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## Introduction

This document captures the complete software requirements for the C3PR V2.1 software as part of the caBIG™ project.

## Project Perspective

The Cancer Central Participant Registry (C3PR) is a web-based application used for end-to-end registration of patients to clinical trials. This includes capturing the consent signed date, eligibility criteria, stratification, randomization, and screening. Clinical workflows are enabled by both subject- and study-centric views into the registration process. C3PR can be run in a standalone mode where study definitions, investigators, study personnel, and sites are entered into the system, or C3PR can be run in an integrated mode with the caBIG Clinical Trials Suite (CCTS). C3PR also enables multi-site clinical trials where registration information is entered locally at affiliate sites and the registration is completed by call-out to the coordinating site.

Throughout the development of C3PR, a number of elaborator and adopter sites are actively being engaged to help define requirements and test the application. Our primary elaborators include Duke, Wake Forest, Mayo, Westat, CALGB, CCR, and the Coalition of Cooperative Groups. Our primary adopters include Duke and Wake Forest with engagement of Georgetown and CCR.

C3PR release 1 was developed by Nortel Solutions and released in 2006. Release 2 was developed by Duke Cancer Center in collaboration with SemanticBits, LLC and was released in March, 2008. We are currently in the next phase of development with releases slated for the end of September, 2008 and March, 2009.

See our [Vision Statement](#) for more information.

## Users and Characteristics

The likely users of C3PR are people with the job responsibilities listed below. The role(s) granted to each user in the application will depend on the specific responsibilities of the person's job and other institutional rules under which they execute their responsibilities.

- Registrar
- Study Coordinator
- Site Coordinator
- System Administrator

## Release Overview

### System scope

The primary features that were developed as part of the C3PR Release 2.0 project include the following:

- **Study Management:** C3PR Release 2 allows for the loading, management, and searching of studies. Eligibility criteria and randomization are accessible and managed through the web interface. C3PR does not aim to be the primary study management system; however, C3PR contains enough basic study information to register participants and track them on the study.
- **Participant Management:** This component can manage all aspects of the participant data including address, contact information, searching, synchronization with external systems and relations management.
- **Registration Management:** Complete registration management is provided within the C3PR system including stratification, assignment to study arms with and without randomization. Registration status and notification will be a central goal of integration with external systems.
- **Reports:** C3PR allows for reports generation by providing data dumps to be incorporated with external data, as well as an internally managed reporting module to be provided through the web interface.
- **Eligibility Criteria Management:** C3PR version 2.0 continues to support the optional import, review and approval process of the eligibility criteria. This support includes distinct eligibility checklists for different phases (or epochs) of the same study. The definition of all the eligibility checklists is optionally maintained in the caDSR within the FormBuilder application and this version of C3PR system provides support to import the eligibility checklist displayed dynamically within C3PR.
- **Auditing/Logging:** The Release 2 system provides complete auditing features, including tracking changes and record data as a snapshot prior to any data modifications.
- **Login:** C3PR leverages the current CSM based security model. Furthermore, the caGrid 1.0 security infrastructure is leveraged for authentication, authorization, and trust fabrics.
- **Data Loading:** Release 2.0 of the system allows participant, registration, and study data to be loaded from external sources. The approach of the C3PR application is to provide data loading, API-based (web service), and web interface based methods to manage all aspects of the C3PR system.
- **Clinical Data Access:** C3PR continues to provide direct access to clinical data in C3D (and other clinical data management systems) for the selected participant on the selected study.
- **Eligibility Criteria Management:** C3PR version 2.0 continues to support the optional import, review and approval process of the eligibility criteria. This support includes distinct eligibility checklists for different phases (or epochs) of the same study. The definition of all the eligibility checklists is optionally maintained in the caDSR within the FormBuilder application and this version of C3PR system provides support to import the eligibility checklist displayed dynamically within C3PR.
- **Auditing/Logging:** The Release 2 system provides complete auditing features, including tracking changes and record data as a snapshot prior to any data modifications.
- **Login:** C3PR leverages the current CSM based security model. Furthermore, the caGrid 1.0 security infrastructure is leveraged for authentication, authorization, and trust fabrics.
- **Data Loading:** Release 2.0 of the system allows participant, registration, and study data to be loaded from external sources. The approach of the C3PR application is to provide data loading, API-based (web service), and web interface based methods to manage all aspects of the C3PR system.
- **Clinical Data Access:** C3PR continues to provide direct access to clinical data in C3D (and other clinical data management systems) for the selected participant on the selected study.

