



*National Institute for
Health Research*

NIHR Information Systems PORTAL USER REQUIREMENTS SPECIFICATION

Portal and National R&D Management Information System

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Distribution

Version	Name	Organisation
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1 Executive Summary

The National Institute for Health Research (NIHR) will implement a 'portal', as a single point of contact through which everyone interested in Health Research will access information about research and manage the life-cycles of research projects.

This document defines the user requirements for the portal system and for some infrastructure within which the system will operate. It also defines the types of resources that users will be able to access through the portal.

This specification derives from the **High Level User Requirements Specification**, document **NIHR 4.2 URS001** and is intended to be consistent with it. This specification does not describe the requirements for a R&D Management Information System (R&DMIS) which will be a key service offered through the portal, except to define the user interface to enter such a system.

The Portal User Requirement specification does not describe the service organisation needed to support the portal except for the tools and facilities that such an organisation would require to work effectively. The support requirements are described in the **Service Requirements** document **NIHR 4.2 SR001**.

The portal will provide a single gateway to applications, information and knowledge bases for the broad community of NIHR stakeholders including researchers, R&D managers, Department of Health managers and the research networks.

The key features of the portal will include:

- **Access/search:** To allow a user to get all the information needed (but no more) in the desired context;
- **Classification:** The portal will organise and present information so that it is delivered to each community of users within the contexts they need;
- **Collaboration:** to enable individuals to collaborate regardless of their geographical location;
- **Personalisation:** The information provided to individuals using the portal will be personalised to match that person's role, preferences, and habits;
- **Expertise and profiling:** Individuals within an enterprise will be profiled according to their experience and competencies. The portal will provide the functionality to allow members of a project to collaborate with each other based on these profiles;
- **Application integration:** The portal will allow individuals to deliver, access, and share information regardless of applications used. This will be achieved by having pre-defined interfaces that all applications will work with;
- **Security:** The portal will provide information to users according to their access rights. It will enable users to share confidential information with named individuals or with a defined target group. Users will log on and have access only to information they are entitled to see.

The resources made available through the portal will be designed to meet the needs of the target user base, but are particularly intended to reinforce the role and activities of the Topic Specific Clinical Research Networks and the Local Research Networks.

The portal will provide access to nine types of resources and applications.

- Information Resources;
- Events Calendar;
- Collaboration Tools;
- Document Repository;
- Search Facilities;
- Project/Study Oriented Facilities;
- Local Research Networks;
- Research Management Applications;
- Help Facilities.

A 'Portal Content Group' will determine the specific content of the portal.

1.1 Operational requirements

- The portal and all associated application systems must be designed to allow for continuous operation on a 24 hours, 365 days per year basis.
- The portal must be designed for an anticipated life span of at least five years and be future-proofed to manage technology changes over this period.
- The portal will offer facilities to thirty classes of users. User registration will be required for all classes of user, except for anonymous public users who will have limited access. Users who wish to register for any class will be required to provide information via an on-line form administered by the portal.
- The portal and all its publicly accessible resources will be designed for accessibility by the disabled. The portal is required to comply with style guides that are current within the DH.
- Users should be able to customise their user profile so that the content available to them can be presented in the most relevant way for their needs.

1.2 Security

- Security is a prime requirement of the portal system.
- The portal will provide access for authorised users while screening out those who do not need to view confidential data.
- A range of web transactions will need to be secured in order that users' personal details are not exposed to inappropriate view. Private data will be encrypted for transfer so that it cannot practically be intercepted by other party.
- The portal must be shown to be capable of maintaining the integrity of all the data which it controls and makes available.

2 Introduction

In January 2006, 'Best Research for Best Health' (BRfBH) was published, a strategy that describes how the Government intends to make the UK the best place in the world for health research, development and innovation.

Section 4 of the strategy – “Goal 4: Manage our knowledge resources” relates to the development of the information systems and information management processes that are required to underpin the whole of the BRfBH programme. It contains the following objectives:

- Create a ***unified knowledge management system*** to meet the needs of stakeholders;
- Use ***information systems to harmonise and simplify research processes***;
- Ensure research knowledge is made readily available to professionals in the service, researchers and the public;
- Facilitate the application of research outcomes to improve health and delivery of services.

And the commitment to implement:

- A unified and coherent system to meet our strategic knowledge management requirement;
- A single IT system for researchers and NHS research management which will “unify and simplify the administrative procedures associated with regulation, governance, reporting and NHS research administration”.

In order to meet these commitments, the National Institute for Health Research (NIHR) will implement a '**portal**', a single point of contact through which everyone interested in Health Research will access information about research and manage the life-cycles of research projects.

This work is being led by the NIHR Information Systems team which will be working closely with:

- The other BRfBH work streams, in particular the development of the NIHR Faculty and also advice services;
- UKCRN Co-ordinating Centre, to ensure the emerging research management information and systems requirements of the research networks are addressed in a strategic and integrated manner.
- Partner organisations, to ensure that NIHR systems are compatible with others used through the health and social care R&D cycle, so as to promote exchange of information across the sector when it serves the aims of the NIHR and its partners.

3 Purpose of Document

This document defines the user requirements for the National Institute for Health Research (NIHR) portal system. This specification derives from the High Level User Requirements Specification, Document NIHR 4.2 URS001 and is intended to be consistent with it. This specification does not describe the requirements for a R&D Management Information System (R&DMIS) which will be a key service offered through the portal, except to define the user interface to enter this system.

The document defines the user requirements for the portal system and for some infrastructure within which the system will operate. It also defines the **types** of resources that users will be able to access through the portal. The specification should provide sufficient information to plan and cost the development of the portal IT systems and service, although the developers may choose to produce a further functional specification to add technical detail to this user oriented content.

The specification does not attempt to list all of the portal resources, document by document and database by database, that may be added over the lifetime of the portal. That level of detail is unnecessary for the purposes of this specification. It is suggested that the question of what content should be added to the portal be managed by a 'Portal Content Group' of people who have a deep and continuing interest in the librarianship of research information. Such a group should also be charged with the responsibility for deciding on issues such as the best way to index the material made available under the portal so that it is accessible for researchers and others. The Portal Content Group will need to develop clear criteria for approving or rejecting information submitted for inclusion on the Portal. Clearly the selection of content source and indexing data is a dynamic issue that will continue for the lifetime of the portal.

The specification does not describe the service organisation needed to support the portal except for the tools and facilities that such an organisation would require to work effectively. It is however assumed that such a support organisation will be available and will handle system maintenance and administration, user support and technical liaison with other organisations, particularly information providers. The services required are defined in an accompanying document, **NIHR Service Requirements NIHR 4.2 SR001**.

4 Portal Objectives

The secure, internet web-based NIHR portal will provide a single gateway to applications for the broad community of NIHR stakeholders; and to information and knowledge bases designed around the needs of particular stakeholder communities such as researchers, research networks, R&D managers, funders and sponsors, including the Department of Health.

The key features of the portal will include:

- **Access/search:** To allow a user to get all the information needed (but no more) in the desired context;
- **Classification:** The portal will organise and present information so that it is delivered to each community of users within the contexts they need;
- **Collaboration:** to enable individuals to collaborate regardless of their geographical location;
- **Personalisation:** The information provided to individuals using the portal will be personalised to match that person's role, preferences, and habits.
- **Expertise and profiling:** Expertise and profiling is essential for the collaboration element of a portal. Individuals within an enterprise will be profiled according to their experience and competencies. The portal will provide the functionality to allow members of a project to collaborate with each other based on these profiles.
- **Application integration:** The portal will allow individuals to deliver, access, and share information regardless of applications used. This will be achieved by having pre-defined interfaces that all applications will work with;
- **Security:** The portal will provide information to users according to their access rights. It will enable users to share confidential information with named individuals or with a defined target group. Users will log on and have access only to information they are entitled to see.

The portal will provide:

- A single point of contact for all defined users to obtain information about NHS research.
- A single point of access to a standard nationwide suite of applications (the R&DMIS) built around the needs of health and social care researchers, research networks and research managers. These will cover the submission of information for applications, approvals and permissions, and for the continuing management of individual studies, programmes and portfolios of R&D
- A single point of entry to a document repository containing reports from research projects, all research policy documentation and any other quality controlled research information. All documents in the system will have document control information such as date modified, modified by etc.
- Access for the general public to information about research projects that are carried out within the NHS, or which require access to NHS patients.
- Easy access to guidance and other resources for researchers to draw on when developing high quality protocols and applications for funding. These will complement the planned national advice service on regulatory issues.
- Improved communications between research teams by providing moderated discussion groups.
- A facility that will enable the Department of Health to gather (with its associated R&D Management Information System) good quality statistics about the status of all NHS research projects, both sponsored and funded by the NHS.

