

# Single ethical review of multi-site clinical trials



Dr Suzanne Hasthorpe  
Project Manager, Biotechnology  
DHS

# Information Session Scope

- Background
- Aims of single ethical review
- Overview of the system
- Concepts
- Roles and responsibilities
- Consent
- Trial commencement
- Information technology platform
- Online forms
- Establishing the system
- Communications

# Background

Changing face of clinical trials globally – a shift to large multi-site projects involving numerous institutions at different locations

Other countries have worked toward adopting approaches to streamline ethics review of multi-site research

- UK – 1997 Multi-centre Research Ethics Committees
- Europe – 2004 Directive 2001/20/European Commission implemented
- Canada – 2003 Ontario Cancer Research Ethics Board has Research Ethics Board responsibility
- New Zealand – 2004 National Multi-Regional Ethics Committee

# Background

The Victorian Government first committed support for a proposal to *Streamline ethical review of multi-site clinical trials* as part of the *Life Sciences Statement* (2005).

# Background

## Stakeholder Consultation and Input

Stakeholder consultation:

- Broad based information and discussion forums
- Targeted consultation
- Specialist workshops

Consultants reports on cost, feasibility and health economics.

# Background

## 2008 Victorian Innovation Statement (VIS)

### *Innovation: Victoria's Future*

Support for streamlining ethical review of multi-site clinical trials is included in the \$20m *Biotechnology Bridges* funding allocation, as part of the 2008 Victorian Innovation Statement, *Innovation: Victoria's future*.

# Aims of Single Ethical Review

- To grow clinical trials in Victoria
- Provide new treatments to patients sooner, improve health outcomes and quality of life

# Aims of Single Ethical Review

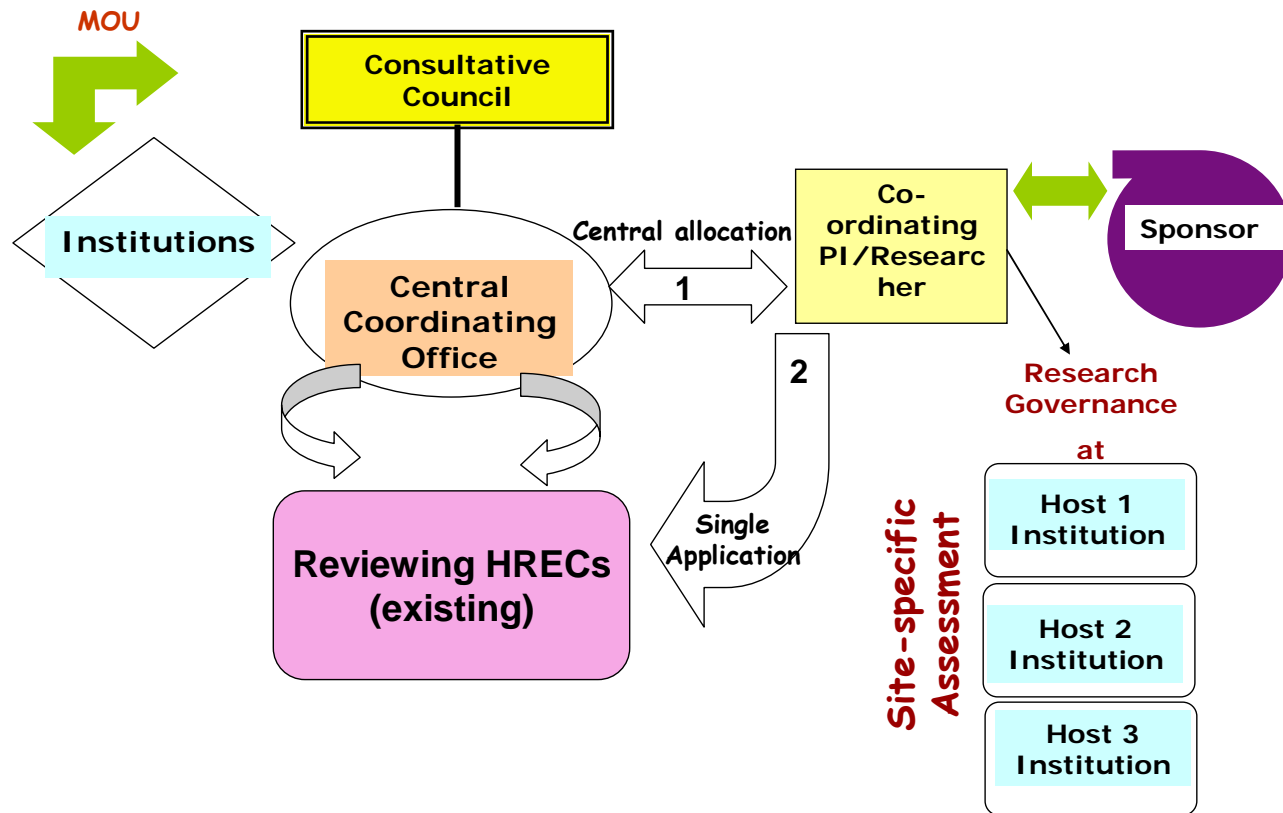
## What has to be Fixed?

