Project: National eResearch Collaboration Tools and Resources

Project #: 2179

Cloud Based Bioinformatics Tools

eResearch Tools Program Proposal

The Centre for Genetic Epidemiology & Biostatistics

University of Western Australia

Section 1 RFP

1.1 RFP Contact Details

RFP Proposals ONLY	proposals-rfp-nectar@unimelb.edu.au
RFP Questions ONLY	questions-rfp-nectar@unimelb.edu.au
General Queries **Questions relating to the RFP should ONLY be delivered via the appropriate email addresses above.**	The NeCTAR Directorate Room 3.11, Level 3 Doug McDonell Building The University of Melbourne, Vic 3010 Contact: (03) 8344 1277

Section 2 Contact Details of the Proposer

2.1 Proposer Contacts

The Contact Details of the Proposer are to be detailed in section 2.1.1 below.
Please add the details of any anticipated participating organisations in section 2.1.2. Add extra lines as required.

2.1.1 Proposer

Organisation Name	Centre for Genetic Epidemiology & Biostatistics, University of Western Australia
Contact Name	Paul White
Position	Manager Informatics Systems Development
Business Address	35 Stirling Highway, Nedlands, WA, 6009
Postal Address	35 Stirling Highway, Nedlands, WA, 6009
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Facsimile	08 6488 6750
Mobile Phone	0412 352 883
E-mail	paul.white@uwa.edu.au

2.1.2 Participating Organisations

Organisation / Group Name	Location	Role
University of Western Australia Centre for Genetic Epidemiology & Biostatistics	Perth, WA	Lead Organisation
St John of God Health Care	Perth, WA	Collaborating research organisation
The Clinical Oncological Society of Australia (COSA)	Sydney, NSW	Collaborating research organisation
The Centre for Mega Epidemiology at Melbourne University	Melbourne, Vic	Collaborating research organisation & co-development organisation
OBiBa	Montreal, Canada	Co-development organisation

Section 3 Compliance Statement

3.1 Proposed Sub-Contract Compliance

Are there any Departures from the Contract (Part C) Terms and Conditions?

☑ **No** There are no departures from the terms and conditions (i.e. Full Compliance)

☐ **Yes** There are departures from the terms and conditions

Detail the departures in Section 3.4 of this document.

The proposing organisation warrants that except for the departures listed in Section 3.4, the response is in full compliance with the Contract terms and conditions and no further contractual issues will be entered in to.

Paul White – Manager Informatics Systems Development, UWA Centre for Genetic Epidemiology and Biostatistics

Signature of authorised person making the statement Name and role (printed)
Date: 02 November, 2011

3.2 RFP Compliance

Are there any Departures from the RFP Terms and Conditions (Part A)?

☑ **No** There are no departures from the terms and conditions (i.e. Full Compliance)

☐ **Yes** There are departures from the terms and conditions (i.e. Does not Fully Comply)

Detail the departures in Section 3.4 of this document.

The proposing organisation warrants that except for the departures listed in Section 3.4, the response is in full compliance with the RFP terms and conditions.

Paul White – Manager Informatics Systems Development, UWA Centre for Genetic Epidemiology and Biostatistics

Signature of authorised person making the statement Name and role (printed)
Date: 02 November, 2011

3.3 Conflict of Interest

Are there any known or potential conflicts of interest responding to the RFP and its Terms and Conditions or in delivering the proposed works?

☑ **No** There are no conflicts of interest

☐ **Yes** Describe the conflicts in Section 3.5 of this document.

Do you commit to inform the University of Melbourne of any future conflicts or potential conflicts as they arise?

☑ **Yes**

Signature of authorised person making the statement Name and role (printed)
Date

3.4 Statement of Departures

	Clause or Reference	Nature of Compliance	Proposed wording of amendment
Proposed Sub-Contract			
RFP Terms and Conditions			

3.5 Conflict of Interest

The Nature of the Conflict	Implications of the Conflict	How the Conflict is to be managed?

Section 4 Fields of Research

DISCIPLINE/FOR Code	Weight (percent)
Bioinformatics Software / 080301	70%
Oncology and Carcinogenesis / 1112	30%
	100%

Section 5 Response

SUMMARY

1 Program and Proposal Title

This proposal is addressing the eResearch Tools program.

Short Title: Cloud-based Bioinformatics Tools

2 Executive Summary

Data is the primary asset of biomedical researchers, and the engine for both discovery and translational medical research. As the volume and sensitivity of research data increases, for example due to new technologies such as 'next-generation' sequencing of human specimens linked to clinical datasets, so too does the requirement for access to application software for integrating and interrogating the different types of research data. Researchers often need to execute complicated queries and conduct analyses across multiple data types, such as phenotypic, genotypic, pedigree and biospecimen data.

The Ark project was established within the Centre for Genetic Epidemiology & Biostatistics at the University of Western Australia in late 2009 to develop an open-source platform to support Australian and International biomedical researchers. The objective of The Ark project is to provide a suite of secure, integrated web-based applications that incorporate the majority of the functionality required to conduct a complex study or clinical trial.

The project has now delivered a Java-based solution that delivers the following capabilities:

1. Create and configure a study;
2. Define users and manage their roles and access permissions;
3. Define and manage a research participant pool;

4. Define and manage the collection of phenotypic research data;
5. Dynamically generate Electronic Data Capture (EDC) forms for collecting most types of textual research data;
6. Manage physical biospecimens and the associated data using a Laboratory Information Management System(LIMS); and
7. Generate reports.

This functionality has now been released as Version 1.0 and is being used in production. The project team is currently focussed on supporting Version 1.0 and gathering the requirements for the functionality described in this Proposal.

The software has been designed and developed in accordance with the following guiding principles:

1. The software should be web-based;
2. One instance of the software should securely support multiple research studies and multiple users;
3. The core application software should not be developed to suit any one study/project but rather should be configurable to suit a broad range of studies;
4. The software should be as user-configurable as feasible through a browser-based graphical user interface;
5. The software must be highly secure; and
6. The software modules should be well integrated.

This proposal has been developed with the goal of implementing the additional functionality required by our collaborators and the majority of medical researchers currently undertaking data collection and analysis projects. In addition to enriching existing capabilities this functionality includes:

- Integration with the AAF authentication services;
- An integrated invoicing and billing module;
- A data extraction for analysis module;
- A pedigree (family) data management and visualisation module. Note that we have developed a prototype for a 3 dimensional pedigree visualisation tool that may be used as the basis for this module;
- Registry Management functionality for managing participant registries, such as the Australian Twin Registry; and
- A genotypic data management module. The preferred approach to providing this functionality is to integrate The Ark tools with the capabilities that would be provided through the Genomics Virtual Laboratory, Galaxy/GDR Integration and Service Centre Data Handover projects through a set of web services, should these project be funded. Note that we have developed a genotypic data management prototype in conjunction with researchers and developers from the international OBiBa project run from McGill University in Montreal that could form a basis for this capability should the other projects not be funded. In the event that these other projects are not funded then we believe that the labour estimates provided in this proposal are sufficient to provide the base set of functionality required for genotypic data management for our target user group.

We are not aware of any equivalent open source software applications available nationally or internationally and we are unaware of any viable alternatives for researchers that do not have the required funding or expertise to purchase commercial solutions or develop their own

solutions. Smaller studies are often able to operate using simple tools, such as Microsoft Access or Microsoft Excel, but there is no doubt that the research being undertaken by these studies is being compromised by the lack of suitable informatics support.

3 Research Community Profile

The University of Western Australia

The Faculty of Medicine, Dentistry and Health Sciences at UWA is a research-intensive faculty, providing high-quality educational and research programs for the spectrum of medical, dental and health science disciplines.

St John of God Healthcare

St John of God Health Care is committed to research across a wide range of medical, surgical and mental health fields with the aim of improving patient outcomes. St John of God Healthcare operates hospitals, home nursing, pathology and Social Outreach and Advocacy services in Australia, New Zealand and the Asia-Pacific region.

The Clinical Oncological Society of Australia (COSA)

The Clinical Oncological Society of Australia (COSA) is the peak national body representing multidisciplinary health professionals whose work encompasses cancer control and care. COSA members are doctors, nurses, scientists and all allied health professionals involved in the clinical care of cancer patients. COSA is affiliated with and provides medical and scientific advice to Cancer Council Australia. COSA aims to improve the care of Australians affected by cancer. In order to improve cancer care and control in Australia COSA seeks to:

- understand and provide for the professional needs of its multidisciplinary membership;
- promote and facilitate research across the spectrum of cancer care;
- promote and provide multidisciplinary and interdisciplinary education;
- contribute to, and advocate for, national issues surrounding cancer care policy in Australia;
- enhance the quality of care.

The Centre for Mega Epidemiology at Melbourne University

The Centre for Mega Epidemiology at Melbourne University oversees a number of longitudinal studies. The Australian Twin Registry; the Australian Breast Cancer Family Study; the Australasian Colorectal Cancer Family Study; and The Australian Longitudinal Study of Male Health have a need to manage their participant pools and to continually update data from regular and systematic follow-up studies. This data needs to be securely accessible to multiple researchers across the world and there is a need for researchers to be able to return new data. Additionally there is a need to be able to track the use of data and biospecimens sent to other researchers.

Current and future users of the software include both clinical and basic science researchers who use clinical specimens and health information from any disease type for molecular and cellular analyses. Current users of our software encompass cancer, diabetes, cardiovascular disease, obesity, eye diseases, mental health and infant and child health. The platforms would also support use by those collecting specimens from clinical trials, both for academic and commercial purposes. The aim is to integrate clinical phenotypic data with biological data, in particular that arising from next generation sequencing technologies. The integration of these elements allows a better comprehension of environmental risk factors and how they interact with underlying genetic variations/mutations. The community that will utilise this infrastructure ranges from individual researchers right through to multinational teams bringing

myriad data sets together. As such the geographical location ranges broadly depending on the project. Our intent is to enable all investigators regardless of the size of their project or their location.