- Controlled access to all the data resources and applications that it contains.
- Support for the work of the Comprehensive Research Network, the Topic Specific Clinical Research Networks and within them the Local Research Networks, covering cancer, dementias and neurodegenerative diseases, diabetes, medicines for children, mental health and stroke, together with a Primary Care Research Network.

The portal could (in addition) provide a 'home' for the proposed Institutional Repositories enabling greater access to research findings for interested researchers, academics and members of the public for documents that have been actively peer reviewed.

4.1 Practical Examples of Portal Usage

Examples of the use of the portal by different types of users to carry out specific tasks could include:

- A chief investigator putting in an application for a new project. In this case the chief investigator might use the portal to review procedures and other applications that they have recently submitted. The investigator might then use the R&DMIS to initiate the application.
- An R&D manager for a participating organisation looking up protocols for a specific project. In this case the authorised manager would expect to find the information required through the portal search facilities and the information resources associated with the portal.
- A GP looking for a trial to enrol their patients in. The GP would use the portal to search for trials that are under way or planned and could then use the collaboration features of the portal to get further information about the trial, and where appropriate, to enrol patients.
- A patient looking to volunteer/participate in research. Since the portal will provide public access to information related to trials, a patient could use it to search for this type of information. However a patient would not directly be able to access the R&DMIS or confidential information about the trial. In order to participate, the patient would need the cooperation of a person with the appropriate access rights, such as a GP or a consultant.
- A pharmaceutical company looking for investigators with an interest in research in a particular area. This scenario will be covered by the portal through the search and collaboration features.
- A researcher looking for "grey literature" (i.e. unpublished results or ongoing trials) made available by the moderation procedures described in this specification when conducting a systematic review (e.g. for the HTA programme or for NICE). Accredited researchers will have access rights that will allow them to review the results (or existence) of trials where the research team responsible has permitted this.
- At a network level, network managers could use the portal to record and monitor local interest in a national study portfolio by identifying research projects which are relevant and appropriate for their local research community. This information could be used to broaden involvement in research projects, improve recruitment

rates and balance a local study portfolio across research interests, to ensure research activity is not focussed in specific areas only.

- The support of initiatives like COMMIT (Consumer Oriented Communication and Information Technologies Project). This is an initiative by UKCRN in association with NCRN and Macmillan Cancer Support. COMMIT envisages a set of web-based group of tools and services which addresses the communications needs of patients, carers and other members of the public involved in providing user-oriented input to clinical research.
 - COMMIT will provide:
 - Controlled access for main functions with registered users who may be consumers, researchers or clinical investigators;
 - One-to-one, many-to-one and one-to-many communications;
 - Registered users can create own discussion fora as open or private, input own documents, add own links, join open discussions etc.;
 - Users can define documents to be accessible to public;
 - Public area aimed at both research awareness and at providing an assured route to accurate information.
 - The Portal will meet the aims of COMMIT and other similar initiatives. Its outcomes and functionality have been covered in this user requirement specification.

5 Portal Resources

Portal resources are designed to meet the needs of the target user base, but are particularly intended to reinforce the role and activities of the Topic Specific Clinical Research Networks and the Local Research Networks.

The portal will provide access to nine types of resources and applications.

5.1 Information Resources

These resources will consist of:

- Static information, maintained by organisations associated with the portal or by the Portal Managers directly. Examples of this type of information resource are:
 - How-To documents such as how to write a research proposal;
 - Flow charts showing the typical stages in mounting a research project;
 - The location of training courses for researchers.
- Database oriented information, actively managed and updated that can be queried by users. Examples of this type of service are:
 - Sources of funding for different types of research;
 - Organisations offering courses for researchers.

The portal will provide an ad-hoc reporting facility to allow users to specify parameters and produce bespoke reports based on the contents of any selection of the information made available by the portal.

Some information resources, such as the National Research Register (NRR), should be publicly accessible (as they are currently) but they may also form part of the scope of the R&DMIS. In these cases, the publicly accessible information may be simply a read-only view of the data maintained as part of an R&DMIS database.

Information Resources will be drawn from a wide range of different sources, including:

- Documents produced specifically for the portal and stored in the portal;
- Documents that are copied from other health related sources;
- Information resources that are actively managed by other organisations but use the portal as the primary method of making them available to the target user population.

In some of these cases, the portal will use links to the primary source where this is the most effective method. The portal must be able to handle such linked documents. Where these links are URLs, the portal must also be able to manage broken links by providing reports on broken links for easier maintenance.

5.2 Events Calendar

The events calendar will contain details of meetings and other events that may be of interest to the full breadth of the portal user community. These events will be classified according to type and will be searchable based on user defined criteria. Events can be added to the calendar by a specific, authorised set of users. The events calendar will support at least the following types of events:

- National;
- Regional;
- Topic based, through the Topic Specific Clinical Research Networks where these cover the topic;
- Project/Trial based.

Users should be able to define the format in which event calendars are displayed, to include:

- Period – weekly, monthly, yearly;
- Ascending or descending date order.

For specified formats and client mail applications, users should be able to download all or part of the event calendar into their local diary systems using a standard calendar format. Similarly, users should be able to synchronise the events calendar with Outlook and other commonly used calendar software.

5.3 Collaboration Tools

The portal must provide tools that support the creation and use of discussion forums in which registered users can participate. This might be through newsgroups – a service based on the Network News Transfer Protocol (NNTP). To deliver news services in this way, the portal must be able to operate as a news server hosting news groups of interest to the research community. All news groups will be moderated. The discussion forums must support threaded discussion with the ability to search any or all forums for content. All contributors to forums must be registered.

Other methods of hosting discussion groups, (including the use of proprietary tools) are also acceptable, provided that the design constraints defined in Section 12 are fully met.

The portal must be capable of providing external alerts and links to users requesting this type of service. For example:

- Alerts – email messages that are generated when ever a change occurs in a specific document or a group of documents. Alert emails should contain a reference in the form of a link to the document or directory that has changed. Users should be able to add or delete alerts at any time.
- Really Simple Syndication (RSS) feeds – the portal must provide the capability to produce RSS feeds to which users can subscribe. The RSS feeds should indicate which documents or groups of documents have been changed or added, as well as any other significant newsworthy information.

- The use of Short Message Service (SMS) messages as alerts for specific types of changes. Messages of this type should be an optional feature configurable by the user.
- The use of iCalendar or iCal format to allow users to send meeting requests and tasks to other users through emails, who can then readily respond to the sender.

The Emergence of Web 2.0 will present further opportunities to expand the capabilities of the portal in collaboration and social networking. This might include:

- Social bookmarking capabilities such as that provided by 'del.icio.us' a web service provided by Yahoo!
- Open, free content knowledge sources based on the approach taken by Wikipedia (a multilingual, Web-based free content encyclopaedia).

These capabilities will be assessed, and where found useful to the research community, added to later versions of the portal.

5.4 Document Repository

These resources will consist of static information placed in the public domain and approved for publication by DH. These resources could take the form of reports, presentations etc. that are the result of research projects that fall within the NIHR domain, carried out within the NHS, involve NHS patients, or other DH sponsored studies.

The Document Repository is intended as an enabling facility, not a mandatory deposit requirement for researchers. There are other document repositories which may be more appropriate for the storage of research reports and these are briefly discussed below.

Documents can be added to the repository by any registered researcher, resource maintainer or by DH officials. Documents added to the repository will not have general anonymous public accessibility unless they are released for this purpose.

Documents that contributors consider may be candidates for public release will be flagged as such by the contributor. A queue of documents awaiting release will be maintained by the portal. A moderator (see Sections 7 and 10) will review documents flagged for release and waiting in the queue. Documents that meet the standards set by the DH can be flagged as 'released' by such moderators, who may wish to obtain the opinions of other persons on such documents before allowing their release.