## New Features in C3PR 2.1/3.0

The following will be implemented in version 2.1 of C3PR:

- **Call-out Randomization:** Programmatic call-out for randomizing subjects through a custom module.
- **Multi-site Studies:** Automated exchange of study definitions or amendments between coordinating sites and affiliate sites that comply with C3PR messaging infrastructure.
- **Hosted Mode:** Optimized to run in a hosted mode where multiple sites will be accessing C3PR functionality (though C3PR can potentially be run in this mode).
- **Custom Diseases and Disease Sites:** Defining of custom diseases and disease sites.
- **Companion Protocols:** Support defining or automated registration to companion protocols will be provided. Companion protocol are studies which are usually carried out along with some particular studies. Companion studies may have separate criteria such as different IRB approval date, consent date, coordinating center or treating physician to name a few. It is not necessary to have separate data in most of the cases. We will consider single level companion protocol. Study with associated companion protocol cannot be used as companion protocol.
- **OPEN Integration**
- **RSS Integration**
- **Custom Fields (local modifications)**
- **Legacy Application Integration (integration/migration)**
- **Basic Science Eligibility Criteria**
- **Study Level Authorization (CCTS req.)**
- **Groups of Study Personnel**

## Traceability

Traceability provides a mechanism to track which requirements are generated from which use cases and which tests are generated from them. Each use case is directly translated into a test script. Traceability is maintained by the name of the file corresponding to the name of the use case. Furthermore, traceability of requirements to use cases to tests is captured in a traceability matrix:

- [http://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/c3prv2/documentation/requirements/c3prv2\\_rtm.xls?cvsroot=c3prv2](http://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/c3prv2/documentation/requirements/c3prv2_rtm.xls?cvsroot=c3prv2)

Currently, traceability to tests is not included. It will be included in iteration 5 of the construction phase.

## Document Key

The C3PR Release 2.1 project continues to follow the iterative development of the Unified Framework Process. Thus, each document is a snapshot of a work-in-progress. The following conventions will be used throughout the document:

- Red highlighting will indicate new items that need to be addressed immediately in the next iteration by the developers.
- Green highlighting will indicate new items that need to be addressed in the next iteration by the elaborators.

## Reference Documents

Management	End User	Analysis	Technical
<ul style="list-style-type: none"><li>• <a href="#">Vision Statement</a></li><li>• <a href="#">Project Plan</a></li><li>• <a href="#">Scrum Artifacts</a></li><li>• <a href="#">Adoption Plan</a></li><li>• <a href="#">Communications Plan</a></li><li>• <a href="#">Test Plan</a></li></ul>	<ul style="list-style-type: none"><li>• End User Guide</li><li>• Training Module</li><li>• <a href="#">Installation Guide</a></li><li>• Administration Guide</li></ul>	<ul style="list-style-type: none"><li>• <a href="#">Use Case Document</a></li><li>• <a href="#">Requirements Specification</a></li><li>• <a href="#">Activity Diagrams</a></li></ul>	<ul style="list-style-type: none"><li>• Architecture Guide</li><li>• Domain Analysis Model</li><li>• Domain Implementation Model</li><li>• <a href="#">Deployment Diagrams</a></li></ul>

- [C3PR Arc Requests](#)

## Definitions

**MUST** - This word means that the definition is an absolute requirement of the specification.

**MUST NOT** - This phrase means that the definition is an absolute prohibition of the specification.

**WILL** - This word means that the definition is an absolute future requirement of the specification.

**WILL NOT** - This phrase mean that the definition is an absolute future prohibition of the specification.

**SHOULD** - This word means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

**SHOULD NOT** - This phrase means that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.

**MAY** - This word means that a requirement is truly optional. The developer may choose to include the item based on the needs of their design.

## System Requirements

### caBIG Compatibility

#### Vocabularies and Data Elements

One of the main goals of caBIG is to ensure that all applications use the same vocabulary and data elements for similar concepts across the grid. This will eliminate any inconsistency in data descriptors (metadata) and make it possible to pass semantically equivalent data with confidence across various applications within the grid

Req. ID	Requirement
<b>VCDE-1</b>	C3PR must use Enterprise Vocabulary Services (EVS) and Cancer Data Standards Repository (caDSR) for data elements and concepts that will be exposed through caBIG silver-compatible APIs, as well as the user interface.