4 Development Organisation Profile

The software development will be undertaken primarily by the following organisations:

1. The University of Western Australia Centre for Genetic Epidemiology and Biostatistics. The Centre for Genetic Epidemiology and Biostatistics comprises a multi-disciplinary team of genetic statisticians, genetic epidemiologists, mathematicians, epidemiologists, bioinformaticists, molecular biologists, and social scientists committed to developing ways of investigating the determinants of complex human disease and exploring ways of using genetic information to improve human health.
2. The Ark (www.the-ark.org.au) project team at the Centre for Genetic Epidemiology and Biostistics, UWA, currently consists of three full-time professional software developers and one part time project manager. The Ark team has been developing and supporting informatics software to support the Centre for Genetic Epidemiology and Biostatistics and collaborating institutions since 2004. Software tools developed by the team have been in production since 2005 and currently provides support to a number of research groups, including:
    - The Western Australian Research Tissue Network at St John of God Health Care
    - The Busselton Healthy Ageing Study (The Busselton Foundation)
    - The Western Australian DNA Bank (which in turns supports over 40 studies using The Ark software)
    - The National Breast Cancer Foundation
    - The Western Australian Institute for Medical Research
    - The Lions Eye Institute
    - Lifepool (BreastScreen Victoria Cohort Study)

    The earlier software tools were developed using a mix of C, Oracle 4GL and Java development languages. The Ark project was initiated two years ago to develop the Java-based research tools that form the basis of this bid, specifically because it was clear that there was demand for this functionality, both nationally and internationally, and that many researchers were not comfortable committing to a solution based on proprietary technology platforms.

    All software development has and continues to be the result of close collaboration with a number of key research groups. This helps ensure that the software is always fit for purpose and is tested using real data by future users of the applications before production deployment. Continual feedback is encouraged and managed by providing most researchers with online access to Jira (www.atlassian.com/en_AU/software/jira/), the web-based issue tracking system used by The Ark team. Researchers are able to submit issues and enhancements online and track their progress online. All issues are reviewed weekly and prioritised. Authorised researchers have access to view the current status of any of the issues associated with The Ark Jira instance.

    All researchers are also able to access The Ark's wiki (wiki.genepi.org.au) to view ongoing analysis, design and user documentation.

    Primary responsibility for supporting a The Ark module is assigned to a specific developer but all developers have sufficient familiarity with all of the software to

provide backup support. Care has also been taken to ensure that a shared set of design patterns is used by all of the developers.

The Ark team is currently funded by UWA and a degree of cost recovery but ongoing funding is not sufficient to continue to develop the software past the end of 2011.

3. The Ark project team member at the Centre for MEGA Epidemiology, University of Melbourne, is responsible for contributing to the application development as well for providing technical and implementation support to local studies. This developer is responsible for the development of the system's registry capabilities.
4. OBiBa (www.obiba.org) is an international software development project based at McGill University, Montreal, Canada. OBiBa is committed to building a full suite of open source software for biobanks. It is comprised of several independent and self-funded teams around the world, each of which is producing stand-alone applications that support particular biobank activities. The applications can be customized and integrated to create a complete biobank information management system.

   OBiBa offers a collaborative infrastructure to its teams and to other developers who may wish to join the OBiBa community. The infrastructure for developers includes integrated tools for documentation, issue tracking, deployment, and project management. The Ark project is a member of OBiBa. Paul White, The Ark Manager, is one of the Principal Investigators of the OBiBa project.
5. St John of God Health Care is committed to research across a wide range of medical, surgical and mental health fields with the aim of improving patient outcomes. St John of God Healthcare have committed experienced research and biobanking resources to the project in analysis and testing roles.
6. The Clinical Oncological Society of Australia (COSA) is the peak national body representing multidisciplinary health professionals whose work encompasses cancer control and care. COSA members are doctors, nurses, scientists and all allied health professionals involved in the clinical care of cancer patients. . COSA is affiliated with and provides medical and scientific advice to Cancer Council Australia. As part of their ongoing work to promote biobanking from clinical trials they have resources available through the Cooperative Cancer Clinical Trials Groups (CCTGs). An experienced Project officer will provide an analysis and testing role for functionality of the clinical trial biobanking modules.
7. The Australian Twin Registry (ATR), run from the University of Melbourne, has been developing software to support the operation of its resource for several years. The ATR's development and operational staff have and will continue to contribute to the specification and testing of The Ark software, especially with respect to its Registry functions.

Please refer to the attached letters of support in Appendix 2

5 Operational Organisation Profile

The Centre for Genetic Epidemiology and Biostatistics at the University of Western Australia.

The Ark project team at the Centre has been supporting hosted bioinformatics solutions for Australian human medical researchers since 2005. The team has been and continues to support researchers from public research institutions and private practice. Researchers with the following affiliations are currently being supported by the group:

- The University of Western Australia
- The Western Australian Institute for Medical Research
- Royal Perth Hospital

- Sir Charles Gairdner Hospital
- Lions Eye Institute
- The University of Melbourne
- The Murdoch Childrens Research Institute
- St John of God Healthcare
- The Western Australian DNA Bank
- Peter McCallum Research Institute
- The National Breast Cancer Foundation

The Centre for MEGA Epidemiology, the University of Melbourne

Currently The Ark programmer in Melbourne supports a number of researchers, including one research group (Lifepool) that is using The Ark's first production release.

OBiBa

The OBiBA project team at McGill University in Montreal, Canada provides operational support to a number of large Canadian research studies. The OBiBA technical resources will be available to provide technical support for this project as required.

Specific Software Support Experience

The 3 teams currently support a mix of open-source and proprietary software used for the following purposes:

- Laboratory specimen management (LIMS)
- Participant Management
- Phenotypic Data Management
- Genotypic Data Management
- Pedigree data management and visualisation
- Paper-based and electronic questionnaire data collection

All teams utilise the same support tools and similar processes. Please refer to section 18 - Operations and User Support for a list of the support tools currently in use.

Please refer to the attached letters of support in Appendix 2 and Appendix 3.

6 Other Participants

The Western Australian Institute for Medical Research (WAIMR) hosts a number of researchers that have expressed a strong desire to continue to be involved in the ongoing development of the software.

The WA Department of Health (DoHWA) and The Population Health Research Network (PHRN) will need to be involved to ensure consistency with existing and future state and national health data linkage infrastructure.

Foundation Health Consumers Council of WA- consumer engagement: In WA there is a strong history of consumer engagement with clinical datasets through the WA Health Data Linkage Unit. These pathways would be used to ensure that the governance of the proposed work is consistent with consumer expectations.

7 Key Personnel

Name	Organisation	Role	Availability
Paul White	Centre for Genetic Epidemiology and Biostatistics, University of Western Australia	Project Manager	40%
Winthrop Professor Eric Moses (Not included in in-kind $)	Centre for Genetic Epidemiology and Biostatistics, University of Western Australia	Project Sponsor	5%
Dr Nik Zeps	St John of God Health Care	Ethics, pathology based - biobanking, clinical trial biobanking	5%
Professor John Hopper (Not included in in-kind $)	Centre for MEGA Epidemiology, Melbourne University; Director, Australian Twin Registry; PI of Australian Breast Cancer Family Registry and Australasian Colorectal Cancer Family Registry	Registry Management; Promotion to other researchers and Registries	5%
Christopher Ellis	Centre for Genetic Epidemiology and Biostatistics, University of Western Australia	Technical Architect and Senior Developer	100%
Programmer (individual to be determined)	Centre for Genetic Epidemiology and Biostatistics, University of Western Australia	Software Developer	100%
Adrian Bickerstaffe	Centre for MEGA Epidemiology, University of Melbourne	Software Developer	50%
Philippe Laflamme	OBiBa Project, McGill University, Montreal Canada	Technical Architect	3%
Andrew Mews	St John of God Health Care	Business Analyst	50%
Kelly Aujard	Centre for MEGA Epidemiology, University of Melbourne	Business Analyst	5%
Project Officer (individual to be determined)	Clinical Oncological Society of Australia (COSA)	Business Analyst	25%
Lisa Spalding	St John of God Health Care	Business Analyst	5%
Support Analyst (individual to be determined)	Centre for Genetic Epidemiology and Biostatistics, University of Western Australia	Software Support	50%
Support Analyst (individual to be	Centre for MEGA Epidemiology, University of Melbourne	Software Support	50%

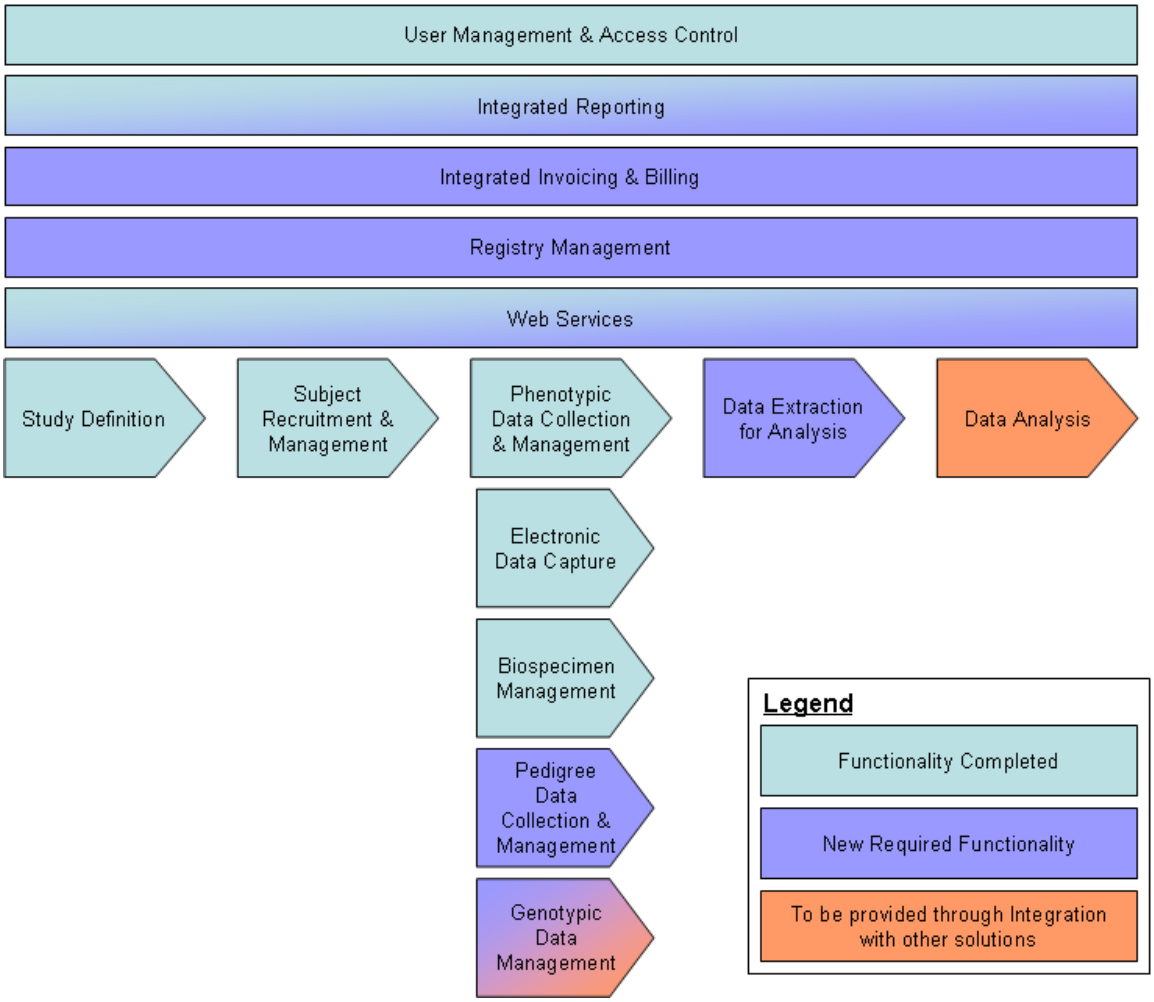
determined)			