The portal will support the use of metadata to describe the contents of each of these resources. The metadata is to be added by the authors of the reports or by content specialists. This specification does not formally define the standard to be used for such metadata, only that it should be possible to add such data and that it will be searchable. The question of what standard or standards will be used is outside the scope of this document and should be decided (if decision is required) by the Portal Content Group (see Section 1). Possible choices include compatibility with metadata harvesters that follow the Open Archives Initiative Protocol for Metadata Harvesting (OAI-PMH) and/or the Dublin Core metadata standard. Further information on standards such as this can be found in Section 12.1.

Some documents may benefit from being made available in multiple versions so that the change over time is made visible. The portal will allow such document versioning on a selective basis (i.e. the portal will not, by default, store all versions of all documents). Where document versions are stored or made available, searches should be possible over multiple versions in a particular time frame or more selectively for a range of versions.

In general, documents will be made available from the document store in read-only format using PDF.

The repository could also include Research Ethics Committee (REC) application form (with electronic signatures when available), patient information sheets, consent forms etc, and study protocols.

5.4.1 UK PubMed Central

The contract to run UK PubMed Central (UKPMC) has been awarded to a partnership between the British Library, The University of Manchester and the European Bioinformatics Institute (EBI). UKPMC will adopt a similar role to PubMed Central in the USA, and will provide free online access to published reports. The document repository facilities described in this specification are not intended to replace or duplicate any of the UKPMC functions. The portal should provide the facility to link to specific documents that are stored in UKPMC (and other specified document repositories) where this appropriate.

5.5 Search Facilities

The document repository and other portal facilities will accumulate significant volumes of information and will require a sophisticated search capability so that users can select the documents that match their needs.

The portal must offer 'smart' search capabilities. The user must be able to search the entire portal for any resource that the user is allowed to access and to retrieve any matching resource. The search criteria must include:

- Keywords;
- Metadata;
- Topics;
- Topic Network;
- Institutions and organisations;
- Project references.

The search facility must provide for text matching based on a text string where the match is to any combination of:

- an exact match to the text string;
- all of the words in the text string;
- at least one of the words in the text string;
- wild card searches using either simple wild cards such as * (match any string) or ? (match any single character). Users should also be able to compose more complex search strings using simple regular expressions. This type of search

should be an option accessible as an 'advanced search' so that users who are not familiar with this method are not confused.

- advanced search options including Boolean Logic statements such as 'Not' 'And' 'Or' as well as multiple field based searches.

Searches should also be possible on:

- a specific file format;
- type of result (e.g. the study project site or a list item such as a task or contact);
- a date range when the report was added to the repository;
- date when last modified;
- metadata attached to a resource. Metadata should be searchable using wild cards in the same way as content text as described above.

Users who have the appropriate access rights should be able to access all documents directly associated with a specific trial or project. Start and expiry dates for access for specific projects should be set and monitored. This facility may be limited in capability until the R&DMIS is fully functional and the portal is able to look up such project links within the R&DMIS database, but it is an important part of the functionality of the portal and should be provided as soon as possible.

Where a search returns many results, the user must be able to scroll through the results and/or narrow the results range using a further search.

The document repository will contain files that will have a wide variety of access restrictions. The search must only return those documents to which the user has access rights. If a user's search matches resources to which the user has no authorised access, the search facility must not indicate the existence of such matches. The search facility will contain a warning advising users that if the search identifies documents for which they do not have access rights, these will not be displayed.

The user must be able to select any document from a search for reading directly through the browser, or for downloading to their PC.

The portal will display the size of every resource in a listing so that the user will have an indication of the time that will be required to download and read it.

The proposed NHS-Wide Enterprise Architecture described in Section 12.1 will, once fully established, enable the possibility of cross-NHS searches of document repositories. This would be an invaluable feature for researchers and implementers should review the appropriate standards defined in that Section to ensure that their solution is potentially capable of making use of this development.

5.6 Project/Study Oriented Facilities

The portal must offer pre-defined combinations of resources that would be valuable to a research project or trial, so that the whole set of resources can be set up in one operation. At minimum the set of resources will be:

- A project document repository;
- Templates for documents such as protocols, contracts etc. (shareable across many projects);
- Study event calendar; milestones, tasks etc.
- Project Lists (To Do work items, issues etc);
- Current status of project/study;
- Meeting notes and outcomes;
- Collaboration tools;
- Contact information (including key organisational contact details);
- Financial Information including budgets, costs etc.

These resources should be accessible only to members of the same project team.

The portal should provide on-line chat facilities so that members of a research team who may be geographically scattered can communicate text, graphics and calendar information in a real-time conversational manner. The portal should enable such facilities to be strictly controlled, logged and restricted to the members of a research team.

5.7 Local Research Networks

The Local Research Networks of the Topic Specific Networks have some specific requirements that will be met by the portal and the R&DMIS in combination. For example,

- Local trial management;
- Accrual tracked at a local level;
- Financial Management of studies (not the networks themselves) at a local level.

The main functionality to support these functions will come from the R&DMIS, not the portal, but the portal should provide a facility similar to the Project/Study capability in Section 5.6 above so that data from a selection of studies can be aggregated and managed in a local environment.

Some of the other project/study oriented facilities would also be useful in this local network environment:

- Templates for documents such as protocols, contracts etc. (shareable across many projects);
- Project event calendar;
- Project Lists (To Do work items, issues etc);
- Current status of project/studies;

- Meeting notes and outcomes;
- Collaboration tools;
- Contact information;
- Financial Information including budgets, costs etc.

5.8 Research Management Applications

This specification does not cover the R&D Management Information System that will be provided, nor any other such management application. The user specification of the R&D Management Information System is covered in document NIHR 4.2 URS003. However, the portal must provide the required architecture and tools to operate such applications and make them a seamless part of the portal.

5.9 Help Facilities

The portal will provide comprehensive help facilities so that a user with no prior experience of similar portals will be able to use the facilities effectively. Help facilities should include:

- Help menu;
- Help buttons;
- 'Wizards' for specific, more complex functions;
- On-line training courses.

The R&DMIS will provide its own comprehensive help facilities as should any other application accessible through the portal.

6 Phasing of Requirements

The portal and its associated resources will be made available in three phases. Basic Portal, Advanced Portal and with the R&DMIS incorporated. These are shown in the Table 1 below.

Ref ¹	Functionality	Start of Implementation	Fully Implemented	Release	Notes
5, 5.9	Basic Portal	March 2007	March 2007	March 2007	
5.1	Information Resources	March 2007	September 2007	September 2007	Continuous development
5.2	Event Calendars	April 2007	June 2007	September 2007	
5.3	Collaboration Tools	May 2007	July 2007	September 2007	
5.4	Document repository	March 2007	September 2007	September 2007	Continuous development
5.5	Search Facilities	May 2007	May 2007	September 2007	
5.6,	Project oriented facilities	August 2007	September 2007	September 2007	
5.7	Research Management applications	September 2007	April 2008	April 2008	

Table 1 - Phasing of Requirements

The roll out of portal requirements as defined in this table will be organised through the Clinical Research Networks, for the topic areas that they cover. While the system will be released simultaneously across the network, each CRN will be responsible for the promotion of the system within their network community.

¹ Refers to the sections of this specification document

7 Users and Roles

The portal will offer facilities to thirty user types grouped within sixteen classes of users, carrying out the roles defined in Table 2 below. R&DMIS roles are more fully defined in the R&DMIS specification.

User Class	User Type	Examples	Roles ²	R&DMIS user?
Anonymous public				
1	Public	Patient, Student, General academic interest as non-accredited researcher. Patients who are looking for details of trials to join	Browse information concerning medical conditions, research projects, general NHS policy etc.	N
Researcher³				
2	Chief Investigator (CI)	In charge of whole project and is agent of sponsor	Review and contribute information to specific projects. Create research applications. Contribute research papers Can access everything to do with the project	Y
3	Principal investigator (PI)	Specific to a site, reporting to the CI	Access to data on their site only.	Y
4	Research Nurse	Typically specific to a site	Work on specific trials, assist with recruitment	Y
5	Trial Project manager	Project management	Manages the detail of a single trial	Y
6	Non-clinical Researcher	Research fellow, PhD or MSc Research student	Interest in medical research projects	Y
R&D Manager				
7	R&D Manager	R&D Manager in NHS Trust. Manages a portfolio of trials	Review research applications, Manage applications and projects for a specific organisation	Y
NIHR Faculty Member⁴ / Honorary NIHR Faculty Member⁵				
8	Investigator	Researchers (the main element of whose salaries related to research is a "research cost")	Similar to researcher roles 2,3,and 6, but with access to additional Faculty based content	Y

² Members of professional bodies will have access rights associated with the role they undertake.