- Duplication of effort and workload
- Inconsistency of review
- Timeliness of ethical review of multi-site clinical trials
- Timely commencement of clinical trials

Whilst maintaining:

- Effectiveness and quality of ethical review
- Patient safety
- Transparency of cost for review

# Overview of the System Structure



# Governance

## Consultative Council for Human Research Ethics

### The Consultative Council will:

- Be responsible for accreditation and selection of the human research ethics committees that undertake review of multi-site studies
- Have oversight of the secretariat that will provide administrative support to the Consultative Council and coordinate ethics review processes within the system
- Report to the Minister for Health and the Department of Human Services on the operational effectiveness of the overall system that undertakes ethics review of the multi-site studies
- Promote best practice ethical review of multi-site human research and provide advice to participating health services in Victoria where required
- Provide timely and authoritative advice to the Minister for Health and the Department of Human Services on relevant human research ethics issues at a state and national level

# Concepts

- Separation of ethical review from institutional business
- Research governance/site-specific assessment
- Linked information platform/research ethics database

# Concepts

## Separation of Ethics from Research Governance

Logical consequence:

- The need for two separate processes that must be linked at some point

Rationale:

- Only one organisation will receive an ethics application but assessment by all organisations is still needed to determine the resources required and the agreement from departments that will be involved

Solution:

- Separate processes for ethics review and research governance.
- An information platform/research ethics database

# Concepts

## Ethics Review

According to the *National Statement on Ethical Conduct in Human Research (2007)*

The Coordinating Office for Human Research Ethics (Coordinating Office) will allocate an ethics application to a reviewing HREC and meeting time slot

Ethics review will be as normal practice, the reviewing HREC will communicate with the Coordinating Principal Investigator (CPI)/or delegate

# Concepts

## Ethics Review

### **How is an ethics application allocated to a reviewing HREC?**

The CPI/or delegate will phone the Coordinating Office and answer questions to determine the reviewing HREC

All further communication in relation to an application will be with the:

- Reviewing HREC Coordinator/Administrator; and
- Reviewing HREC

# Concepts

## Ethics Review

- The CPI/or delegate must access the application form from the Australian Research Ethics Database (AU RED) Online Forms website
- Complete the HREC application, print and sign (CPI only)
- Send the HREC application to the reviewing HREC Coordinator with the required number of copies, etc
- The application will then be put on the agenda for the allocated meeting time

# Concepts

## Research Governance

- Each Principal Investigator (including the CPI) must access the Site Specific Assessment (SSA) Form from the AU RED Online Forms website
- Each PI must submit an SSA Form to their own organisation
- The SSA Form must be submitted as soon as possible after the HREC application has been submitted
- An SSA Form is printed, signed and submitted to the Research Governance Officer/or equivalent

# Concepts

## Research Governance

### **How does a Principal Investigator (PI) get a SSA Form for a study?**

- The CPI will transfer an SSA Form for that study to each of the PI's using the AU RED Online Forms website
- An email alert will be sent to each PI informing that a SSA Form is waiting to be completed
- The PI registers for an account on the AU RED Online Forms website (once only)

# Roles and Responsibilities

## Reviewing HREC

- Single ethical review of multi-site clinical trials, reporting (annual reports, AE reporting), amendments, etc

## CPI/or delegate

- Fill out the HREC application (National Ethics Application Form - NEAF) on the Online Forms website, attach supporting documents to the NEAF electronically on the Online Forms website, lock the form, print and sign
- Submit the HREC application and supporting documents as hard copy to the reviewing HREC Coordinator
- Ongoing communication with the reviewing HREC
- SSA and research governance (see next slide for PIs)