None of the above individuals has any commitments that will conflict with his or her availability during the project period in any major way.

The Project Manager, Paul White, will have sufficient authority over the project resources to fulfil the role as described in section A-4.3.

8 Infrastructure

The logical functional diagram below illustrates the functionality that will be delivered. The shading on the diagram indicates which functionality has already been developed, which needs enhancements and which is intended to be provided through integration with third party software.



User Management & Access Control (In production)

A single instance of the software has the capability to support multiple users working with multiple studies across multiple locations.

Security features incorporated into the Ark include:

- Single sign on;
- Fine grained study and user access control;
- Clear separation of identifying and de-identified data;
- Secure web access and data transfer; and

Integration with the AAF services is planned for user authentication.

Integrated Reporting (In production with enhancements planned)

An integrated reporting tool provides the ability for researchers to report across the different data areas supported by the system, subject to data access constraints. Extensions to this tool are planned in order to provide the ability to report across multiple research data types.

Integrated Invoicing and Billing (Planned)

An integrated invoicing and billing system will provide the ability to track resources that have been expended supporting an internal or external research project.

Registry Management (Planned)

The Registry Management module will allow registry and study administrators to track which other studies have been provided with access to their participants and what the status of those studies is. There are also additional reporting requirements for Registry Management.

Study Definition (In production)

The Study Management module provides a System Administrator with the ability to define new studies or registries and then designate a new or existing user as the administrator for that study or registry. This module also allows users with Study Administrator rights to then configure the specific study. Functions available to the Study Administrator include:

- Maintaining the details about a study or registry
- Creating new users and assigning access rights
- Defining study protocols and consent components

Subject Recruitment & Management (In production)

The participant Management module incorporates the functionality required for tracking prospects and participants throughout the lifetime of the project. Functionality includes:

- Management of subject demographic data
- Consent management
- Contact management
- Correspondence management

Phenotypic Data Collection & Management (In production)

The Ark's phenotypic data management module provides researchers with the ability to store and manage phenotypic/clinical data without the need to engage in database design or coding. An overarching data dictionary, that can be defined through the user interface or loaded from file, ensures that all phenotypic data within the system adheres to quality standards. Data elements can be grouped together as required for storing questionnaire, biochemistry, clinical or any other type of textual data.

Data can either be bulk loaded from other sources as text files with loaded data being flagged for consistency with the defined data dictionary so that inconstant data values can easily be corrected.

Electronic Data Capture (Undergoing final testing)

Data entry forms can be created dynamically using the defined data dictionary, negating the need for custom web development whenever there is a need for researchers to enter clinical, questionnaire or any other type of textual data.

Biospecimen Management (Undergoing final testing)

The Ark incorporates a laboratory information management system (LIMS) that provides the functionality required for tracking biospecimens. The history and location of all biospecimens is maintained along with the essential data about each specimen. The data attributes collected about each specimen can be extended dynamically without the need for additional software coding.

Pedigree Management & Visualisation (Planned)

The pedigree management and visualisation module will permit the capture of pedigree (family) information (relationships and data) by establishing the relationships between subjects as part of the contact management process or through data import. Researchers will then be able to view these relationships diagrammatically. Note that we have developed a prototype for a 3 dimensional pedigree visualisation tool that may be used as the basis for this module. Alternatively integration with an existing open-source toolset may be provided.

Data Extraction for Analysis (Planned)

The data extraction for analysis module will provide study administrators and researchers, where permitted, with a software wizard to define, store and execute queries for extracting data from the system in formats that can be directly imported into analysis tools, such as SAS, SPASS or Stata.

Genotypic Data Management & Analysis

The preferred approach to providing this functionality is to integrate The Ark tools with the capabilities that would be provided through the Genomics Virtual Laboratory, Galaxy/GDR Integration and Service Centre Data Handover projects, should they be funded. Note that we have developed a genotypic data management prototype in conjunction with the OBiBa project at McGill University in Montreal that could form a basis for this capability should the other projects not be funded. This prototype permits users to load sequence and SNP data from proprietary formats into a standard internal format that supports:

- Linkage with other data types
- Efficient storage and extraction for analysis
- A degree of in-situ statistical analysis

Data Analysis

The objective of this project is not to build and support data analysis tools. Rather the objective of this project is to provide those infrastructure components that are not readily available and affordable to facilitate the collection and management of medical research data.

RESEARCH COMMUNITY NEEDS & BENEFITS

9 Target Research Community

All clinical and basic science researchers that use human biospecimens, health data or both will potentially obtain a benefit from this infrastructure. With an increasing need to examine the molecular basis of drug interactions, all clinical trials will also have a requirement for such infrastructure to enable management of specimens, clinical data and outcomes. Outside of industry, such infrastructure is non-existent. The Cancer Cooperative Clinical Trials Groups (CCTGs) under COSA are included here as one example of clinical trial usage that will result from this initiative and this includes 16 CCTGs and several hundred investigators.

It is therefore somewhat difficult to specify the precise number of users of this infrastructure but based upon the groups identified in the proposal there are already several groups in each of WA, NSW, ACT, VIC, QLD and SA that will make immediate use of this either directly or through the collaborations that will be enabled. The listed investigators comprise a research community of over 500 people and it is likely the broader utility will encompass several thousand Australian researchers. There are already several international collaborations underway and therefore the numbers will increase with those too.

10 Needs and Impact

Researchers conducting epidemiological medical research require a range of functionality in order to conduct their research studies efficiently, securely and cost effectively. Only a small percentage of Australian and international research studies utilise professionally developed software tools to manage their research. The remainder rely on paper-based solutions and overly simplistic tools developed using non Internet-enabled technologies such as Microsoft Excel or Microsoft Access. These solutions are often extremely inefficient, insecure and not scalable.

There is a strong need in the medical research community for a suite of integrated software tools that can be used to manage the key functions associated with running a research biobank, registry, or study.

In Australia there are a diverse range of groups that use specimens linked to health data and these cover all aspects of human disease. Many of these organisations were previously supported by the NHMRC through its Enabling Grant scheme which provided some funding toward their everyday core activities but in general very little specifically for their IT capabilities and needs. Briefly, there are three main categories of samples about which researchers require information to be managed. They are:

1) Healthy controls;
2) People with diseases receiving standard care in routine healthcare settings; and
3) People with diseases on clinical trials.

For each of these there needs to be comprehensive clinical phenotyping and at present none of this is held in a way that can be interrogated easily. There are a myriad of different ‘databases’, many in fact being excel spreadsheets or clinical management systems that can’t be searched readily, eg pathology laboratory information systems or outpatient records. Once identified, the information has to be extracted and held in a secure data management system to comply with ethical and legal requirements. Again, there is no standard by which this information is compiled and over the years many groups have developed their own systems with little or no regard to being able to ‘talk’ to others by using standard data definitions. It is impossible to describe how large this problem is in a short space but it is perhaps sufficient to state that even within one cancer centre, oncologists cannot readily find out what patients

were actually given so that a comparison of treatment with basic demographic information can be performed. Whilst organisations like BioGrid in Victoria have made significant advances in addressing this issue, they do not have the scope to merge with biobanks or research data like genotyping or proteomic information and are unlikely to be able to do so in the short to medium term.

Within the biobank community there are also a myriad of approaches to databases and each has its own difficulties and limitations. Through the Australasian Biospecimen Network we are aware of several of these and we have been able to review their pros and cons. We have also done this with groups internationally, such as the Uppsala Biobank and CTRnet in Canada. Again, none of these activities have solved being able to bring together information from the clinic, biobank and laboratory in a way that researchers can easily use it. Significant investment in the IT capabilities has been made and is ongoing in each of these jurisdictions and it is clear that without similar investment in Australia we have no possibility of remaining competitive in health research of this nature.

Clinical trials have become a central focus for Australia, illustrated by the Clinical Trial Action Group (CTAG) report. Whilst the recommendations in that document focus on being able to make trials known to potential participants, there is a major need to be able to support the trials themselves, particularly with respect to managing samples linked to patients on the trials. Many new agents have specific biological effects and it is fair to say that all new drug trials from industry or cooperative trial groups have a biological sub-component. As we enter the era of targeted therapies the need to have the ability to integrate genomic and clinical data becomes more pressing. COSA have recently published a report (by Deloitte) highlighting this for the cancer trials groups. The Royal College of Pathologists Australia (RCPA) have commissioned a working group examining biobanking and the role of pathology recognising this as an important area of need.