³ "Researchers" include researchers who have a project in development, as well as approved.

⁴ The NIHR Faculty will encompass research, clinical and support staff from all relevant professional backgrounds. Faculty members will be those individuals who conduct or support patient- or people-based research; and whose salary is funded, in part or in whole, from NIHR funding and/or DH Policy Research Programme (PRP) funding; and who are employed by an NHS organisation or by a University. The NIHR/PRP funding which supports a faculty member's salary may be paid directly to their employer, or may be paid to a partner organisation which then makes a funding transfer to the faculty member's employer.

⁵ Honorary Faculty membership will be offered to individuals who are not Faculty members; and who are conducting or supporting people- or patient-based research. This will encompass individuals employed by partner organisations including Industry.

9	Senior Investigator	The most outstanding leaders of patient and people-based research, selected from NIHR Investigators through competition.	Similar to researcher roles 2,3,and 6, but with access to additional Faculty based content	Y
10	Associate	Faculty members who support research led by others (the main element of their salary related to research is a "service support cost".)	Similar to researcher roles 3, 4 and 6, but with access to additional Faculty based content	Y
11	Trainee	Researchers whose salaries are supported through NIHR research training schemes	Similar to researcher roles 2,3,and 6, but with access to additional Faculty based content	Y
12	Honorary Investigator	Researchers conducting or supporting people-based research, employed by partner organisations including Industry.	To be determined. Access to Honorary Faculty content.	N
Clinician Enroller				
13	Clinician Enroller	A GP or other clinician who would like to enrol a patient in a trial	Review details of active research projects and trials that are in planning	N
Network Manager				
14	Topic Specific Network manager	Cancer network, Comprehensive network	Manage activities in a topic specific network	Y
15	Local network manager	Network manager for one of the thirty three regional cancer networks	Manage activities in a local network	Y
Funder				
16	Funder	Research Funder (both public and commercial)	Review projects that require funding Gather information about funded projects e.g. approval status, recruitment figures, trial documents etc	N
Regulator/Approver				
17	MHRA drug trials approver	N/A	Drug trials approver.	Y
18	MHRA devices approver	N/A	Device trials approver	Y
19	PIAG	N/A	Patient Information approver	Y
20	GTAC	N/A	Gene Therapy approver	Y
21	RATE	N/A	To be defined	Y
22	COREC	N/A	Ethics approval	Y
Resource maintainer				
23	Resource maintainer	Providers of information about funding sources	Maintenance of specific information resources	N

Moderator				
24	Moderator	Collaboration tool – discussion forum and document release moderator	Edit/exclude contributions as necessary	N
Policy and oversight				
25	Policy and oversight	DH	Overview of all NHS projects, Extraction of statistics, Overview of all information resources and tools	Y
Registration approver				
26	Registration approver	DH, Research Managers	Approving the registration of users	N
Systems Administrator				
27	Systems Administrator	Members of Portal management Team	Access to all Portal facilities	Y
Sponsor				
28	Sponsor	NHS Trust, University, pharmaceutical company and other institutions	Make applications, review approval status, recruitment figures, trial documents etc.	Y
Business administrator				
29	Financial Administrator	NHS Trust, University, pharmaceutical company and other institutions, financial admin in trust	Approval status, recruitment figures, trial documents etc.	N
Media				
30	Media	Journalist and other accredited members of the press	Access all published information and press releases available through the Portal	N

Table 2 - User Classes and Roles

This list of Users and Roles will need to change over time to accommodate new types of users and new portal facilities. The portal design must allow for the extension (or reduction) of the list of user classes, and must ensure that such a change can be carried out only under the direct control of the System Administrators and the Policy and Oversight (DH) personnel in combination. Such a change is a potential source of security breaches and must be strictly controlled.

7.1 User Registration

No user registration will be required for user type 1 – Anonymous Public. These users will be able to access the portal and browse all resources that are not specifically restricted to other user types. No identification will be required for this class of user. The portal will, however, track usage by all users including user type 1 users and retain statistics about visits. (See Section 14 below for details.)

User registration will be required for all other classes of user. In order for these users to take part in the exchange of, and gain access to information, they will need to apply for a digital certificate.

User registration will be handled in different ways depending on the class of user. In general, user registration will be approved by a 'Registration Approver', who will be a person recognised either directly or indirectly by the DH. The objective is to establish a chain of trust for all users and registration approvers. Registration approval will be based on defined pre-requisites.

Facilities will be needed for the removal of user registrations and notification to the user, based on agreed procedures. Policies and protocols will need to be devised to ensure that Clinicians and Health Care Professional who have been suspended or removed from their respective professional register have their access rights to the Portal amended immediately.

Table 3 below shows the methods to be used for user registration for each user type.

User Type		Registration Pre-Requisites	Registration Approver⁶
Anonymous public			
1	Public	None	None
Researcher			
2	Chief Investigator	Recognised research leader	To be defined in R&DMIS specification
3	Principal investigator	Recognised research leader	To be defined in R&DMIS specification
4	Research Nurse	Member of an approved research project	Research Manager, facilitated by possession of a valid Research Passport
5	Trial Project manager	Member of an approved research project	Research Manager, facilitated by possession of a valid Research Passport
6	Non-clinical Researcher	Member of recognised non-medical UK academic institution	Proposed by recognised UK academic institution
R&D Manager			
7	R&D Manager	Employee of NHS Trust or other organisation recognised by the DH	To be defined in R&DMIS specification
NIHR Faculty Member/Honorary NIHR Faculty Member			
8	Investigator	Membership of the faculty as an investigator	Faculty
9	Senior Investigator	Membership of the faculty as a senior investigator	Faculty
10	Associate	Membership of the faculty as an associate	Faculty
11	Trainee	Membership of the faculty as a trainee	Faculty
12	Honorary Investigator	Membership of the faculty as an Honorary Investigator	Honorary Faculty
Clinician Enroller			
13	Clinician Enroller	Registered clinician	DH
Network Manager			
14	Topic Specific Network manager	Employee of NHS Trust or other organisation recognised by the DH	To be defined in R&DMIS specification
15	Local network manager	An employee of an organisation that has funds available to support research or that has made such funds available in the past.	DH
Funder			
16	Funder	Research Funder (both public and commercial)	DH
Regulator/Approver			
17	MHRA drug trials approver	Member of the recognised regulatory group	DH
18	MHRA devices approver	Member of the recognised regulatory group	DH
19	PIAG	Member of the recognised regulatory group	DH
20	GTAC	Member of the recognised regulatory group	DH

⁶ The registration approver approves the registration for the associated class of user.

21	RATE	Member of the recognised regulatory group	DH
22	COREC	Member of the recognised regulatory group	DH
Resource maintainer			
23	Resource maintainer	Designated employees of maintaining organisation	DH
Moderator			
24	Moderator	Designated person for that particular resource	DH
Policy and oversight			
25	Policy and oversight	DH employee	Senior manager DH
Registration approver			
26	Registration approver	Validation of identity and role	DH
Systems Administrator			
27	Systems Administrator	DH employee	DH
Sponsor			
28	Sponsor	Member of NHS Trust, recognised UK academic institution or pharmaceutical company	Proposed by NHS Trust, recognised UK academic institution or pharmaceutical company
Business administrator			
29	Financial Administrator	Member of NHS Trust, recognised UK academic institution or pharmaceutical company	Proposed by NHS Trust, recognised UK academic institution or pharmaceutical company
Media			
30	Media	None	DH

Table 3 - Registration requirements

The possession of a valid Research Passport will make the approval of a registration request a much faster process. The Approver need only check that the passport is valid and appropriate for the class of registration. Where the Research Passport is given on a per-project basis, the system will record and track the date of expiry of the passport and automatically remove the registration at that time.

Users who wish to register for any class will be required to provide information via an on-line form administered by the portal. This information will be forwarded by the portal to the appropriate approver. On approval, the user will be provided with Digital Certificate which can be used to access the relevant parts of the portal.

A user who wishes to access controlled parts of the portal will be required to log in once only for every session with the Digital Certificate and will then be granted access to all the areas relevant to that user type.