# Roles and Responsibilities

## Reviewing Organisation's HREC Coordinator (with Agreement)

- Ongoing communication about the application with the CPI/applicant
- Forward the HREC application and supporting documents, electronically, to PIs to upload on their SSA Online Form so they can submit these to the site's Research Governance Officer
- Communication of correspondence between CPI and the reviewing HREC to the PIs, sponsors and Research Governance Officers
- Forward HREC application updates/amendment documents and any new version of supporting documents (electronically) to PIs to upload on their SSA Online Form so that they can submit these to the site's Research Governance Officer

# Roles and Responsibilities

## Principal Investigator(s)

- Complete an SSA Form on the Online Forms website, attach all supporting documents (electronic), lock, print and sign
- Submit the printed SSA Form and supporting documents to the Research Governance Officer/or equivalent, at their site
- Submit a site CTN/CTX form
- Site Radiation assessment
- Ongoing communication with the Research Governance Officer, at their site

# Roles and Responsibilities

## Research Governance Officer

- Upload the SSA Form and supporting documents on AU RED
- Review the SSA Form
- Complete research governance requirements
- Recommend SSA authorisation/or not to the Chief Executive/or delegate
- Ongoing communication with the PI

# Consent

## Participant Information and Consent Form (PICF)

It is advisable that the DHS Participant Information and Consent Form (PICF) template is used

### **CLINICAL DRUG/DEVICE RESEARCH PROJECTS**

[www.health.vic.gov.au/ethics/downloads/picf\\_drug.doc](http://www.health.vic.gov.au/ethics/downloads/picf_drug.doc)

# Consent

## Master PICF

A **Master PICF** which contains the required wording (applicable to all study sites) and the details relating to the **Coordinating Principal Investigator**

Including:

- Letterhead, organisation/site where recruitment will occur, Investigator name and contact details, details for complaints, name and contact details of the reviewing HREC
- The version number and date must appear in the footer of each page

*Note: There may be more than 1 Master PICF if special consent requirements apply (e.g. Parents/Guardians of Children, Person Responsible, Participant Continuation)*

# Consent

## Master PICF – All Sites

Following HREC approval, the Master PICF(s) must be used for all study sites and ONLY modified to reflect the details of individual organisations.

This includes:

- Printing on institutional letterhead
- Stating the organisation where recruitment is occurring
- Showing the organisation's PI name and contact details
- Naming the person dealing with complaints and their contact details

# Consent

## Master PICF Requiring Site - Specific Wording

Where there is specific-site policy and standard wording is required by one or more institutions, for religious or other reasons, the CPI/or delegate may submit either:

- A **Master PICF** which contains the required site-specific wording
- The version number and date must appear in the footer of each page

**OR**

- A **Master PICF** without the site-specific wording
- The version number and date in the footer of each page and
- A **Site PICF** with the site-specific wording inserted
- The organisation/site name, version number and date in the footer of each page

# Consent

## PICF (when Site-Specific wording is required)

**Master PICF** which contains the required wording (applicable to all study sites and the details relating to the **Coordinating Principal Investigator**)

Including:

- Letterhead, organisation/site where recruitment will occur, Investigator name and contact details, details for complaints, name and contact details of the reviewing HREC
- The version number and date must appear in the footer of each page

**Site PICF** which includes site-specific wording

# Consent

## Site PICF

Site PICF with site-specific wording

On the front page a statement must appear such as:

“Based on the **[project title] [HREC Reference Number]** Master Consent Document **[version number]** and **[date]**”

- On letterhead of the **site that has the special policy** requirements
- State the name of the site where recruitment is to occur
- State the PIs name and contact details
- State the name of the person dealing with complaints and their contact details;
- State the name and contact details of the reviewing HREC
- The Master PICF version number and date (*on which the site-specific document is based*) must appear in the footer
- The Site PICF version number and date must appear in the footer