### System Environment

C3PR system will be developed on open source Java/J2EE platform using JDK 1.5.

The caBIG compatibility guidelines do not address the issue of the number of platforms and databases on which caBIG applications must run. Because caBIG is an open source project, it is desirable that testing be performed on the Linux platform.

Req. ID	Requirement
<b>ENV-1</b>	The client software will be tested locally with the following operating systems: <ul style="list-style-type: none"> <li>• Windows XP</li> <li>• Linux</li> </ul>
<b>ENV-5</b>	The client software will be tested locally with the following browsers: <ul style="list-style-type: none"> <li>• Internet Explorer 6.0x, 7.0x</li> </ul>

	<ul style="list-style-type: none"> <li>• Mozilla Firefox</li> </ul> <p>There will be no IE specific code used for C3PR. This includes technologies like DHTML and IE Specific JavaScripts.</p>
<b>ENV-10</b>	<p>The application server will require at least the following:</p> <ul style="list-style-type: none"> <li>• 1 GHz CPU</li> <li>• 1 GB RAM</li> <li>• 2 GB hard disk</li> </ul>
<b>ENV-11</b>	<p>The application server will require the following 3rd party software:</p> <ul style="list-style-type: none"> <li>• Java 1.5.6</li> <li>• Ant 1.6.5</li> <li>• Oracle 9i, Oracle 10g, or Postgres 8.2</li> <li>• Apache Tomcat 5.1.28</li> <li>• caGrid 1.0</li> </ul>
<b>ENV-15</b>	<p>The client computer will require at least the following:</p> <ul style="list-style-type: none"> <li>• 1 GHz CPU</li> <li>• 512 MB RAM</li> </ul>

## Security Environment

Req. ID	Requirement
<b>SEC-5</b>	C3PR will use CSM APIs for user authentication; that is, to verify a user's credentials and allow access to the application and authorization services.
<b>SEC-25</b>	Each C3PR user must be authenticated against a specific trusted Identity Provider (IdP) registered with Dorian in the caGrid in order to execute the Federated Query. The C3PR GUI should provide a means for users to login.
<b>SEC-30</b>	In Phase one of the C3PR project, the login will be based on two fields; username and password.
<b>SEC-35</b>	The login infrastructure may provide "Remember Me" feature in which the username and password are stored on the user's client machine.

## C3PR Requirements

### Functional Requirements

#### Manage Study

Req. ID	Requirement
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<b>FR-1</b>	The system must allow manual creation of a basic Study definition through the web interface.
<b>FR-5</b>	The system must support loading of a Study definition from a structured text file.
<b>FR-6</b>	The system may support the exporting of a Study definition into a structured text file.
<b>FR-10</b>	The system must expose a programmatic interface for creation of a Study definition.
<b>Fr-15</b>	The system must provide functionality that enables propagation of a new Study definition to other systems. Minimally this includes another instance of C3PR.
<b>FR-20</b>	The system must support optional verification/QC for the new Study definition.
<b>FR-25</b>	The system must provide functionality to search for a Study based on data elements that make up the Study object. The specific data elements are still being enumerated.
<b>FR-30</b>	The system must allow updating a Study definition.
<b>FR-32</b>	When a study definition is updated, notification will be made if needed concerning patients that registered on the modified portion of the study.
<b>FR-35</b>	The system must allow activating and deactivating information about the various sites where the Study is being implemented.
<b>FR-40</b>	The system must allow managing basic trial design aspects of a Study. This includes ability to manage Epochs, Arms, Stratification, and Randomization.
<b>FR-45</b>	The system must provide functionality to enable tracking of Study history, which includes who modified the study and when it was modified. Entire versions of the study will not be tracked (i.e. full provenance is not tracked), but study amendments will be tracked.
<b>FR-50</b>	The system must allow maintaining Study status information. It must provide programmatic interfaces for updating the status of a Study.
<b>FR-55</b>	The system must provide functionality to enable storing multiple identifiers for a Study. It must also support site/institution specific identifiers.
<b>FR-60</b>	The system must allow capturing the eligibility criteria for each Epoch in the Study
<b>FR-61</b>	The system must provide functionality to enable capturing of Study amendments.