Within a user class such as Researcher or Research Manager, access will be granted only to those resources that belong to the Researcher or are managed by the Research Manager.

It will be possible for a user to belong to several different classes. The user will initially be registered for the class that most closely fits their normal role (a primary class) but the user can also then apply for registration for secondary classes. No matter how many classes a user is registered for, they will only receive one

certificate. The portal must maintain an up to date record of the classes that the certificate is valid for and provide the user with the logical union of all the access rights that the combination of registrations will provide. In this way, the user will require only one certificate to log in to the portal and all associated systems such as the R&DMIS.

Some combinations of registration should not be allowed for security reasons.

These combinations may require modification as experience is gained in the operation of the portal and it should be possible for the Systems Administrator to make this change. The portal must ensure that these constraints are enforced. Note that any of classes 2-30 inclusive could also act as anonymous public class 1 in their private capacity.

See section 14 below for full details of the security implications of user registration.

8 User Interface Characteristics

The portal and all its publicly accessible resources will be designed for accessibility by the disabled.

Users should be able to customise their user profile so that the content available to them can be presented in the most relevant way for their needs.

To facilitate this, the portal will provide different layouts for each of the user types defined in Section 6. These layouts will display links to resources that are accessible to that class of user, and not those that are not accessible.

The portal will provide tools and interfaces such that applications which are accessed through the portal have a consistent look and feel.

All resources will carry a clear copyright notice where the resources are not in the public domain.

8.1 Portal Look and Feel

The portal is required to comply with style guides that are current within the DH. The portal look and feel should be upgraded as and when the DH determines that a new branding is required for its web-sites and portals.

The current guide for NHS identity is available at <http://www.nhsidentity.nhs.uk/websites/index.htm> and this guide must be followed for the portal except where there is a conflict with this specification. In those cases, this specification is to be followed.

All resources accessed through the portal will use a consistent title bar that will clearly identify the NIHR.

Sample Cascading Style Sheets (CSS) code that is used with the current NIHR web site is available on request. The CSS is for information only and does not form part of the requirements of the specification.

The DH is considering the introduction of a new look and feel for the portal that would have an entirely fresh image, modelled more along the lines of the major search engines. The portal must be able to accommodate such a radical revision of branding without major changes to core code or functionality.

8.2 Personalisation of the Portal

The portal must offer personalisation features to registered users. The personalisation settings should be stored in a user profile⁷ that the user can change in a simple fashion. Personalisation will include:

- A welcome message that greets the user by name on entry to the portal.
- The selection or suppression of types of information resources so that resources the user is not interested in seeing are not displayed. This feature is not intended to increase the range of resources that the user has access to, only the filtering of the available resources.
- User created bookmarks so that the user is able to rapidly select a resource that they have viewed and found useful in the past. A list of bookmarks will be optionally displayable on entry to the portal.
- A 'History' feature recording the history of document retrieval from the portal. The history facility should be user configurable so that the number of entries or the time over which the history is kept can be controlled.
- The user profile should also show the users class registrations and the resulting access that this permits. This section of the profile should be read-only – the user should not be able to change it.
- A significant aspect of personalisation is an interest in a Topic Specific Clinical Research Network or the Comprehensive Research Network. Users who have this orientation, or whose primary interest is in the topic, should be able to select a user profile which gives them access to a fully tailored default view of the portal. The design of this network specific profile should be partly devolved to the network itself so that the selection of features and content, and even the look and feel can be specified by the network and automatically made available to all users who have registered their interest in that network. The choice of such a profile should not in any way prevent a user from adding other personalising features and accessing any of the resources for which they are registered. The intention is simply to provide a useful starting point for personalisation.
- Similarly a user must be able to personalise their profile to suit the particular needs of a Local Research Network, so that they can conveniently track a portfolio of trials through local regulatory processes etc.

⁷ A profile is a list of features that defines the portal's look and behaviour to suit a user's preferences and requirements within the access rights granted.

9 Documentation

It is essential that the effective documentation is available for the portal, the R&DMIS and any other systems that are operated through the portal.

The following minimum set of documentation will be provided to support the use of the portal.

Documentation name	Type	Purpose
Portal User Guide	User	Describes the functions that a user can perform in the portal itself.
Portal Systems Manual	System	Describes the operation of the portal systems from the perspective of a system manager, describing all the functions needed to keep the portal operating correctly.
Portal Business Continuity Plans	System	Describe how the portal can be recovered from a disaster. This should contain Crisis Management plans and the method of invoking a recovery site or facility.

User documents must be presented through the portal and made available for download in Portable Document Format (PDF). System Documentation is intended primarily for internal portal management team use and will not be made available through the portal.

Documentation must be under configuration management and document control information provided at the start of the document in the same way as this document.

10 Portal Management

The portal system will provide tools to help the efficient management of the portal. This will include:

- Statistical tools that will allow the extraction of data and production of reports about all aspects of the usage of the portal.
- Administrative facilities that can manage the portal as a whole and control all data associated with it.
- The portal should have easy to use tools for the management of users. This will include
 - Reports on registered users;
 - Tools to remove user registration;
 - Tools to manage digital certificates;
 - Tools to change user's access to resources.
- For ease of maintenance, there must be a copy facility so that similar users can be given the same access rights without duplicating data.

The portal will present Portal Managers with lists showing actions that are pending and need attention. This will include:

- Registrations awaiting approval;
- Changes requested.

The portal will present moderators with lists showing actions that are pending and need attention. This will include:

- Contributions to forums that require checking for release to a forum;
- Documents that require review before being made publicly available.

The portal will provide tools that will help System Administrators manage applications (such as the R&DMIS) so that such applications can be added to or removed from the portal environment easily.

The portal will provide tools that can analyse and report on the logs that are produced so that the Portal Managers can extract useful information about:

- Volume of usage;
- Trends in usage;
- Amount of data transferred;
- The profile of usage across a specific date range;
- And any other such information.

The portal will provide tools that will help System Administrators archive documents to off-line storage on a selective basis and allow for their rapid retrieval on demand from this archive. The use of SAN technology may make it less important (or unnecessary) to archive material off-line.

The portal will provide tools that assist with the auditing of usage – This will include the capability to design and implement reports that analyse the way in which the portal is being used. These tools should also report on incidents of non-usage where recorded logins are associated with no apparent use of the portal. The portal must provide tools that will report on attempts at unauthorised access. See Section 14 for further details.

11 Performance Requirements

11.1 Anticipated Use

Initially the system must simultaneously support:

- A throughput of 2000 new research applications per month;
- 1000 concurrent users⁸ for the portal services.

The system must be designed to allow scalability to:

- A throughput of 4000 new research applications per month;
- 1500 concurrent users for the portal services.

The performance requirements above are for sustained average loading, measured over a period of 4 hours. In addition, the portal must be capable of sustaining a peak loading of 30% in excess of these performance levels for a period of 30 minutes maximum.

The proposed design architecture should be incremental and enable the increase in the users to be met by the addition of hardware and software at a cost proportionate to the increase in performance

11.2 Data Volumes

The portal must provide facilities to store and make available the following minimum numbers of documents. The total includes all documents managed directly by the portal, but excludes those that are stored in other systems and to which the portal simply maintains links. The predicted data volumes are shown in Table 4.

End Year 1	End Year 2	End Year 3	Growth Year4 onwards
100,000	150,000	200,000	15% p.a.

Table 4 - Predicted data volumes

An average document is assumed to be 500KB.

A document is assumed to be a single version. In some cases, multiple versions of key documents may need to be maintained. Each of these versions will be considered to be an individual document for the purposes of data volume calculation.

The data volumes assume that from Year 4 onwards the document repository will be managed so that older and less requested documents will be progressively archived to off-line storage. Such documents should be capable of restoration to the portal on request.

It would be desirable to maintain all documents on-line and the use of Storage area Network (SAN) technologies may make this feasible and easier to manage than off-line archival. In this case, the growth rate for year 4 and thereafter should be pro-rata that for year 2 to 3.

⁸ '1000 concurrent users' means 1000 different persons accessing the portal at the same time.

11.3 Performance Requirements

The system will deliver the performance characteristics shown in Table 5 given these sizing requirements. The system must respond to requests as indicated in the following table e.g. in a request for any static data the download must start within 2 seconds of completing the request. These are the minimum requirements.