At this moment in time it is impossible to track samples linked to trials in an effective and efficient manner. Each trial independently manages information concerning pathology practices that they liaise with for blocks and blood samples. An integrated central hub that can facilitate this will save thousands of person hours each year.

Therefore, having a means to collect and store data in a manner in which it can be linked with consent information and then interrogated and linked to biological specimens and data arising from their analysis will significantly enable our capabilities to be competitive in discovery, translational and clinical research.

There are also significant operational benefits to be derived from the proposed cloud-based bioinformatics tools:

- Research projects that would be too costly to conduct due to constraints on time and funding become feasible;
- Existing funding can be spent more efficiently. For example, data can be collected using web-based forms or scannable documents so researchers no longer need to manually transcribe research data from paper into electronic formats for analysis;
- Data quality can be improved by reducing transcription errors and by defining and enforcing data validation rules at the point of data collection or aggregation;
- Data are more secure, from both a loss perspective as well as from a privacy perspective;
- Collaboration between researchers on the same project is improved as geographically dispersed researchers can work securely together with a single copy of the data;
- Researchers will be able to reduce the amount of funding being requested from grant bodies while at the same time strengthening their applications;
- Management of post graduate research projects will be easier and cheaper;
- Preparation time for research papers will be reduced; and

Reporting requirements and ethics compliance will be easier to satisfy.

The utilisation and uptake of the project by the research user community will be measured by collecting and reporting on the following metrics:

- The number of active studies supported by the system
- The number of active users
- The number of subjects per study
- The total number of biospecimens defined to the system
- The number of research papers that acknowledge The Ark

11 Broader adoption

As a result of having provided hosted informatics tools to the Australian human medical research community for several years we have created visibility of our objectives and capabilities across a number of Australian research institutions. Many of these organisations have expressed their frustration at the lack of cost-effective informatics solutions and at the inability of available tools to provide an integrated view of their research projects. We believe that once the tools are available within the Research Cloud then uptake will be very strong. The long-term objective is to have other organisations become part of The Ark project from both a development and support perspective.

The Ark software is designed to be extremely flexible and user-configurable. As a result the software will support a broad range of different medical research and clinical trials groups where multiple data types need to be associated with a single physical entity. The software and data linkages are written in such a way that they can readily link to electronic health record systems as they come online

The software is also applicable to other research disciplines as demonstrated by:

1. We are currently working with a commercial partner, Patrick Rose, to configure the system to support the collection of health and incident data in remote communities in regional Western Australia;
2. The UWA Crime Research Centre has approached us regarding using The Ark software to manage crime research data.

12 Value adding

The project is closely aligned The Promoting and Maintaining Good Health National Research Priority (NRP).

The Ark project builds upon a software development and research project initially funded by a NHMRC Enabling Grant. This predecessor project, commonly referred to as WAGER, has provided a solid foundation in terms of informing the functionality, design, development and support approaches that have been adopted by The Ark team. Through the course of the WAGER project, the team also built strong relationships with a number of Australian research groups, some of which are collaborators and supporters of this proposal.

The Ark team have been working with the Western Australian Data Linkage Unit since 2005 to facilitate the linking of research data with public health data. The Ark team intends to continue this relationship with the Western Australian Data Linkage Unit and with the Australian-wide equivalent - The Population Health Research Network (PHRN).

The Ark project will integrate with existing capability platforms as follows:

- The existing The Ark LDAP authentication services will be integrated with AAF so that existing researcher credentials may be used to access The Ark software;
- Over the course of 2012 The Ark will retire its existing server hardware and migrate all of its existing applications to the Research Cloud. Note that The Ark already has access to two National Server Program virtual servers. The applications on these servers will be moved to the Research Cloud at the appropriate time;
- One of the objectives of The Ark project team is to position researchers to take advantage of the significant HPC capability currently being provided by NCI. To gain new insights from the increasingly large data sets being made available through technologies such as high throughput ómics' technologies will require seamless access to high performance computing hardware and the relevant software tools. The preferred approach to achieving this is to integrate The Ark with the capabilities to be delivered by the Genomics Virtual Laboratory, Galaxy/GDR Integration and Service Centre Data Handover NeCTAR projects.
- The Ark project team currently has its own SAN for data file storage. It is planned that during the course of the NeCTAR project this will be retired and RDSI data storage will become the preferred storage medium for image and genotypic data files; and
- There is the possibility that, if the issues associated with fully de-identifying data sets can be addressed, then some of the collaborator data sets could be moved to ANDS. This is not currently within scope for this proposal.

There are a number of components of The Ark solution that could be leveraged by other research communities, including:

- The Laboratory Information Management System (LIMS) for biospecimen management; and
- The Phenotypic data management module for storing phenotypic data about an entity.

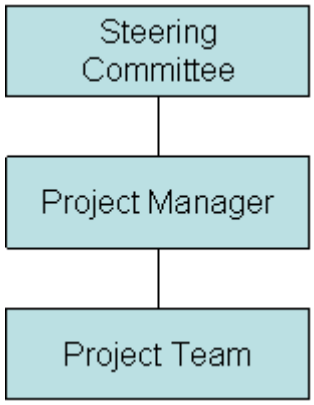
PROJECT MANAGEMENT

13 Governance

The project Steering Committee will have carriage of all aspects of the design and conduct of The Ark Bioinformatics Tools project and will be accountable for assessing project performance. The Ark Manager, Paul White, will in turn report to the Steering Committee.

The Steering Committee will have the following membership, consisting of one representative from each of the collaborating parties and an external researcher representing the wider research community:

- Winthrop Professor Eric Moses, Director of the Centre for Genetic Epidemiology and Biostatistics, UWA
- Dr Nik Zeps, Research Group Leader, St John of God Health Care
- Professor John Hopper, Professor & Director (Research), Centre for Molecular, Environmental, Genetic and Analytic (MEGA) Epidemiology, Melbourne School of Population Health
- David Goldstein/John Zalcberg, Clinical Oncological Society of Australia
- Professor Lin Fritschi , Western Australian Institute for Medical Research (We are awaiting final confirmation on Professor Fitschi's acceptance)



NeCTAR is invited in an ex-officio capacity onto the Steering Committee. Note that the hardware infrastructure will be operated by NeCTAR and the eResearch Tools will be operated and supported by The Centre for Genetic Epidemiology & Biostatistics.

The Steering Committee will meet on a quarterly basis.

Paul White, the Project Manager, will be a standing invitee to all Steering Committee meetings. The Steering Committee will also have the right to invite project or other resources to provide technical advice to the Steering Committee.

We manage our projects using the Agile methodology. A key principle of Agile is its recognition that during a project the customers can change their minds about what they want and need, and that unpredicted challenges cannot be easily addressed in a traditional predictive or planned manner. As such, Agile adopts an empirical approach — focusing on maximizing the team's ability to deliver quickly and respond to emerging requirements.

The Project Manager will manage the project by coordinating and communicating with the rest of the team. The collaborating research groups will be kept up to date on major project issues and sprint results through email updates and Work in Progress (WIP) meetings, emails and/or phone calls.

Risk management is a key aspect of project management. Project specific risks will be identified, documented and managed. The earlier the risk can be identified, quantified and effectively contained, the more successful the risk management process will be.
Key Project Management deliverables include:

- Communications Plan
- Project Definition Statements (Microsoft Word)
- Project Budget (Microsoft Excel)
- Project Status Reports (Microsoft Project)
- Project Management Plans (Microsoft Project)
- Project Backlog (Jira issue management software)
- Project Burn-down Charts (GreenHopper Agile software development tools)
- Issue management (Jira issue management software)
- Request for Change
- Risk Management Plan (Microsoft Word)

14 Project Scale

The development scope of the project equates approximately to 2.5 software programmers for 10 months with the corresponding project management and business analyst/testing support. Subsequent to the completion of the development phase operations support will be provided by the equivalent of one full time support officer.

The total effort associated with the project is 1080 FTE days or 4.9 FTE years at a total cost of approximately $630,000. We are asking for $290,598 from NeCTAR for this project.

Resources contributed by the other participants include:

- St John of God Health Care (SJOG) – two part time (20% and 10%) business analysts, both with extensive experience in the biobanking and medical research area. One 50% support officer for the operational phase of the project (01 Jan 2013 - 30 June 2014)
- The Centre for MEGA Epidemiology (MEGA)– one 50% software developer and one part time (5%)business analyst/software developer;
- The Clinical Oncological Society of Australia (COSA) – one 25% business analyst with considerable experience in conducting clinical trials;
- The OBiBA Project (OBiBa) – one part time (5%) technical architect;
- The University of Western Australia (UWA) – infrastructure support and a cash contribution to cover non-salary expenses.

A number of other organisations have also expressed a willingness to contribute to the project by participating in the requirements analysis and testing phases of this project but these resources have not been included in the project budget.

15 Project Approach

The required services will be delivered using the following approach:

1. Establishment of support tools and processes for both software development and ongoing customer support. Note that many of these processes are already defined but will need to be modified to support operations within the Research Cloud. The Ark project has already established a test environment on the National Server Program infrastructure. This will need to be migrated to the Research Cloud.
2. Integration with AAF authentication services.

3. Initial Research Cloud deployment. This activity will include comprehensive system, security and user acceptance testing to ensure existing software is cloud ready. This will also include deployment to a production environment in the Research.
4. Incremental development of functionality to support collaborative partner requirements. The software will be developed as a set of discrete modules that can be plugged into the overall application framework. Within each module the software will be developed in a number of sprints. Each sprint will deliver a set of working functionality that can be tested as a functional deliverable.
5. Deployment of each module in a production environment for access by the project collaborators.
6. Staged deployment to the broader research community:

Each of these sub-projects/deliverables will be developed and delivered using our standard development process whereby each project goes through a number of stages:

1. **Project Definition** - The project stakeholders and the development team document the problem to be solved and the key criteria acceptance. A product Owner is identified for each project/deliverable.
2. **Elaboration** – The documentation and tools required to manage the project are developed, including the risk management plan, project management plan, user stories/requirements definition documentation and the Product Backlog. The product backlog is a living document which changes whenever the Product Owner receives new information. The Product Backlog helps guide the team in selecting work that best reflects business priorities for each iteration of development.
3. **Development** – Application development will be done in a series of two to four week sprints. Each sprint commences with a Sprint Planning Meeting where the development team selects items for the Sprint. These items are then frozen in the Product Backlog by the Product Owner and are not changed for the duration of the Sprint. The outcome of each sprint is a set of functioning tested code.
4. **Deployment** – After the final sprint the software has been tested and documented and is ready for deployment into production. We will assist our collaborators in conducting additional acceptance testing on each module using production data that has been migrated from existing systems.