# Trial Commencement Requirements

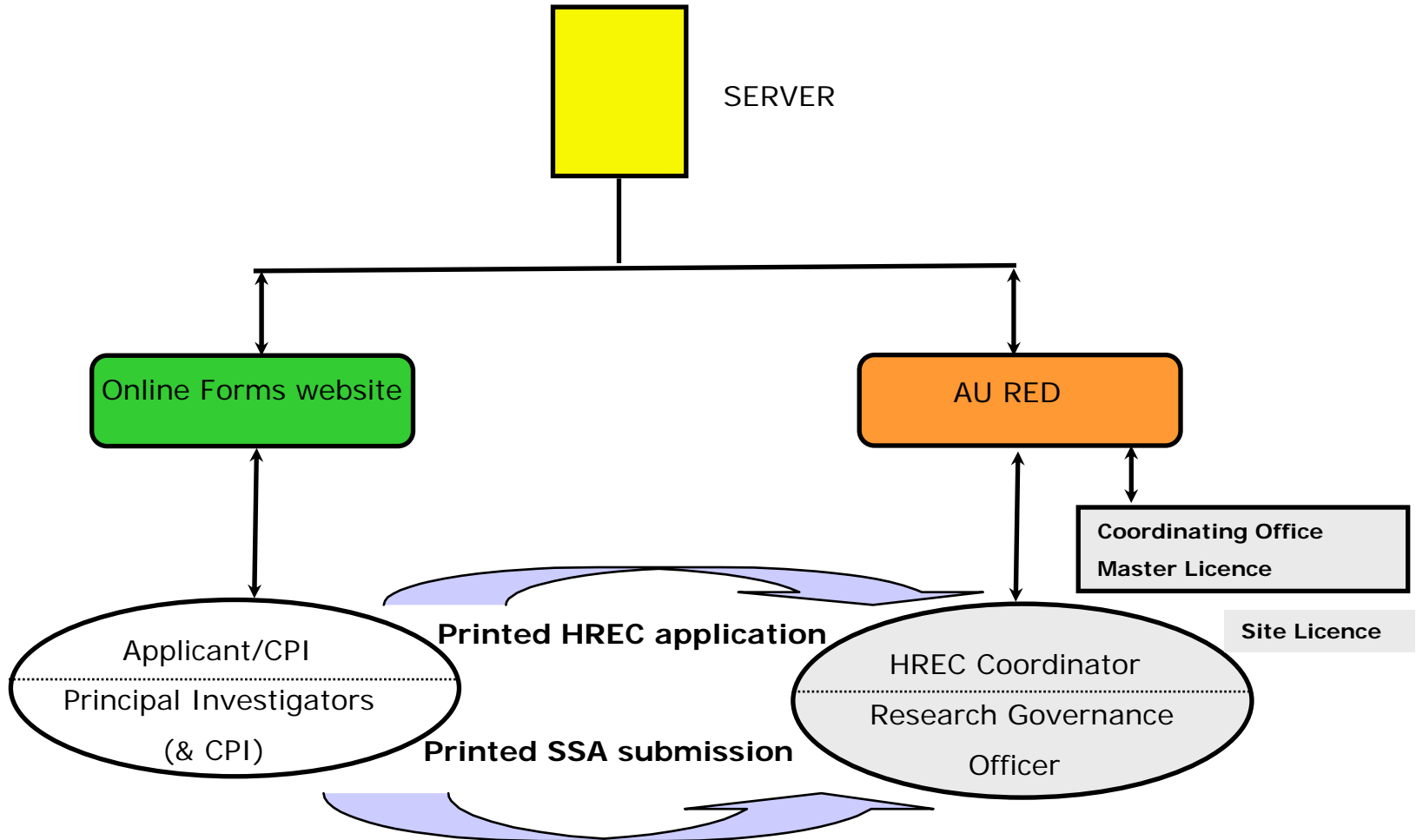
- Ethics approval
- SSA authorisation

# Trial Commencement

## How can this be Faster?

- Streamlining ethical review of multi-site clinical trials
- Efficient processes for research governance at organisations

# IT Platform



# Online Forms

## National Ethics Application Form (NEAF)

- Accessed from the AU RED Online Forms website

[www.ethicsform.org/au](http://www.ethicsform.org/au)

## Site-Specific Assessment Form (SSA)

- Accessed from the AU RED Online Forms website

[www.ethicsform.org/au](http://www.ethicsform.org/au)

# Online Forms

Learn more about the forms in the Application & Forms Workshops

## **How?**

*Streamline E-bulletin*

Email *Multisite.Ethics@dhs.vic.gov.au* to subscribe


*DHS Multi-site Ethics webpage (now)*

*[www.health.vic.gov.au/ethics/multi/](http://www.health.vic.gov.au/ethics/multi/)*

*CCHRE webpage (from September 2009)*


# AU RED Online Forms Website

## Researcher/Applicant - Register an Account

[LOGIN](#) | [CREATE ACCOUNT](#) | [HELP](#) | [CONTACT](#) Helpline 

Australian National Ethics Application Form (c) 2006 Commonwealth of Australia

The Online Forms use .pdf files to print. You need to have the free Adobe PDF Reader installed on your computer.  
[Click here to download the Adobe Reader](#)



If you have difficulty installing this software please contact your computer administrator.

### Please Login

If you are a first time user of the Online Forms website please read the information on the [help page](#) before you proceed to login.