Function	Performance Requirement
Home Page	1.5 seconds
Static Information Resources	2 seconds
Dynamic Information Resources	5 seconds
Event Calendars	2 seconds
Collaboration Tools	7 seconds
Document repository	2 seconds
Search Facilities	10 seconds
Project oriented facilities	5 seconds

Table 5 - Performance requirements

Note that these performance requirements exclude the R&DMIS system.

Measurement will be made from the completion of the key stroke which sends the request from the client to the receipt of the first byte of the response back from the portal by the client.

Performance is to be measured so that the bandwidth and latency of the network between the web server and the user's machine does not contribute to the response time, i.e. performance will be measured with a direct connection to the web server, not through the Internet.

The system will undergo appropriate load, stress and performance tests to ensure that it responds within the required parameters for initial use and future transactional volumes. i.e. all current users, and expected numbers of future customers.

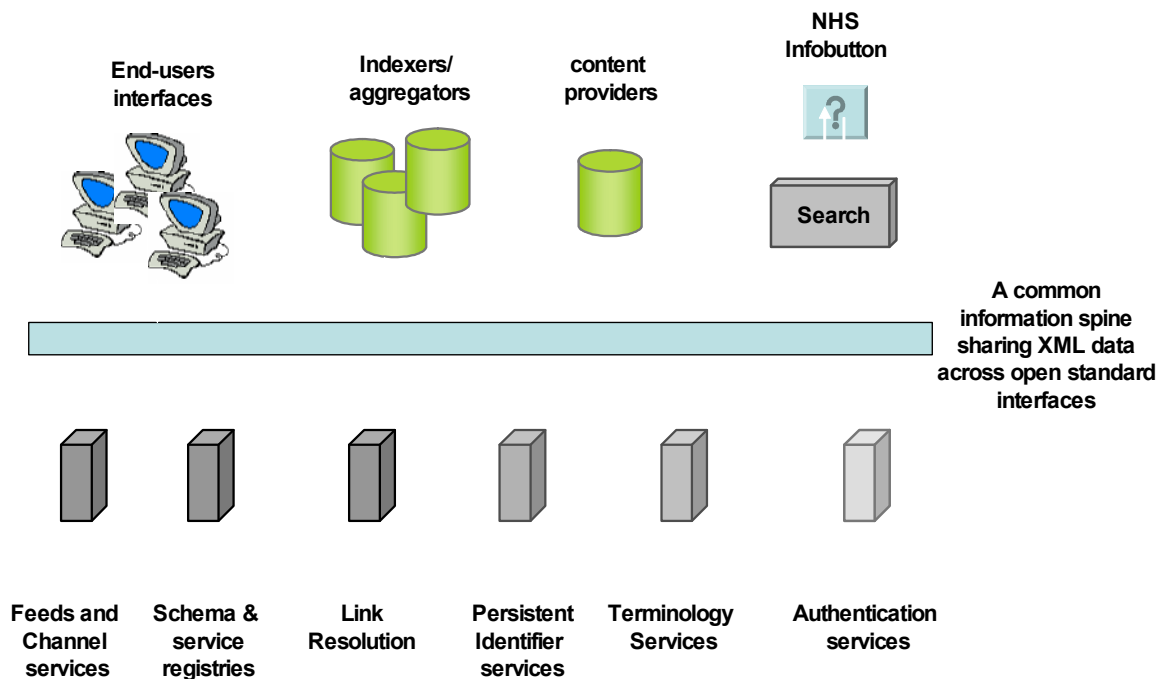
12 Design Constraints and Standards

Compliance with design constraints and standards is critically important in order that the portal can deliver information to all the defined user population.

12.1 Proposed NHS-Wide Enterprise Architecture

This architectural proposal covers library and knowledge management systems and is currently under construction. Since the portal has these functions (amongst others), the portal should aim for compatibility with this emerging internal standard architecture. The full definition of the architecture will be available from the NLH who have established a Design Authority to lead this work. This definition will include a web accessible metadata schema registry, collections register and service bindings.

The overall model of the proposed architecture is shown in the Figure 1 below:



After - Andy Powell (UKOLN, University of Bath), 2005

Figure 1- Proposed NHS-Wide Enterprise Architecture

In the case of the portal, the architectural components on the top of this 'spine' could map to the requirements in this specification as shown in Table 6 below.

Component	Section	Content
End User Interfaces	5, 8, 12	User functionality, presentation and associated standards
Index, Aggregation	5.3, 5.6	RSS feeds and similar services
Content Providers	5.1	Organising the presentation of content from other organisations
Search	5.5	Search facilities are required throughout the portal and for users from other NHS domains who are registered to access the portal

Table 6- Mapping of Requirements to the Model

The full scope of the planned services offered by this architectural model is:

- **Service Registry**
The Service registry will provide metadata about the services available and the document collections available through those services or the possible translations.
- **Preferences Service**
This service returns the profile of the user and their institutions so that choices can be presented.
- **Terminology Services**
Loads the vocabularies used to drive the collection search/browse interfaces.
- **Search/Browse Service**
Accepts structured queries on document collection(s) and allows the user to navigate results.
- **Link Resolution Service**
Takes openURLs and resolves them to the URIs of the appropriate services.
- **Identifier Resolution Service**
Takes URIs and returns the physical location of the resource.
- **Index Service**
Returns the publicly available summary details on the results.
- **Document Delivery Service**
Allows user to select delivery source and options.
- **Identity Management and Authentication**
Provide a user registration and login service returning unique IDs and attributes about a user which can be used to authenticate access to gated resources.

These services cover many of the requirements documented in this specification, and provided that the Architecture is sufficiently stable at the time of implementation should be considered for the portal. The Architecture should therefore be viewed as a guide for implementers, not a mandatory requirement, unless and until it is formally adopted by the NHS.

12.1.1 Associated Standards

The architecture is based on a series of standards:

- **Service Registry**
UDDI, OAI-PMH, Z39.50, SRW, DC Collection Description schema, WSDL
- **Search**
SOAP, Z39.50 SRW, DC, eGMS, MeSH, SNOMED-CT
- **Alerting/current awareness**
OPML, RSS
- **Metadata Schema Registry**
Z39.50, SRW, OAI-PMH
- **Harvest**
OAI-PMH, DC,
- **Identity Management and Authentication**
SAML, Shibboleth
- **Identifier Resolver**
DOI
- **Link server**
OpenURL
- **Document Identification**
DOI

These standards are largely compatible with the requirements as defined in this specification and should be used by implementers as a guideline unless and until the entire Enterprise Architecture is formally adopted by the NHS, at which point the standards will be mandatory.

The use of Digital Object Identifiers (DOI) for all documents managed directly by the portal should however be considered to be a current formal requirement since this decision was taken in principle by a working group of involved NHS organisations and agents at a workshop held in NICE on 7 September 2006.

12.2 Compliance with General Standards

In contrast to the previous section which deals with a proposed new architecture and a collection of standards which are largely advisory, this section defines the standards which are all mandatory for the portal.

All data delivered by the portal, whether from static resources or from application systems must comply with:

- HTML 4.01 or XHTML 1;

OR

- PDF Version 1.4 or later.

Documents may be stored in the portal document repository using many other formats, e.g. Word, Excel etc. However, the portal is required to deliver all documents irrespective of their internal native format in one of the standard formats listed above. The portal must maintain the capability to read all the formats of all the documents that it manages, or has links to, irrespective of the age and version of the original native format of the document. The Portal Managers may choose to convert documents from their original format to PDF where this would reduce the difficulty of maintaining the ability to convert from old formats.

All data and applications delivered through the portal must be fully usable with all common web browsers, to include Microsoft Internet Explorer, Netscape Browser, Safari, Mozilla, and Firefox. In each case the version of the browsers is the latest available for full release.

No special client software should be required to use any aspect of the data or applications delivered through the website. In particular client software that requires a separate commercial licence to use is not acceptable.

No specific client Operating System (OS) will be required to use the portal. Any OS that is able to support a standard web browser should be able to use all the features of the portal. The portal should not therefore use any proprietary controls or code that the client must execute in order to make full use of the portal.

All applications will need to be compliant with the current eGovernment Interoperability Framework (e-GIF).