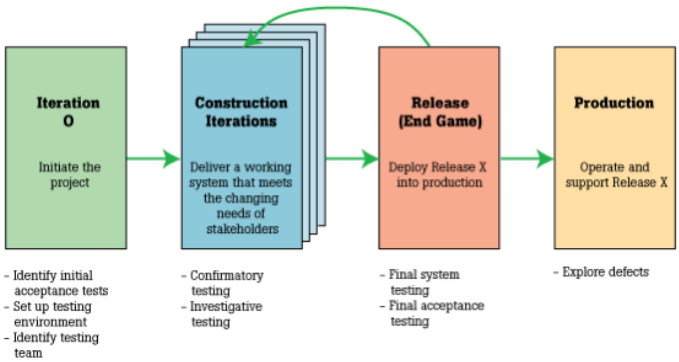
16 Key Deliverables and Acceptance Criteria

Key Deliverable	Acceptance Criteria
Support tools & processes	Appropriate tools and processes are documented and deployed. Support staff is suitably trained.
Software integrated with AAF authentication	User creation and maintenance functionality is integrated with AAF authorisation service User authentication is implemented through AAF interfaces
Initial production Research Cloud deployment	Software is available in a production environment in the Research Cloud or on National Server Program infrastructure (we currently have access to 2 NSP virtual servers) Software has passed user acceptance using real data.
Integrated Invoicing & Billing	Resource utilisation for internal and external service provision can be tracked

	Cost recovery processes are supported
Data Extraction for Analysis module	Users can specify criteria for subject and data selection by applying customised filters to demographic, pedigree, phenotypic (questionnaire) and biospecimen data. Selected data elements for filtered subjects can be extracted in specified formats, including .csv and popular statistical analysis package formats. Extracted data can be de-identified as appropriate
Pedigree Storage & Visualisation Module	Relationships between participants is easily captured and maintained by identifying a specified individual as the proband for a family and establishing the family relationships between subjects in the subject management module. Relationships between subjects can also be defined by loading a file specifying the proband for a family and the mother/father relationships between the subjects within that family. Pedigrees can be visualised and explored
Enhanced Data Linkage & Reporting capability	Data sets matching chosen criteria can be identified using criteria that span multiple data sources and types
Registry Management module	Access to and usage of subjects and data by third parties can be captured, controlled and monitored
Genotypic Data Management capability	Genotypic data can be aggregated and stored efficiently Genotypic data can be accessed easily for analysis

17 Quality Control

The Ark team will follow an Agile software development approach where working software will be developed in a number of incremental sprints.



Members of The Ark project team will be responsible for developing the functional requirements and acceptance tests in conjunction with the business analysts from the collaborating organisations. Representatives from the collaborating organisations will be responsible for signing off these requirements and acceptance tests. All requirements/user stories and acceptance criteria will be documented in Confluence, the project wiki.

All issues identified, be they requests for enhancements or bugs, will be documented in Jira, the project issue tracking system which will be made available online to all project participants.

Confirmation Testing

Throughout each development iteration or sprint the software will undergo continual confirmation testing to ensure that it is functioning correctly and to ensure that new software doe not "break" existing functionality. This confirmation testing will be done by the business analysts on the project. The Hudson continuous integration tools will be used to ensure that as software is checked into Subversion, the source code repository, it will still compile and run.

Usability Testing

Visual mockups will be created for the application screens using Balsamic, a mockup tool that has been integrated with the Confluence wiki. Representatives from the collaborating organisations will be responsible for signing off these user interface designs.

System Testing

The business analysts will be responsible for conducting system testing for each module to ensure that the software developed meets the requirements and acceptance criteria defined.

Security Testing

The Ark project team will be responsible for conducting security testing in accordance with any guidelines developed by the AAF and NeCTAR for applications hosted on the Research Cloud.

User Acceptance Testing

User Acceptance Testing will be undertaken by our partner organisations using real production data. Prior to each cycle of User Acceptance testing we will migrate production data into a secure testing instance for these partners to test in order to ensure that both the migration scripts and the application functionality, performance, security, etc. meet the required levels.

18 Risk and Issue Management

The key risks to the successful delivery of the proposed project include:

- Availability of appropriately skilled development resources. This risk is significantly mitigated through the ability of the project to retain development staff at competitive salaries;
- Ongoing availability of partner organisation resources. Each of the partner organisations has made a commitment to providing these resources but in the event that availability becomes an issue then alternative resources will need to be identified.
- Availability and support of infrastructure services, including RDSI, AAF and the Research Cloud. Successful implementation will be dependent on these facilities being available at the appropriate time points.

There are no open issues that need to be resolved before the project can start delivery.

There are no key questions that need to be resolved before the project can start delivery however the scope and approach to be taken to the delivery of the genotypic data management functionality will be dependent on the success of the complementary NeCTAR proposals.

Risk Management Approach

The Project Manager will develop a risk management plan that will detail the approach to be taken to risk identification; risk quantification; risk mitigation; and risk monitoring and control. All project risks will be documented within a risk register and assigned a risk rating. Risk mitigation plans will then be developed for each of the major risks and then an ongoing

process will be implemented to continually monitor risks to identify any changes in status, to identify outstanding actions, to remove risks that have passed and to identify new risks.

LEVERAGING

19 Standardisation and Interoperability

The Ark team is developing all of the software to be as flexible as possible so that it can be used to support studies that have chosen to adopt specific ontologies or have developed their own coding standards for data storage. The ability for researchers to define their own data dictionary and data entry forms as well as to define custom fields exists in all modules. All field definition is by way of a graphical user interface.

All software development will be done according to the relevant W3C software development standards.

The Ark team and the project supporters will work collaboratively to encourage the adoption of standard sets of operating procedures and common ontologies across research projects within a given research disease discipline.

- The project team will work with the (P3G) Public Population Project in Genomics' DataShaper group (www.datashaper.org) to encourage the adoption of their Data Schema and Harmonization Platform for Epidemiological Research.
- The project team will collaborate with leading proponents of common SOPs, such as The Canadian Tumour Repository Network (www.ctrnet.ca).

The project team will work together with other funded NeCTAR funded project teams that are developing genotypic data management and analysis capabilities. A common set of web services will be defined so that our software is able to leverage the capabilities being developed by the Genomics Virtual Laboratory, Galaxy/GDR Integration and Service Centre Data Handover projects.

FINANCIAL

20 Budget Breakdown

Milestone	Associated Deliverable Start Date	Milestone Date	EIF Funding	Co-investment Funding
Contract signed **(Linked to Funding Milestone 1)**	When contract signed	When contract signed		
Funding Milestone 1	**When contract signed**	**When contract signed**	**$52,000**	
Established Support Tools & Processes **(Linked to Funding Milestone 2)**	15-Mar-12	30-Mar-12		**SJOG In-kind - $406** **Total $406**
Integrated existing application with AAF Authentication Services **(Linked to Funding Milestone 2)**	30-Mar-12	15 May-12		**SJOG In-kind - $1,217** **OBiBa In kind - $2,114** **Total $3,331**
Funding Milestone 2		**15-May-12**	**$52,000**	
Integrated Invoicing & Billing **(Linked to Funding Milestone 3)**	15-Mar-12	15 Jul-12		**SJOG In-kind - $14,390** **MEGA In-kind - $25,773** **Total $40,163**
Initial Production Research Cloud Deployed **(Linked to Funding Milestone 3)**	15-Mar-12	15 Jul-12		**SJOG In-kind $- $9,462** **Total - $9,462**
Funding Milestone 3		**15 Jul-12**	**$52,000**	
Implemented Data Extraction for Analysis Module **(Linked to Funding Milestone 4)**	30-Jun-12	31-Aug-12		**SJOG In-kind - $1,420** **Total - $1,420**
Implemented Pedigree Storage & Visualisation Module **(Linked to Funding Milestone 4)**	15-May-12	15 Sep-12		**SJOG In-kind - $7,064** **COSA In-kind - $4,582** **Total - $1,1645**

Milestone	Associated Deliverable Start Date	Milestone Date	EIF Funding	Co-investment Funding
Funding Milestone 4		**15-Sep-12**	**$52,000**	
Enhanced Data Linkage & Reporting Module **(Linked to Funding Milestone 5)**	15-Sep-12	15 Dec-12		**SJOG In-kind - $4,503** **COSA In-kind - $2,921** **Total - $7,424**
Implemented Registry Management Module **(Linked to Funding Milestone 5)**	15-Jul-12	15 Dec-12		**SJOG In-kind - $2,434** **MEGA In-kind - $18,900** **Total - $21,334**
Integrated Genotypic Data Management Capability **(Linked to Funding Milestone 5)**	30-Aug-12	30 Jan 13		**SJOG In-kind - $3,651** **OBiBA In-kind - $3,170** **COSA In-kind - $12,886** **Total - $19,708**
Funding Milestone 5		**30 Jan 13**	**$52,000**	
Funding Milestone 6 - Final Admin Closure		**30Sept-13**	**$29,000**	
System Support	1-Jan-13	30-Jun-14		**SJOG Cash - $94,500** **MEGA In-kind –- $94,500** **Total - $189,000**
Travel Budget (UWA Centre for Genetic Epidemiology and Biostatistics (CGEB))				**UWA Cash - $10,000**
Other Expenses (UWA Research Matching Funds)				**UWA Cash - $10,000**
Total EIF Request			**$290,598**	
Total co-investment				**$323,892**
Total Project Budget			**$614,490**	

Please refer to Appendix 1 - Resource breakdown by Milestone – for a detailed breakdown of allocated resource costs per milestone and deliverable.