<b>FR-62</b>	The system must provide functionality to enable capturing of diseases or patient populations that are the focus of the Study.
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## Manage Participant



FR-65 and FR-66 delineate between the two types of participants: Subject and Study Personnel. Where not otherwise noted, the rest of the use cases refer to both types of participants.

Req. ID	Requirement
<b>FR-65</b>	The system must allow manual creation of a basic Study Personnel definition.
<b>FR-66</b>	The system must allow manual creation of a basic Subject definition.
<b>FR-70</b>	The system may support loading of a Participant definition from a structured text file .
<b>FR-71</b>	The system may support the exporting of a Participant definition to a text file.
<b>FR-75</b>	The system may expose a programmatic interface for creation of a Participant definition.
<b>Fr-80</b>	The system must provide functionality that enables propagation of a new Participant definition to other systems. Minimally, this includes other instances of C3PR.
<b>FR-85</b>	The system may support optional verification/ QC for a new Participant definition created programmatically through an API (loaded from a file or via propagation).
<b>FR-90</b>	The system must provide functionality to search for a Participant based on the data elements that make up the Study object.
<b>FR-95</b>	The system must allow updating information pertaining to a Participant.
<b>FR-100</b>	The system must allow maintaining contact information of a Participant.
<b>FR-105</b>	The system must allow maintaining address information of a Participant.
<b>FR-110</b>	The system must allow maintaining multiple identifiers for a Participant.
<b>FR-115</b>	The system must allow maintaining multiple roles for Study Personnel on any given study.

## Register/Enroll Subject

Req. ID	Requirement
FR-110	The system must allow enrollment/registration of a Subject to an Arm of a Study.
FR-111	The system must allow saving the registration in an incomplete status.
FR-112	The system must allow retrieving the saved registration in an incomplete status and add complete information and accept it as a valid registration.
FR-115	The system must provide functionality to enable viewing of registration history of a Subject.
FR-120	The system must allow propagation of registration information from C3PR to other CTMS systems. Minimally this must include other instances of C3PR, but may also include other systems such as Study Calendar and caAERS.
Fr-125	The system may allow storing of screening data of a Subject on a Study.
FR-130	The system must allow closing the registration of Subjects on a Study.
FR-135	The system must allow registration of Subjects that do not count towards the total accrual for a Study.
FR-140	The system may support reservation of a registration on a Study for a Subject.
FR-145	The system may allow automatic registration to all the correlative studies that exist for a Study.
FR-150	The system must provide functionality to override the eligibility criteria and allow registration of a Subject even if all the eligibility criteria are not met.
FR-155	The system must track accrual
FR-160	The system must provide for accrual ceilings
FR-165	The system must provide notification when accrual limits have been met
FR-170	The system may provide for interim accrual ceilings
FR-175	The system may allow storing of screening data of a Participant on a Study.
FR-180	The system must ensure the participant meets the eligibility criteria prior to registration.



<b>FR-185</b>	System must provide automatic registration to companion protocol while registering for study.
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## Randomization

<b>FR-170</b>	The system must support randomization done externally (e.g. via phone)
<b>FR-175</b>	The system should provide functionality for capturing the book that could be used for performing the randomization.
<b>FR-180</b>	The system should support programmatic randomization by interfacing with the randomization hub that is currently being developed.
<b>FR-185</b>	The system should support Blinded Randomization (via phone) .

## Manage Eligibility Criteria

<b>Req. ID</b>	<b>Requirement</b>
<b>FR-180</b>	The system must provide for management of eligibility criteria through the web interface.
<b>FR-181</b>	The system must provide for yes/no/NA questions in eligibility criteria checks.
<b>FR-185</b>	The system must provide for yes/no/NA flag for an eligibility criteria check.
<b>FR-190</b>	The system must support eligibility criteria loading from the caDSR
<b>FR-195</b>	The system should support eligibility criteria loading from a file
<b>FR-200</b>	The system may support eligibility criteria exporting to a file

## Manage Investigators & Study Personnel

<b>Req. ID</b>	<b>Requirement</b>
<b>FR-245</b>	The system must allow manual creation of a basic Investigator definition.
<b>FR-246</b>	The system must allow manual creation of a Principal Investigator definition.
<b>FR-247</b>	The system must allow manual creation of a basic Research Staff definition.