12.3 Accessibility Standards

The design should have regard for Part III of the Disability Discrimination Act. All data and applications delivered through the portal must comply, as a minimum, with the usability standards defined by:

- The RNID/RNIB advice for web content;
- the Web Content Accessibility Guidelines (WCAG) Version 1 to conformance Level AA i.e. all Priority 1 and 2 checkpoints are satisfied (Compliance with this standard to be established by 'Bobby' or comparable tests.);
- and e-Government website guidelines (including Quality standards).

Where there is any difference between these standards, the option providing wider accessibility will be used.

12.4 Other Design Considerations

The system must be designed to allow expansion through additional web applications.

The system will need to be able to integrate other non-web applications. There should be consistent branding and the application of a strong style that is immediately recognisable.

The system should be "device aware" and vary content and access based on which device a user is utilising i.e. users can securely access the portal via alternate devices, such as handheld PDAs and mobile phones.

DH style guides are referenced in Section 8.1.

13 Reliability, Availability, Maintainability and Integrity

The portal must be designed for an anticipated life span of at least five years and be future-proofed to manage technology changes over this period.

A change control process is required for all changes to the portal system.

All enhancements to the portal systems will be subject to testing, including User Acceptance Testing.

13.1 Reliability

All LAN and WAN infrastructure must be fully resilient so that the failure of any single component or link cannot cause interruption of service.

All computer hardware (particularly all servers) and associated equipment including power supply, network interfaces, air conditioning etc must offer full fail over capability so that the failure of any one server or other component cannot cause interruption of service.

It must be possible to upload new material to be viewed through the portal without interruption to normal use.

13.2 Availability

The portal and all associated application systems must be designed to allow for continuous operation on a 24 hour, 365 day per year basis.

The portal and all associated systems must deliver an overall availability of 99.95% with the maximum length of a single downtime incident in any one calendar (January-January) year being 4 hours.

13.3 Maintainability

Essential maintenance to the portal and all associated applications must be capable of performance without interruption to service.

If downtime is experienced for any application delivered through the portal, a notice must be displayed on the portal stating the expected time to repair.

Within one hour of any malfunction, the problem will be logged, analysed to gauge the severity of the problem and a course of remedial action identified with appropriate persons notified.

13.4 Integrity

The portal must be shown to be capable of maintaining the integrity of all the data which it controls and makes available. Integrity testing must form part of the system acquisition and acceptance process.

14 Security/Confidentiality

The portal will manage, deliver and receive sensitive information. Security is a prime requirement of the portal system.

14.1 General Requirements

These security requirements are the common, minimum requirements that will apply to the portal and all associated application systems. Individual data resources and applications will have significantly more complex and restrictive security requirements which will take precedence for the use of those resources and systems.

The portal will provide access for authorised users while screening out those who do not need to view confidential data.

The portal must provide transparent and automated security management of digital IDs, security policy enforcement and automated password resets. These features should significantly reduce the ongoing administration and management costs associated with web portal security. Without transparent and automated security management processes, the burden of administration for both end users and administrators would quickly grow unmanageable and the portal would not scale.

The portal and all applications associated with it will comply with all UK legal requirements, including Data Protection Act 1998, Caldicott guidelines and the Freedom of Information Act 2000 and Copyright, Designs and Patents Act 1988.

A range of web transactions will need to be secured in order that users' personal details are not exposed to inappropriate view. Where personal data is collected there should be appropriate data protection notices provided to raise awareness on how that personal data will be processed. This should be reinforced with an accessible Data Protection policy statement. The terms and conditions of the use of such personal data should be provided including details of the sanctions that will be invoked if these conditions are not observed. The portal should facilitate the swift retrieval of data in line with requests under this legislation.

The portal and its accompanying R&DMIS system is NOT suitable for direct interfacing with Connecting for Health in this version. A full security study will be required before this is possible.

The system should meet Information Security Management requirements as detailed in ISO 27001 (BS7799). This will require a full risk assessment of the system implementation and the identification of suitable counter-measures where indicated.

The system's security and measures will be independently evaluated and audited by a third-party.

The portal should comply with a designated policy for the processes of secure data disposal from the system.

There must be adequate and current anti-virus provision, including an anti-virus filter for all incoming and outgoing data.

14.2 Access and Authentication

All data accessible through the portal will be flagged at the lowest level of granularity available to indicate the classification of access that is to be provided to it.

Private data must be encrypted for transfer so that it cannot practically be intercepted by other party. The performance requirements defined in Section 11 are for fully encrypted data.

A secure link must be used for all transactions concerned with user registrations, log in and the upload or download of all private (i.e. non public domain) data.

There should be the facility to create an overall 'Super Administration User', who will maintain the security for user access at front office level through the ability to create, amend, suspend and delete users and carry out all other security functions, including setting start and expiry dates for a user's access rights.

All applications that may access data associated with the portal or any external data will provide access to those resources only through a valid sign-on using a standard authentication method.

All users seeking to access any resources other than those that are flagged for public non-controlled use must log in to the portal using a standard authentication method. This must then allow them access only to those resources that their identification and classification permits.

A user identifier must be suspended if the number of unsuccessful attempts to gain access to the system exceeds a predetermined limit.

Inactive users must be automatically logged off after a default period of time set by the portal System Administrator or a Registration Approver. This period should be configurable by the portal management by class of user. Users will be informed that they will be logged off within a defined time limit if they continue to remain inactive. Public users do not need to log in and their inactive time is not therefore time limited.

The process of user authentication (sign-on) should be required only once for any user's single session through the portal. No further user sign-on should be required to access any other resource or application through the portal.

The following generic access levels in Table 7 are proposed:

Level 0	Access to UNCLASSIFIED material in the public domain
Level 1	Access to published data in the public domain
Level 2	Access to COMMERCIAL IN CONFIDENCE/RESTRICTED information which if compromised may have adverse effect
Level 3	Access to CONFIDENTIAL information which if compromised would cause some damage
Level 4	Access to HIGHLY CONFIDENTIAL information which if compromised would cause serious damage

Table 7 - Proposed Access Levels

The application of these security levels to the users and roles defined in Section 6 results in the requirements shown in Table 8:

User Class	User Type	Read Access	Write Access	Identification
Anonymous public				
1	Public	Level 0	None	None
Researcher⁹				
2	Chief Investigator	Levels 0,1 and 2 Levels 3 and 4 by agreement	None	Digital Certificate
3	Principal investigator	Levels 0,1 and 2 Levels 3 and 4 by agreement	None	Digital Certificate
4	Research Nurse	Levels 0 and 1 Levels 2,3 by agreement	Level 1 Levels 2,3 by agreement	Digital Certificate ¹⁰
5	Trial Project manager	Levels 0 and 1 Levels 2,3 by agreement	Level 1 Levels 2,3 by agreement	Digital Certificate
6	Non-clinical Researcher	Levels 0 and 1 Levels 2,3 by agreement	Level 1	Digital Certificate
R&D Manager				
7	R&D Manager	Levels 0, 1 and 2 Levels 3 and 4 by agreement	Level 1	Digital Certificate
Faculty Member / Honorary Faculty Member				
8	Investigator	Levels 0,1 and 2 Levels 3 and 4 by agreement	Level 1	Digital Certificate
9	Senior investigator	Levels 0,1 and 2 Levels 3 and 4 by agreement	Level 1	Digital Certificate
10	Associate	Levels 0,1 and 2 Levels 3 and 4 by agreement	Level 1	Digital Certificate
11	Trainee	Levels 0 and 1	Level 1	Digital Certificate
12	Honorary Investigator	Levels 0,1 and 2	To be determined	Digital Certificate
Clinician Enroller				
13	Clinician Enroller	Levels 0 and 1	None	Digital Certificate
Network Manager				
14	Topic Specific Network manager	Levels 0, 1 and 2 Levels 3 and 4 by agreement	Level 1	Digital Certificate
15	Local network manager	Levels 0, 1 and 2 Levels 3 and 4 by agreement	Level 1	Digital Certificate
Funder				
16	Funder	Levels 0,1 and 2 Levels 3 and 4 by agreement	None	Digital Certificate

⁹ "Researchers" include researchers who have a project in development, as well as approved

¹⁰ A Digital Certificate ensures that messages or documents sent over the Internet will remain completely confidential even if somehow the data is intercepted. It is also important to ensure that identity is verified. Digital Certificates provide a reliable and robust means to meet both of these requirements.