The system support phase of this project for 2013/2014 will be funded by the UWA Centre for Genetic Epidemiology and Biostatistics and the project collaborators. The Centre for MEGA Epidemiology has committed a support resource at 0.5 FTE for the duration of the support period. St John of God Healthcare has committed to cover the salary costs for the UWA support resource at 0.5 FTE for the duration of the support period.

Supplementary income is likely to be derived through cost recovery for other research projects. The project team has utilised a partial cost-recovery model for its hosted services for the last 12 months. Users of the existing proprietary hosted services have been willing to pay between $3,000 and $25,000 per year, depending on the breadth of functionality used and the

degree of support required. Cost recovery so far this year has been in the order of $70,000 for hosting support. Additional resources, outside the scope of this proposal, will be responsible for supporting researchers from non-collaborating organisations.

Access to the open-source software as it is deployed will not be restricted only to the collaborating organisations. Any researcher may gain access to the source code and deploy it on their choice of infrastructure. Given sufficient demand, new staff may also be allocated at the UWA Centre for Genetic Epidemiology and Biostatistics to support additional instances of the software in the Research Cloud.

SERVICES AND SUPPORT

21 Service Levels

The Ark service desk personnel will primarily be located at the Centre for Genetic Epidemiology at the University of Western Australia with additional support being provided from the Centre for MEGA Epidemiology at the University of Melbourne. This will ensure that support personnel will be available from 9am to 5pm Monday to Friday for all Australian locations.

All The Ark users will have access to an instance of the Jira issue tracking software application hosted in the Research Cloud to enable them to log and then follow the progress of issues, including bugs, enhancements and requests for assistance with tasks like project configuration and data migration.

Customer support will primarily be provided through the Jira issue management software with response times by support staff of less than 24 hours on average.

The service levels provided by The Ark software will be dependant on the service levels being offered by the NeCTAR Research Cloud as it is intended that all The Ark software will be hosted in the cloud. Independent of the Research Cloud availability, The Ark will endeavour to provide access to the application software at a 95% level between the hours of 9am EST time to 5pm WST time. All major software upgrades will be conducted after 3pm WST time to ensure maximum availability for Eastern States users.

All The Ark documentation is currently, and will continue to be, hosted on The Ark's Confluence wiki. This is currently hosted on our own servers but will be migrated to the Research Cloud.

Training will be conducted using a number of mechanisms:

- Face-to-face training will be conducted by The Ark staff from either Melbourne or Perth. Where travel is required then these costs will be borne by the research institution receiving training.
- Online video presentations. The intent is to develop a number of online video training sessions that will be accessible from The Ark website.
- How-to documentation will be developed that provides a step-by-step approach to configuring and using The Ark tools.

22 Operations and User Support

The Centre for Genetic Epidemiology and Biostatistics at the University of Western Australia and the Centre for MEGA Epidemiology at Melbourne University will support the software tools implemented by The Ark project. The support mechanisms provided to users will include:

- Online support by providing all users with access to the Jira issue management tracking tools;
- Telephone support as appropriate;
- Access to online documentation through The Ark's wiki; and
- Access to answers to frequently asked questions on The Ark's wiki.

Significant face-to-face support will also be provided to the project collaborators during the development, implementation and support stages of the project.

23 Sustainability

Support for the project infrastructure during the operational stage through until 30 June 2014 will be funded by the project collaborators through the contribution of in-kind labour and cash.

Subsequent to 30 June, 2014 the infrastructure will continue to be operated through a cost recovery model.

Note that a cost recovery model is already in use at the UWA Centre for Genetic Epidemiology and Biostatistics for hosted software support. The current cost recovery model has the following features:

- Hosting and support charges are on a per-module basis. Researchers have access to and only pay for the modules that they require;
- Hosting and support charges are independent of the size of the research project;
- Configuration and training is charged on a per module basis;
- Fees are for access within a calendar year – charged pro rata;
- All client-specific work is charged on an hourly basis;

Changes to the existing business model to support the open-source software include:

- Researchers may choose to host their own instance of the software and may elect to enter into a technical support contract as long as they are running a supported, non-modified version of the software;

The intent is to have the production and test instances of the software hosted in the Research Cloud. Costs for this are as yet unknown but if this does incur a charge then this will be passed onto the organisations using the software on a pro-rata basis.

Currently if new The Ark functionality is requested by a specific client then the work is typically only undertaken if will contribute to the main branch of the software, even if the client is willing to pay for the development. During the course of the NeCTAR project the new functionality will be driven by the requirements of the key project collaborators.

24 IP, Licensing and Access

All software development will be undertaken under the GPLv3 open source software license. The GNU General Public license is a copyleft license for general use, which means that derived works can only be distributed under the same license terms. Under this philosophy, the GPL grants the recipients of a computer program the rights of the free software definition and uses copyleft to ensure the freedoms are preserved, even when the work is changed or added to.

There will be no other Intellectual Property or licensing restrictions relevant to the services that will be delivered.

There will be no restrictions on access to the services that will be delivered.

Software licenses used for software development will include:

- Macintosh Operating System
- Windows Operating System
- Centos Linux Operating System (Local & NeCTAR Research Cloud)
- Navicat Data Modelling Tool
- MySQL Database (open source license)
- Atlassian Jira issue tracking and project management (open source license)
- Atlassian Confluence wiki (open source license)
- Subversion source code management

- Hudson Continuous Integration
- Microsoft Project
- OpenLDAP
- Balsamic GUI Mockup Tool

25 Communications and Engagement

An Agile software development approach will be used for the project. Software will be developed in short iterations, typically 2-4 weeks. At the end of each iteration a working product will be demonstrated to stakeholders. This will minimise overall risk and allow the project to adapt to changes quickly. This approach will provide the project customers the opportunity to provide timely feedback that can rapidly be integrated into the software development process.
Subsequent to each sprint there will be a Sprint Review Meeting during which feedback will be solicited and discussed to determine product and process deficiencies and improvements.

26 Constraints and Dependencies

External Party	Capability Required	Date first required	Milestones or Deliverables dependent on that capability
AAF	ARCS Access Service	April 2012	Integrated existing application with AAF Authentication Services
RDSI	Research Data Service Infrastructure	August 2012	Integrated Genotypic Data Management Capability
The Research Cloud	Application and database hosting	We already have access to National Server Program servers so this is not a criitcal requirement	Initial Production Research Cloud Deployment
IVEC	HPC Infrastructure & Services	August 2012	Integrated Genotypic Data Management Capability
Genomics Virtual Laboratory Project	Interface Definitions	July 2012	Integrated Genotypic Data Management Capability

No expenditure, scalability or performance constraints have been identified.
The successful completion of the project is dependent on the availability and performance of other national infrastructure elements, including:

- AAF Authentication services
- RDSI
- The Research Cloud
- HPC infrastructure and services

The approach and scope of the solution to be implemented for genotypic data management, analysis and HPC integration will be dependent on the funding outcome of the Genomics Virtual Laboratory, Galaxy/GDR Integration and Service Centre Data Handover projects.

Section 6 Selection Criteria

Removed from the document

Section 7 Milestone and Funding Milestone Template

7.1 Funding Estimate

Organisation / Group Name	Anticipated Distribution of EIF Funds (%)
Centre for Genetic Epidemiology & Biostatistics at the University of Western Australia	**100%**

7.2 Milestones

Note – Items in "Deliverables/Completed Activity" are mandatory.

No.	Funding Milestone Yes / blank	Milestone Title	Deliverables/Completed Activity	Target Milestone Date	NeCTAR (EIF) funds ($thousands)				Co-investment (budgeted contribution value) ('000)
					Requested ('000)	Planned Expenditure breakdown			
						Labour ('000)	Equipment ('000)	Other ('000)	
1		Sub-contract signed (Linked to Funding Milestone 1)	Sub-contract	When contract signed					20 (Cash)
2	Yes	Funding Milestone 1	Linked to Milestone 1	When contract signed	52	52			
3		Established Support Tools & Processes (Linked to Funding Milestone 2)	Support Tools & Processes	30 Mar 2012					1
4		Project Initiation complete (Linked to Funding Milestone 2)	*Communications plan prepared and sent to NeCTAR (Signed contract + two months).*	15 Apr 2012					
5		Integrated existing application with AAF Authentication Services (Linked to Funding Milestone 2)	Integrate existing application with AAF Authentication Services	15 May 2012					3
6	Yes	Funding Milestone 2	Linked to Milestone 3, 4 and 5	15 May 2012	52	52			

7		Integrated Invoicing & Billing Complete (Linked to Funding Milestone 3)	Integrated Invoicing & Billing Module	15 July 2012					40
8		Initial Production Research Cloud Deployed (Linked to Funding Milestone 3)	Initial Production Research Cloud Deployment	15 July 2012					9
9	Yes	Funding Milestone 3	*Linked to Milestone 7 and 8*	15 July 2012	52	52			
10		Implemented Data Extraction for Analysis Module (Linked to Funding Milestone 4)	Data Extraction for Analysis Module	31 Aug 2012					2
11		Implemented Pedigree Storage & Visualisation Module (Linked to Funding Milestone 4)	Pedigree Storage & Visualisation Module	15 Sept 2012					12
12	Yes	Funding Milestone 4	*Linked to Milestone 10 and 11*	15 Sept 2012	52	52			
13		Enhanced Data Linkage & Reporting Module Complete (Linked to Funding Milestone 5)	Enhanced Data Linkage & Reporting Module	15 Dec 2012					7
14		Implemented Registry Management Module (Linked to Funding Milestone 5)	Registry Management Module	15 Dec 2012					21
15		Integrated Genotypic Data Management Capability (Linked to Funding Milestone 5)	Integrate Genotypic Data Management Capability	30 Jan 2013					20

16	Yes	Funding Milestone 5	**Linked to Milestone 13, 14 and 15** **Note that all development should be completed by 30 Jan 2013**	30 Jan 2013	52	52			
17	Yes	Final Admin Closure (Funding Milestone 6)	*Post-implementation Review (PIR) conducted and sent to NeCTAR.* *Practical Completion Certificate accepted by NeCTAR.*	30 Sep 2013	29	29			
18		Operations to June 2014	*Service Levels met and reported to NeCTAR as defined.*						189

Note that all development software licenses and all development hardware required for the projects will be supplied by The Centre for Genetic Epidemiology and Biostatistics.