<b>FR-248</b>	The system may support loading of a Investigator definition from a structured text file
<b>FR-250</b>	The system must expose a programmatic interface for creation of an Investigator definition.
<b>FR-251</b>	The system must provide functionality that enables propagation of a new Investigator definition to other systems. Minimally, this includes other instances of C3PR.
<b>FR-252</b>	The system may support optional verification/QC for a new Investigator definition created through an API (loaded from a file or via propagation).
<b>FR-253</b>	The system must provide functionality to search for an Investigator based on the name.
<b>FR-254</b>	The system may allow updating information pertaining to an Investigator.
<b>FR-255</b>	The system may allow updating information pertaining to a Research Staff person.
<b>FR-256</b>	The system must allow maintaining contact information of an Investigator.
<b>FR-257</b>	The system must allow maintaining contact information of a Research Staff person.
<b>FR-258</b>	The system must allow choosing the healthcare sites the investigator is associated with.
<b>FR-259</b>	The system must allow choosing the healthcare site the Research Staff person is associated with.
<b>FR-260</b>	The system must allow updating the status of an Investigator.
<b>FR-261</b>	The system may allow adding multiples roles to an Investigator.
<b>FR-262</b>	The system must allow updating the status of a Research Staff person.
<b>FR-263</b>	The system may allow adding multiple roles to a Research Staff person.
<b>FR-263</b>	The system may allow creation of Investigator groups and allow associating them with studies.

## Call-out Randomization

<b>Req. ID</b>	<b>Requirement</b>
<b>FR-1</b>	

## Multi-site Studies

Req. ID	Requirement
FR-65	The system must provide management of multi-site studies and registrations to them. This includes capturing of multiple study sites, study personnel, local IRB approvals, activations and managing accrual ceilings at each of these sites. This requires sending study activation, amendments and status change messages from the coordinating center to the sites. This also supports registration messages propagating from the sites to the coordinating center and the approval messages from the coordinating center to the sites. The system also should provide a way to manage the total accrual across the sites and a way to assign arms for studies with reservations and those that use common book for randomization.

## Hosted Mode

Req. ID	Requirement
FR-110	The system must provide the capability of allowing the affiliate sites to use the coordinating center C3PR instance to manage registrations. The system should make this configurable per study. The workflow should automatically change if the study is conducted in hosted mode. This includes conducting multi-site studies.

## Custom Diseases and Disease Sites

Req. ID	Requirement
FR-170	

## Companion Protocols

Req. ID	Requirement
FR-180	The system must provide a way to create companion protocol along with study creation. System must provide automatic registration to companion protocol while registering for study

## Integration with other caBIG systems

Req. ID	Requirement
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<b>FR-200</b>	The system must provide integration with the C3D for reserving a patient position on a study.
<b>FR-201</b>	The system must send a registration message, to be received by C3D, and then get the patient position back.
<b>FR-205</b>	The system must integrate with the Patient Study Calendar (PSC).
<b>FR-206</b>	The system must send a registration message to be received by PSC.
<b>FR-210</b>	The system must integrate with the Cancer Adverse Event Reporting System (caAERS).
<b>FR-211</b>	The system must send a registration message to be received by caAERS.
<b>FR-215</b>	The system may integrate with Study Lifecycle Tracking (PLT) system for receiving Study Lifecycle events.
<b>FR-220</b>	The system must provide integration points to facilitate integration with legacy systems existing at the adopter institutions.
<b>FR-225</b>	The system may integrate with caMatch.
<b>FR-230</b>	The system must integrate with the Cancer Data Standards Repository (caDSR) and Enterprise Vocabulary Services (EVS) (e.g. for eligibility criteria)
<b>FR-235</b>	The system must integration with the CTOM LabViewer.
<b>FR-236</b>	The system must send a registration message to be received by CTOM LabViewer.
<b>FR-237</b>	The system must provide an exception handling contingency for all caBIG integration extension points.