Regulator/Approver				
17	MHRA drug trials approver	Levels 0, 1,2,3 and 4	Levels 1,2 3	Digital Certificate
18	MHRA devices approver	Levels 0, 1,2,3 and 4	Levels 1,2 3	Digital Certificate
19	PIAG	Levels 0, 1,2,3 and 4	Levels 1,2 3	Digital Certificate
20	GTAC	Levels 0, 1,2,3 and 4	Levels 1,2 3	Digital Certificate
21	RATE	Levels 0, 1,2,3 and 4	Levels 1,2 3	Digital Certificate
22	COREC	Levels 0, 1,2,3 and 4	Levels 1,2 3	Digital Certificate
Resource maintainer				
23	Resource maintainer	Levels 0,1, 2 and 3 Level 4 by agreement	Levels 1, 2 and 3 Level 4 by agreement	Digital Certificate
Moderator				
24	Moderator	Levels 0, 1 and 2	Levels 0, 1 and 2	Digital Certificate
Policy and oversight				
25	Policy and oversight	Levels 0, 1,2 and 3	Levels 0, 1,2 and 3	Digital Certificate
Registration approver				
26	Registration approver	Levels 0,1,2,3 and 4	Levels 0,1,2,3 and 4	Digital Certificate + Biometric Authentication ¹¹
Systems Administrator				
27	Systems Administrator	Levels 1,2,3 and 4	None to portal content	Digital Certificate Biometric Authentication
Sponsor				
28	Sponsor	Levels 0,1 and 2 Levels 3 and 4 by agreement	None	Digital Certificate
Business administrator				
29	Financial Administrator	Levels 0,1 and 2 Levels 3 and 4 by agreement	None	Digital Certificate
Media				
30	Media	Levels 0 and 1	None	Digital Certificate

Table 8 - Security Levels assigned to User Classes

¹¹ *Biometric authentication refers to technologies that measure and analyse human physical and behavioral characteristics for authentication purposes. Examples of physical characteristics include fingerprints, eye retinas and irises, facial patterns and hand measurements*

14.3 Audit Trail

All user access to the portal that involves access to non-public data should be centrally logged and tracked, so that a record of the user identity, time in, time out resources/applications visited and data changed is kept.

Where the portal may use cookies the system should generate keys for their encryption and the systems should notify the user of the content and purpose of the cookie.

Users should have the ability to refuse any or all cookies without it affecting the basic usability of the system. The user's choice should form part of the user's profile.

An audit trail showing all the changes made to data accessible through the portal will be kept.

14.4 Prevention of Malicious Actions

The portal and all associated applications must use best practice in design for security, specifically to avoid access to and unauthorised updating of content, stealing of personal data, subversion of the portal and its application for other purposes and any other such exploit.

The strength of the portal design and implementation will be tested by periodic penetration testing as well as other audit and validation processes.

The web server (and firewall and any proxy server) should be hardened to reduce the risk of compromise under attack by removing unnecessary services;

Transactional data should not be stored on the portal.

The system should support robust intrusion detection and a notification system to alert system management that an attack on the portal may be under way and allow them to take appropriate and timely countermeasures.

The portal must provide a facility for recording and managing security incidents.

14.5 Business Continuity

All data accessible through the portal, all application code, all application associated data and all portal configuration data will be backed up on a daily basis to a geographically remote secure location so that it is possible to restore any individual part of the portal or the entire portal state from scratch.

Continuity plans, to include a complete IT Disaster Recovery plan will be produced to cover the entire state of the portal and all associated applications. This will be updated six monthly, and audited and tested yearly.

The continuity plans must be part of a full Business Continuity Management (BCM) environment, based on a full analysis of the Mission Critical Activities, Risks, Recovery Strategies and Provisioning. The BCM should be based on a recognised standard or specification such as PAS56.

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16 Glossary of Terms

API	Application Program Interface – the method by which one program can work with another
CCF	Central Commissioning Facility - manages and administers the NHS National Research and Development Programme
CfH	Connecting for Health – previously known as the National Programme for IT (NPfIT) – see www.connectingforhealth.nhs.uk
COREC	Central Office of Research Ethics Committees - COREC is part of the National Patient Safety Agency and provides help and leadership for Research Ethics Committees (RECs) and the REC system by coordinating the development of operational and infrastructure arrangements in support of their work
CSS	Cascading Style Sheets - a computer language used to describe the presentation of a document or a website
CTA	Clinical Trial Authorisation - issued by MHRA and necessary to launch a clinical trial
DH	Department of Health
DOI	Digital Object Identifier- a standard for persistently identifying a piece of intellectual property on a digital network and associating it with metadata
e-GIF	The (electronic) Government Interoperability Framework aims to improve public services by interlinking them and making these services, including the NHS, more accessible to the public
eGMS	The UK e-Government Metadata Standard
HTA	Health Technology Assessment Program - provides all those who make decisions in the NHS with high-quality information on the costs, effectiveness and broader impact of health care treatments and tests
HTML	HyperText Markup Language is a language designed for the creation of web pages with hypertext for display in a web browser
Metadata	Data that describes other data -usually a set of metadata describes a single set of data, called a resource
MHRA	Medicines and Healthcare Products Regulatory Agency - the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.
NLH	National Library for Health
NNTP	Network News Transfer Protocol, the Internet protocol used to post, distribute, and retrieve USENET (discussion group) messages
NPfIT	The NHS National Programme for Information Technology
NRR	National Research Register - a database of ongoing and recently completed research projects funded by, or of interest to, the NHS
OAI-PMH	Open Archives Initiative Protocol for Metadata Harvesting - a protocol used collect the metadata descriptions records in an archive
OpenURL	A type of URL that contains resource metadata for use primarily in libraries.
OPML	Outline Processor Markup Language - XML format for outlines
OS	Operating System – software that that manages the hardware and software resources of a computer. Microsoft Windows is an example of an OS
PAS56	Publicly Available Specification 56 - describes the objectives of business continuity management and makes recommendations for good practice.
PDA	Personal Digital Assistant – a device that combines multiple functions such as a calendar, address book, email, mobile phone etc.
PDF	Adobe Portable Document Format - a standardised platform independent format for documents
RSS	Really Simple Syndication (RSS 2.0) or Rich Site Summary (RSS 0.91, RSS 1.0) or RDF Site Summary (RSS 0.9 and 1.0) – all are versions of the same type of web feed format
SAML	Security Assertion Markup Language – an XML standard for exchanging authentication and authorization data between security domains, i.e. between an identity provider and a service provider.
SAN	Storage Area Network – a way of organising data storage devices and networks to deliver large scale, easy to administer data storage
Shibboleth	An architecture and open-source implementation for federated identity-based authentication and authorization infrastructure based on SAML.
SDO	Service Delivery and Organisation - the Service Delivery and Organisation (SDO), Research and Development Programme aims to produce research evidence directed at improving the organisation and delivery of health services, and to promote the uptake and application of that evidence in policy and practice
SNOMED-CT	Systematized Nomenclature of Medicine - a system of standardized medical terminology,

	evolved into SNOMED Clinical Terms, or SNOMED-CT
SOAP	Originally, Simple Object Access Protocol - a protocol for exchanging XML-based messages over a computer network.
SRW	Search/Retrieve Web service - a web service for search and retrieval of resources
SUSAR	Suspected Unexpected Serious Adverse Reaction - a reaction which is not expected from current knowledge of a drug's toxicity profile.
UDDI	Universal Description, Discovery, and Integration – a platform-independent, XML-based registry that organisation can use to list services and discover each other
UKCRN	UK Clinical Research Network - provides support for clinical research and facilitates the conduct of randomised prospective trials and other well-designed studies.
URL	Uniform Resource Locator which identifies a resource and provides a means of locating it
URN	Uniform Resource Names -intended to serve as persistent, location-independent resource identifier
URS	User Requirement Specification – this document is an example of this type of specification, which defines what a system should do from a user's perspective.
Web Service	Web services - provide a standard means of interoperating between different software applications, running on a variety of platforms and/or frameworks.
WSDL	Web Services Description Language - an XML format published for describing Web services.
XML	Extensible Markup Language – a language developed specially for Web documents. It allows designers to create their own customized tags, enabling the definition, transmission, validation, and interpretation of data between applications and between organisations
Z39.50	A protocol for searching and retrieving information from computer databases