Milestone No.	Name of Service/Deliverable	Date of deployment for pilot use	Date of deployment as production
3	Established Support Tools & Processes (Linked to Funding Milestone 2)	15 July 2012	15 Aug 2012
5	Integrated existing application with AAF Authentication Services (Linked to Funding Milestone 2)	15 May 2012	15 Aug 2012
7	Integrated Invoicing & Billing Complete (Linked to Funding Milestone 3)	15 July 2012	15 Aug 2012
8	Initial Production Research Cloud Deployed (Linked to Funding Milestone 3)	15 Jul 2012	15 Aug 2012
10	Implemented Data Extraction for Analysis Module (Linked to Funding Milestone 4)	31 Aug 2012	30 Sep 2012
11	Implemented Pedigree Storage & Visualisation Module (Linked to Funding Milestone 4)	15 Sep 2012	15 Oct 2012
13	Enhanced Data Linkage & Reporting	15 Dec 2012	30 Jan 2013

	Module Complete (Linked to Funding Milestone 5)		
14	Implemented Registry Management Module (Linked to Funding Milestone 5)	15 Dec 2012	30 Jan 2013
15	Integrated Genotypic Data Management Capability (Linked to Funding Milestone 5)	30 Jan 2013	30 Mar 2013

Appendix 1 - Resource Breakdown by Milestone

Milestone	Associated Deliverable Start Date	Milestone Date	Assigned Resources	FTE	Cost	EIF Funding	Co-investment Funding
Sub-contract signed (Linked to Funding Milestone 1)	Sub-contract	When contract signed					
Funding Milestone 1		**When contract signed**				**$52,000**	
Established Support Tools & Processes (Linked to Funding Milestone 2)	15-Mar-12	30-Mar-12	Paul White	0.15	$1,217	1,217	
			Programmer	1	$5,727	$5,727	
			Nik Zeps	0.05	$406		$406
Milestone Totals						**$6,944**	**$406**
Integrated existing application with AAF Authentication Services (Linked to Funding Milestone 2)	30-Mar-12	15-May-12	Paul White	0.15	$3,651	$3,651	
			Nik Zeps	0.05	$1,217		$1,217
			Philippe Laflamme	0.1	$2,114		$2,114
			Programmer	1	$17,182	$17,182	
Milestone Totals						**$20,833**	**$3,331**

Milestone	Associated Deliverable Start Date	Milestone Date	Assigned Resources	FTE	Cost	EIF Funding	Co-investment Funding
Funding Milestone 2		**15-May-12**				**$52,000**	
Integrated Invoicing & Billing (Linked to Funding Milestone 3)	15-Mar-12	15-Jul-12	Paul White	0.2	$14,605	$14,605	
			Nik Zeps	0.05	$3,651		$3,651
			Adrian Bickerstaffe	0.5	$25,773		$25,773
			Andrew Mews	0.25	$10,739		$10,739
						$14,605	**$40,163**
Initial Production Research Cloud Deployed (Linked to Funding Milestone 3)	15-Mar-12	15-Jul-12	Paul White	0.15	$7,911	$7,911	
			Nik Zeps	0.05	$2,637		$2,637
			Chris Ellis	1	$39,000	$39,000	
			Andrew Mews	0.1	$3,102		$3,102
			Lisa Spalding	0.1	$3,723		$3,723
Milestone Totals						**$46,911**	**$9,462**
Funding Milestone 3		**15-Jul-12**				**$52,000**	
Implemented Data Extraction for Analysis	30-Jun-12	31-Aug-12	Paul White	0.2	$5,680	$5,680	

Milestone	Associated Deliverable Start Date	Milestone Date	Assigned Resources	FTE	Cost	EIF Funding	Co-investment Funding
Module (Linked to Funding Milestone 4)							
			Nik Zeps	0.05	$1,217		$1,217
			Chris Ellis	1	$21,000	$21,000	
Milestone Totals						**$26,680**	**$1,420**
Implemented Pedigree Storage & Visualisation Module (Linked to Funding Milestone 4)	15-May-12	15-Sep-12	Paul White	0.2	$12,982	$12,982	
			Nik Zeps	0.05	$3,245		$3,245
			Andrew Mews	0.1	$3,818		$3,818
			Project Officer (individual to be determined)	0.1	$4,582		$4,582
			Programmer	1	$45,818	$45,818	
Milestone Totals						**$58,800**	**$11,645**
Funding Milestone 4		**30-Sep-12**				**$52,000**	
Enhanced Data Linkage & Reporting Module (Linked to Funding Milestone 5)	15-Sep-12	15-Dec-12	Paul White	0.2	$8,276	$8,276	
			Nik Zeps	0.05	$2,069		$2,069

Milestone	Associated Deliverable Start Date	Milestone Date	Assigned Resources	FTE	Cost	EIF Funding	Co-investment Funding
			Andrew Mews	0.1	$2,434		$2,434
			Project Officer (individual to be determined)	0.1	$2,921		$2,921
			Programmer	1	$29,209	$29,209	
Milestone Totals						**$37,485**	**$7,424**
Implemented Registry Management Module (Linked to Funding Milestone 5)	15-Jul-12	15-Dec-12	Paul White	0.2	$9,736	$9,736	
			Nik Zeps	0.05	$2,434		$2,434
			Kelly Aujard	0.05	$1,718		$1,718
			Adrian Bickerstaffe	0.5	$17,182		$17,182
Milestone Totals						**$9,736**	**$21,334**
Integrated Genotypic Data Management Capability(Linked to Funding Milestone 5)	30-Aug-12	30-Jan-13	Paul White	0.2	$14,605	$14,605	
			Nik Zeps	0.05	$3,651		$3,651
			Philippe Laflamme	0.05	$3,170		$3,170
			Chris Ellis	1	$54,000	$54,000	
			Project Officer	0.25	$12,886		$12,886

Milestone	Associated Deliverable Start Date	Milestone Date	Assigned Resources	FTE	Cost	EIF Funding	Co-investment Funding
			(individual to be determined)				
Milestone Totals						**$68,605**	**$19,708**
Funding Milestone 5		**30-Jan-13**				**$52,000**	
Funding Milestone 6 - Final Admin Closure		**30-Sep-13**				**$29,000**	
System Support	1-Jan-13	30-Jun-14	Support Analyst (Centre for Genetic Epidemiology & Biostatistics)	0.5	$89,500		$89,500
			Support Analyst (Centre for MEGA Epidemiology)	0.5	$89,500		$89,500
Milestone Totals							**$189,000**
EIF Salary funds requested						$290,598	
Salary co-investment							$303,892
Travel Budget (UWA Centre for Genetic Epidemiology & Biostatistics)							$10,000
Other Expenses (UWA Research Matching							$10,000

Milestone	Associated Deliverable Start Date	Milestone Date	Assigned Resources	FTE	Cost	EIF Funding	Co-investment Funding
Funds)							
Total EIF Request						**$290,598**	
Total co-investment							**$323,892**
Total Project Budget						**$614,490**	

Appendix 2 - Letters of Support for this Proposal

ST JOHN OF GOD
HEALTH CARE

HOSPITALS DIAGNOSTICS OUTREACH

ST JOHN OF GOD PATHOLOGY
PO Box 646
Wembley WA 6913
Tel: 1300 367 674
Fax: 08 9389 7836
www.sjog.org.au/pathology

14 March, 2012

Re The ARK NeCTAR proposal

Dear Paul,

I am writing to formally acknowledge our intent to provide 0.5 FTE of Mr Andrew Mews' and 0.1FTE of my time to this project. It is essential that we have appropriate database infrastructure and support for our molecular research into cancer as there is no way to manage the genotypic and phenotypic data without it.

Please feel free to contact me if you should need any further information.

Yours Sincerely

Nik Zeps

Dr Nikolajs Zeps
Research Group Leader
Nik.zeps@sjog.org.au
+61400223097

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ST JOHN OF GOD PATHOLOGY
PO Box 646
Wembley WA 6913
Tel: 1300 367 674
Fax: 08 9389 7836
www.sjog.org.au/pathology

14 March, 2012

Re The ARK NeCTAR proposal

Dear Paul,

I am writing to formally acknowledge our intent to provide 0.25 FTE of a project officer toward this project if successful. Their role will be focused on the area of biobanking samples from patients enrolled in cancer clinical trials of the cooperative groups.

Please feel free to contact me if you should need any further information.

Yours Sincerely

Nik Zeps

Dr Nikolajs Zeps
Research Group Leader
Nik.zeps@sjog.org.au

+61400223097

Level 3, 207 Bouverie Street
Carlton Victoria 3010
Freecall 1800 037 021
Facsimile +61 3 9349 5815
Email twins-atr@unimelb.edu.au

Dear Paul,

Re: NeCTAR Cloud-based Bioinformatics Tools Proposal

The Australian Twin Registry (ATR) is fully supportive of this NeCTAR proposal for cloud-based informatics tools.

The ATR is a national NHMRC funded volunteer registry of Australian twin pairs and higher order multiples of all zygosity types and ages who are willing to consider involvement in public health and biomedical research. The ATR facilitates collaborations between twin volunteers and researchers wishing to conduct studies involving twins. Twin studies can provide unique insights into the genetic and environmental causes of human characteristics, including disease and health-related traits.

Established in 1980 as a national research the ATR has facilitated more than 450 studies producing more than 650 publications of peer reviewed papers.

The ATR is in a unique position to facilitate the sharing of data generated from research involving twins so that future studies can build upon the more than 30 years of research has been conducted to date. The establishment of an integrated archive of data collected on ATR members would considerably enhance this position.

