4. City 5. Province/State 6. Postal/Zip Code 7. Country 8. Primary Subject ID 9. Secondary Subject ID 10. Sex 11. Age 12. Race | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 5\_FR\_08 | Patient Add/Edit patient details form shall have two buttons:   1. Save 2. Cancel   “Save” button shall store all information updated by user.  “Cancel” button action must dismiss all changes made. If “Cancel” button pressed during new patient entry, then new patient shall not be added to the database.  In any case, regardless which button has been pressed, system must bring user back to patient/subject grid form. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 5\_FR\_09 | Patient/subject grid shall have button to update (grant or revoke) patient consent | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 6\_FR\_01 | System must provide consent form templates registry feature | Clinical Research Coordinator,  Study Director,  Project Sponsor,  System Administrator |
| 6\_FR\_02 | System must have feature that maintain have unique name and version ID for each consent form template | Clinical Research Coordinator,  Study Director,  Project Sponsor,  System Administrator |
| 6\_FR\_03 | System shall have adding new consent form template feature. | Clinical Research Coordinator,  Study Director,  Project Sponsor,  System Administrator |
| 6\_FR\_04 | System shall have updating consent form template feature.  This feature must mark each consent form modification as the new version of specific consent form template. | Clinical Research Coordinator,  Study Director,  Project Sponsor,  System Administrator |
| 6\_FR\_05 | System shall have automatic incremental consent form template versioning feature.  Nobody shall modify consent form template version ID. This is accessible in read-only mode for all type of users. | Clinical Research Coordinator,  Study Director,  Project Sponsor,  System Administrator |
| 6\_FR\_06 | System shall have consent form deletion feature. This feature shall allow deleting consent form template version only in case if there are no even single patient/subject who signed off this specific version of the consent template.  Otherwise consent template cannot be removed to preserve data integrity and audit trial. | Clinical Research Coordinator,  Study Director,  Project Sponsor,  System Administrator |
| 7\_FR\_01 | System shall have Consent tracking feature | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 7\_FR\_02 | System shall have full electronic signature capture feature.  This feature must use mouse, touch screen or other type of cursor manipulator supported by browser or client device host operation system to obtain picture of the full electronic signature. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 7\_FR\_03 | Full electronic signature shall be stored in the database. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 7\_FR\_04 | This full electronic signature capture feature shall not allow modifying the picture once signature is taken. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 7\_FR\_05 | The full electronic signature capture feature shall allow rendering the picture of signature in read-only mode. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 7\_FR\_06 | Consent tracking feature shall be able to capture full electronic signatures of both Clinical Research Coordinator and patient/subject. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 7\_FR\_07 | Consent tracking feature shall be able to capture date and time (timestamp) of the moment of time when patients/subject-full electronic signature obtained.  This timestamp shall not be modified in any mean and must be available in read-only mode. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 7\_FR\_08 | Consent tracking module shall have consent revoke feature. Using this feature by patient request, Clinical Research coordinator shall be able to document consent revoke of any previously signed specific consent or all consents at one time.  Consent revoke form must be available as a part of consent form registry and must be versioned as other consent form templates | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 8\_FR\_01 | System shall provide patient/subject search feature | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 8\_FR\_02 | Patients/subject feature shall allow user to search by:   1. First name, 2. Last name, 3. Home address, 4. Data of birth | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 8\_FR\_03 | System shall provide Consent form template search feature | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 8\_FR\_04 | Consent form template search feature shall allow user to search by:   1. Consent form template name 2. Consent form template version   Full text search by consent form content is optional. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 8\_FR\_05 | System shall provide option to search patients who signed specific consent form templates feature i.e. “Search patient by consent” | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 8\_FR\_06 | “Search patient by consent” feature must allow choice more than one consent form template and show list of patients who signed those forms grouped by consent form, version number and sign-off date. | Clinical Research Coordinator,  Study Director,  Project Sponsor |
| 8\_FR\_07 | “Search patient by consent” feature must allow exporting search result into Microsoft Office Excel format or CSV. | Clinical Research Coordinator,  Study Director,  Project Sponsor |

Table 6 System Features

# Assumptions

## Accessibility

There would not be any specially designed accessibility features in the application due to the time limitation.

Users may use built-in host operation system accessibility features if necessary. Most of modern operations systems such as Windows 8, OS X, iOS and Android have build-in accessibility features which are available through the browser such as Chrome, Safari or IE.

## HTML5 support

System would use responsive design methodology that allows using devices with different screen size and resolution such as mobile phones, tablets and desktop computers. System will analyze screen resolution and screen size and adjust page layout to make content shaped best for the device. For example, some second priority details might be removed from page when mobile phone is used. Due to responsive design support, client web browser must be HTML5 compatible.

# Constraints

## Internet connection

The system will be implemented as web application and would require permanent Internet connection. The will be no off-line mode.