## OPEN Integration

Req. ID	Requirement
FR-200	

## RSS Integration

Req. ID	Requirement
FR-245	

## Custom Fields (local modifications)

Req. ID	Requirement
FR-245	

## Legacy Application Integration (integration/migration)

Req. ID	Requirement
FR-245	

## Basic Science Eligibility Criteria

Req. ID	Requirement
FR-245	

## Study Level Authorization (CCTS req.)

Req. ID	Requirement
FR-245	

## Groups of Study Personnel

Req. ID	Requirement
FR-245	

## Non-functional Requirements

### General Requirements

Req. ID	Requirement
GEN-5	The use cases for the C3PR V2.1/3.0 system call for grid-enablement. Therefore, the C3PR V2 system will be deployable as a service on the caGrid. This would entail developing an analytical service and deploying it on caGrid.
GEN-15	The C3PR V2.1/3.0 web interface should be driven by metadata registered in the caDSR.
GEN-20	The C3PR V2.1/3.0 system should be able to interact with other grid services deployed on caGrid 1.0.

<b>GEN-25</b>	An intuitive user friendly graphical user interface must be developed.
<b>GEN-30</b>	Performance is a major consideration for any enterprise system like C3PR. Web page requests must resolve in a timely manner, which essentially is on the order of few seconds.
<b>GEN-40</b>	The application will address section 508 of the Rehabilitation Act of 1973 where appropriate and reasonable.
<b>GEN-50</b>	The application will address Title 21 Code of Federal Regulations (21 CFR Part 11) Electronic Records where appropriate and reasonable.
<b>GEN-51</b>	The system must be adequately validated during the system development lifecycle
<b>GEN-52</b>	The system must provide the functionality to generate and manage accurate data records during the development processes.
<b>GEN-53</b>	The security of data records must be adequately protected to retain confidentiality, integrity and availability.
<b>GEN-54</b>	The system must limit access to authorized individuals.
<b>GEN-55</b>	The system must comply with the caBIG™ Common Security Model.
<b>GEN-56</b>	The system must be auditable.
<b>GEN-59</b>	Electronic Signatures should meet necessary requirements as described in 21 CFR part 11.
<b>GEN-60</b>	The system development lifecycle must include validity checks for all data fields.
<b>GEN-61</b>	System documentation should be maintained in a controlled environment.
<b>GEN-62</b>	System developers must adhere to the caBIG™ Data Sharing & Intellectual Capital Policy and Procedures.
<b>GEN-70</b>	The system must be caBIG silver-level compatible.

## Security

The following table contains the different kinds of user groups:

<b>System Administrator</b>	<ul style="list-style-type: none"> <li>• Is a "super-user" who manages the application</li> <li>• Approves and manages user registration process</li> <li>• Grants users to a role within the application</li> </ul>
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<b>Study Administrator</b>	<ul style="list-style-type: none"> <li>• Reviews completed Study definitions to determine if they are complete and correct</li> <li>• Determines which studies will be editable/viewable for each Clinical Research Coordinator and viewable for each Research Associate</li> </ul>
<b>Study Coordinator</b>	<ul style="list-style-type: none"> <li>• Creates new Study definitions in the system</li> </ul>
<b>Registrar</b>	<ul style="list-style-type: none"> <li>• Enrolls Participants to Studies for which approval has been granted</li> </ul>

The following is a list of security requirements:

<b>Req. ID</b>	<b>Requirement</b>
<b>NFR-5</b>	System Administrator will assign user to role (see table above) using UPT
<b>NFR-10</b>	Role-based security must be enforced throughout the SCM

## Auditing

The system must audit each and every user action that results in database access (read or write). Examples include: add/edit study or participant data, user login, query etc

The audit information must contain the following information:

- User who performed the action
- IP address of the computer from which the action is performed
- Timestamp of action
- Object and data element (i.e. table name and column name)
- Previous value and current value of the data element

<b>Req. ID</b>	<b>Requirement</b>
<b>AUD-5</b>	C3PR will capture required audit information (see list above)
<b>AUD-10</b>	Auditing information must be accessible in a timely manner to system administrators.
<b>AUD-15</b>	Auditing features must at least be available through standard database logging/auditing.

## Logging

Logging must be implemented in all the architectural layers - presentation, business logic and data access layers - of the C3PR system. Log4J, which is a well known open source logging framework will be used for implementing the logging functionality. In the case of the C3PR middle tier, logs will be written to a file that will be stored on the application server's file system. The log file for the database will be stored on the database server. This will greatly facilitate de-bugging problems that arise during the use of the C3PR system.