Rather than attempting to build a facility wholly in house, the ATR has identified that collaborating with The Ark project best serves the ATR and its stakeholders. The ATR requires access to an online service which can facilitate the ongoing management of the registry and the storage and sharing of data from independent researchers.

The Ark's ability to adapt to specific requirements and the sophisticated informatics support it will provide will play a vital role in the ATR's ability to achieve its goal of maximising the research potential of the registry and its members.

Yours sincerely,

Professor John Hopper, AM
Director, Australian Twin Registry

The Australian Twin Registry is supported by an Enabling Grant from the National Health and Medical Research Council and administered by The University of Melbourne.

Patrons
Sir James Balderstone AC
Mr Robert Balderstone CMG MC
Mr Stephen Waugh
Mr Mark Waugh

www.twins.org.au

To: Mr Paul White

Centre for Genetic Epidemiology and Biostatistics, University of Western Australia

From: Professor William Ardrey

WA Institute of Skin Cancer Medicine & Rural Health, and Australian National University

Date: October 28, 2011

RE: Letter of Support, Cloud Based Informatics Tool

Please accept this letter of support for your grant applications to advance your Java-based, Cloud-based approach to support biomedical researchers.

By way of background, the WA Institute won Royalties for Regions and other grant support to establish a Registry for sufferers of non melanoma skin cancer. The Institute has published its first studies on ocular health, and skin cancer wellness, in rural areas and on remote work sites. We have been working to establish an enterprise based system to capture, catalogue, manage, safeguard and deliver confidential patient data in order to advance this study, and there are no currently ideal tools for this. Through your Centre, your team has commenced collaboration and offered helpful advice, however the system which your Grant funding proposes to support is exactly what GP-led primary care researchers need.

With such a tool available, we would be able to further advance our mission of rural based, GP-led primary care research on other medical issues such as rural women's health, rural mens wellness, and improved programs for skin cancer prevention, treatment and management ideal for regional areas such as Geraldton. It also is a good tool for commercial medical practices and Australian biotechnology companies, as it adds features and functions to make this sort of primary care research more 'manageable' for busy commercial organizations.

Thank you again.

PROF WILLIAM ARDREY www.wainstitute.com.au
DIRECTOR, WA INSTITUTE OF SKIN CANCER MEDICINE AND RURAL HEALTH

5 HERMITAGE STREET
GERALDTON, WA 6035

Email: director@wainstitute.com.au

Letter of Support

for The Ark, a "Cloud-based Bioinformatics Tools" proposal of the

UWA Centre for Genetic Epidemiology and Biostatistics

For many years, our teams at the Centre for Clinical Research in Neuropsychiatry and the Western Australian Institute for Medical Research have been involved in studies of the phenotypic and genetic heterogeneity of schizophrenia. Funded by multiple NHMRC grants, the Western Australian Family Study of Schizophrenia (WAFSS) has developed a unique database with extensive information on over 1,000 individuals covering clinical manifestations (including hospital records and video-recorded interviews), cognitive ability (performance on tests assessing different domains of cognition, such as memory, attention, executive function and general intelligence), electrophysiological and neuroimaging data. This is supplemented by a rich collection of biological materials, including DNA, RNA, protein, serum, WBC pellets and cultured transformed lymphocytes. The scope and amount of genetic information is already very large and growing: we have accumulated genotyping data from candidate gene and GWA studies and an increasing amount of sequencing data. Over the years, we have had a very productive collaboration with the team at the UWA Centre for Genetic Epidemiology and Biostatistics, without whose highly professional help and support it would have been impossible for us to manage and use this wealth of information.

The Ark is a major step towards building a tool that will meet future needs for increasingly complicated integration and interrogation of our data coming from multiple diverse fields. Our requirements include expanding capacity (e.g. accommodating additional information on physical morbidity), linking records (e.g. on family members), highly flexible outputs that will save time in generating datasets and reports and allow diverse approaches to data analysis, and of course high security.

The WAFSS collection of data and biological samples is globally unique and The Ark will allow its full use in terms of data mining, current management, and design of future studies.

Winthrop Professor Assen Jablensky 27/10/2011

Director, UWA Centre for Clinical Research in Neuropsychiatry (CCRN)

Eyeco Pty Ltd

acn 109 283 892

31/Oct/2011

Registered Office:
Level 33
William Street
Melbourne, Victoria 3000
Australia

Dear Paul White

University of Western Australia

Please accept this letter of support for your cloud computing initiative.

EyeCo Pty Ltd is aPartner Investigator to the ARC Funded Centre Of Excellence in Vision Science at ANU. We are an ophthalmic drug development company with our first commercial product on the market (for age related macular degeneration). We have developed additional proprietary products which will require clinical trials, data collection, and interface with investigators, regulators, grant supporters and other stakeholders in a confidential way, which also permits data analysis. The system you are proposing is ideal for the sort of clinical investigations we need to launch in the retinal disease market, and we are very supportive.

Please tell us how we can get involved. Our team has close linkages with leading universities in Australia and also contributes significantly to peer reviewed research in top journals.

Yours Faithfully

A/Professor Dr Philip L Penfold

Chief Scientist EyeCo Pty Ltd

Appendix 3 – Past Letters of Support Commending our Operational Support Capabilities

Mr. Paul White
Manager Informatics Systems Development
University of Western Australia
Ground Floor, B Block
QE-II Medical Centre
Hospital Avenue
Nedlands WA 6009
AUSTRALIA

19th May 2009

Dear Paul,

As Manager of the Western Australian DNA Bank (WADB) I am pleased to provide you with this letter of support for the Western Australian Genetic Epidemiology Resource (WAGER).

The WADB is a National Health and Medical Research Council (NHMRC) Enabling facility which provides the infrastructure, consumables and laboratory personnel for low cost biospecimen processing and dual-site storage of human DNA samples in Western Australia for medical research purposes. The WADB itself does not recruit these donors, but stores DNA for medical researcher's who have collected a DNA sample from consenting donors participating in ethically approved research studies.

The decision was made at the time the WADB was founded to utilise WAGER's Laboratory Information Management System (LIMS) as the core application for managing the WADB's biospecimen repository. The cost of purchasing , configuring and maintaining a commercial off-the-shelf LIMS package that could also meet the WADB's specific requirements was deemed to be cost-prohibitive. WAGER has been instrumental in providing the WADB with a storage and management system for biospecimens in WA that meets best-practice standards.

Over the course of the last 3 years WAGER has become an indispensable resource for the WADB, not only providing cost-effective access to LIMS software, but also providing a high level of technical and data support. During that time the WAGER informatics team have made significant improvements to the LIMS software to facilitate the integration of new WADB clients and the smooth operation of the WADB facility. The WADB currently employs 4 full-time laboratory staff and now manages more than 33,000 biospecimen samples from more than 30 studies using the WAGER LIMS.

I strongly support the continuation of WAGER in both Western Australia and as a national facility. WAGER is an essential component of our plans to eventually have a physical presence in other states.

Yours sincerely,

Dr Marion Macnish PhD

University of Western Australia's Centre for Genetic Epidemiology and Biostatistics
MBDP 519, B block, Hospital Avenue, Nedlands WA 6009, Australia
www.wadb.org.au

Mr Paul White
Manager Informatics Systems Development
Centre for Genetic Epidemiology & Biostatistics
Western Australian Institute for Medical Research
Ground Floor, B Block
QE-II Medical Centre
Hospital Avenue
Nedlands WA 6009
AUSTRALIA

14th May 2009

Dear Paul,

Re: WAGER NHMRC Enabling Grant renewal letter of support

I am pleased to provide a letter of support for WAGER as Director of the WA Sleep Health study (WASHS). This study is a prospective, sleep clinic cohort study which has been designed to investigate the aetiology and consequences of obstructive sleep apnoea. Thus far since 2005 we have collected questionnaire data, sleep study data, anthropometric data and blood samples for genetic and biochemical analyses from all consenting new sleep clinic patients at the Sir Charles Gairdner Hospital Sleep Clinic. We currently have over 3000 patients enrolled in this study which is already approaching the largest single database of obstructive sleep apnoea patient data in the world. Furthermore we established the capacity to link the health information from these patients to other key databases, including core WA Department of Health data sets and therefore obtain longitudinal health information on these subjects. This resource is an invaluable tool for investigating the causes, complications, and survival of OSA patients and may contribute to improved management of patients with OSA.

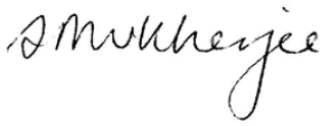
Our decision to utilize the services of WAGER was a relatively easy one. We planned to collect large amounts of clinical information from over 5000 participants; it was clear that we needed highly sophisticated, time efficient informatics support to allow careful storage of data but also the ability to utilize, access and analyse these data as needed. WAGER meets all our requirements and has been a major factor in the success of our project. It would be financially impossible to manually enter the data contained in WAGER; several data entry staff would be necessary and our study has been funded thus far with a few small grants. We currently have 4 Doctoral students, 11 medical students and 2 Honours students working on analyzing the data and will have several important publications in press by end 2009. Another important advantage to the WAGER system has been the ability to add in various components as new clinical information is added, e.g. DEXA scanning and carotid intimal media thickness scanning.

We have also been able to foster collaboration with interstate and international groups because of the state of the art informatics system that underpins our research. There has been fruitful exchange of questionnaire and other data collection instruments between institutions and we hope that the WASHS data collection tools will be adopted in various sites in Melbourne and Brisbane in 2009 and WAGER will provide the informatics support to allow this to happen. It is clear from long discussions with my colleagues internationally and interstate that no such informatics support is available to these colleagues and they are particularly interested and envious of the resource that exists here in Australia.

It is essential for our study that a resource such as WAGER continues to be funded since after 4 years we are finally in a good position to apply and receive hard funding to continue and extend our research further and to develop interstate and international collaborations which will require high-level informatics input, such as WAGER.

I strongly support the continued funding of this invaluable research tool and commend the WAGER team on their professionalism and ability to provide high level expert support to varied clinical research groups in WA and interstate.

Yours sincerely,



Dr Sutapa Mukherjee MBBS, FRACP, PhD
Sleep Physician, WASDRI