## Exception handling

Any runtime exceptions or errors must be reported to the user in a graphical window containing the probable cause of the problem and how to rectify that.

The exceptions and errors shall be divided into two groups:

- User errors
- OS and System/Application errors.

## Reliability

The developers will do their best, within the time-limits imposed on them, to deliver a perfectly working product. No actual guarantees to the amount of software faults (bugs) in the finished product will be made, other than the fact that the product must pass a previously created set of tests. The details of this test bench are beyond the scope of this document, and will be specified in a separate document (see the test approach).

## Portability

Since Java is platform-independent, the only portability requirement is to stay well clear of using native libraries and platform dependent 3rd party tools and java libraries.

All the paths for the local file system must not be hard coded. Example C:\myDir etc.

## Version control

The source code generated will be kept in CVS on GForge site.

## Software generation and integration

All code produced must be commented and documented. The process for building the finished product and all its sub-components from source code must be documented.

## Online User Documentation and Help System Requirements

Req. ID	Requirement
HLP-10	Help includes URLs pointing to external web sites, and the system will launch the browser with the target URL.
HLP-15	There shall be a variety of help levels and documentation formats accessible from the UI. Ex. user cookbooks with examples, FAQ, email contacts etc.
HLP-20	The Help System may allow user to store his/her own FAQ into the Help System for later use.
HLP-30	The user may be able to print the Help documentation from the UI directly.
HLP-35	Help may be context-sensitive (relevance based view of the contents) where relevant. In the web interface, mouse-over banners will indicate use of buttons and fields.
HLP-40	The help infrastructure may allow user to search within the help content based on keywords.



## End User Account Management and Login

A potential user who wants to have access to the C3PR system must have a valid username/password combination and appropriate access privileges. C3PR users will be provisioned using the User Provisioning Tool (UPT) provided by the CSM.

Req. ID	Requirement
UACCT-1	The system must allow anyone who can navigate to the C3PR URL and has a valid account with appropriate access privileges and using the browser listed in requirement ENV_5 to have access to the system.
UACCT-5	The system must provide a mechanism to specify a designated email for the system administrator.
UACCT-10	The application's help page must provide access to the following information: <ul style="list-style-type: none"><li>• Name of the System Administrator</li><li>• Email address of the System Administrator</li><li>• Phone or pager number of the System Administrator</li><li>• Instructions for contacting Application Support</li><li>• Log in functionality</li></ul>
UACCT-15	The system must allow a user to log out of the application.
UACCT-20	If a user forgets his or her password, he or she will be able to contact the System Administrator to reset the password.

## Assumptions and Dependencies

### Assumptions About System Users

AS-USER-1: All users are familiar with the basic conventions of web user interfaces. If they are not familiar with these conventions, they will be trained independently of the C3PR project.

AS-USER-5: All users are familiar with medical terminology to the extent required to do their jobs. The definitions provided as system metadata are not intended to provide comprehensive understanding of the concepts in the domain, but rather to unambiguously identify them to a knowledgeable user.

## Usability

### Design for Ease of Use

The user interface shall be designed for ease-of-use by the designated end-users, shall use terms common to the user's normal business environment, and shall require little to no additional training on the system. Drop down menus, Google-like searches, and tooltips should be used wherever appropriate.

## Sortable Columns

The results from the query execution will be shown in a tabular fashion and the user will be able to sort based on any column's data.

## Accessibility

The C3PR user interface should be accessible via a web browser.

## General Assumptions

Following is a list of assumptions

- The user is connected to the Internet continuously during a session.
- For all workflows before saving in a pending status (if possible), the user is able to maintain their session until the workflow is complete in order for the final business rules to be executed.
- The caBIG and other systems (services) used in the C3PR project are up and running so that the application can communicate with them
- C3PR doesn't support any service level auditing; it is assumed that the auditing is taken care at the individual service level.
- Every C3PR user has username and password stored in an identity provider.

## Dependencies

Dep. ID	Dependency Description
DEP-5	Since C3PR system will be based on the infrastructure provided by caGrid 1.1, there is a very strong dependency on it. We anticipate working very closely with the caGrid 1.1 development team. We will be using the interim stable builds of caGrid 1.1 during our development cycle. SSO functionality may require a version of caGrid beyond 1.1.
DEP-10	Interoperability with C3D implies a dependency on C3D, though the system can function without C3D.