Login:   
(Your full e-mail address)

Password:

Forgotten Password? [Click here](#)


\*The NEAF v2 xml import/export facility is now available. To import NEAF v2 from the [www.neaf.gov.au](http://www.neaf.gov.au) website, click on the 'Import (NHMRC) XML Form' button on the Forms page.

\*\*Users who have created applications on NEAF v1 are now able to convert these to NEAF v2. Please visit the General Guidance section on the Help page for more information.

# AU RED Online Forms Website




## Researcher/Applicant – Create/Existing Forms

LOGOUT
FORMS
EDIT ACCOUNT
MY CONTACTS
HELP
CONTACT


  
**Helpline**

Online Applications List
Australian National Ethics Application Form (c) 2006 Commonwealth of Australia

### Applications

 [Active Forms](#) (9)
 [Lots of Stuff](#) (0)
 [Cancer Research](#) (1)

[Manage Categories](#)

Create New Form
Import (NHMRC) XML Form

To convert a NEAF v1 application to NEAF v2, save the NEAF v1 application as an xml file and import it by clicking on the 'Import (NHMRC) XML Form' button on this page.


Form Title:	<a href="#">Not named yet</a>		<a href="#">Edit HREC Form</a>
Created on:	11/06/2009		<a href="#">Manage/Lock HREC Form</a>
Status:	Active		<a href="#">Move To Another Category</a>
1	<a href="#">Victoria SSA - 816 [No PI typed (No research organisation typed)]</a>	Active	<a href="#">Edit SSA</a> <a href="#">Manage/Lock this SSA Form</a>

Form Title:	<a href="#">Tissue regeneration in arthritis</a>		<a href="#">Edit HREC Form</a>
Created on:	01/06/2009		<a href="#">Manage/Lock HREC Form</a>
Status:	Active		<a href="#">Move To Another Category</a>
1	<a href="#">Victoria SSA - 805 [No PI typed (The Arthritis Institute)]</a>	Active	<a href="#">Edit SSA</a> <a href="#">Manage/Lock this SSA Form</a>
2	<a href="#">SSA - 814 [No PI typed (No research organisation typed)]</a>	Active	<a href="#">Edit SSA</a> <a href="#">Manage/Lock this SSA Form</a>

# AU RED Online Forms Website

## HREC Form for Victoria

LOGOUT | FORMS | EDIT ACCOUNT | MY CONTACTS | HELP | CONTACT Helpline 

HREC Form Australian National Ethics Application Form (c) 2006 Commonwealth of Australia

NAVIGATE | PRINT | EXPORT Page 1 SAVE NOW | UNDO CHANGES | << PREVIOUS | NEXT >>

Date:                      Ref:

Form Section: 1. TITLE and SUMMARY of Project

Within which organisations will the research sites be located: *(tick all that apply)*

New South Wales

Queensland

Victoria


Name/ID of HREC reviewing the research project:

HREC Application Reference Number:       Submission date:  Lock HREC Details

**1. TITLE AND SUMMARY OF PROJECT**

# AU RED Online Forms Website

## SSA Form for Victoria

[LOGOUT](#) | [FORMS](#) | [EDIT ACCOUNT](#) | [MY CONTACTS](#) | [HELP](#) | [CONTACT](#) Helpline 

[SSA Form](#)

NAVIGATE PRINT EXPORT Page 1 SAVE NOW UNDO CHANGES << PREVIOUS NEXT >>

Date: \_\_\_\_\_ HREC Ref: \_\_\_\_\_  
Victoria SSA - 816 [No PI typed (No research organisation typed)]

**Where is this site located?**

New South Wales

Queensland

Victoria

**SSA Form type.**

SSA (default)

**Site-Specific Assessment (SSA) Form - Victoria**

- *This form must be completed by the Principal Investigator responsible for the research project at this site.*
- *The completed form must be forwarded to the site's Research Governance Officer for authorisation and the signature of the Chief Executive/or delegate.*

*SSA is a component of research governance and involves assessment of the suitability of the site and the Investigator(s) for the proposed research.*

# Establishing the System

## A Phased Approach

- The AU RED/Online Forms system will be 'live' from mid/late July 2009
- Submission of applications and commencement of single ethical review will be in the last quarter of 2009

# Establishing the System

## Consultative Council for Human Research Ethics

The Consultative Council appointments  
are anticipated to be finalised  
in August 2009

# Establishing the System

## Coordinating Office for Human Research Ethics

The Coordinating Office will begin operations on Monday 6 July 2009

The team:

- Dr Suzanne Hasthorpe – Manager
- Dr Campbell Simpson – Senior Coordination Officer
- Mr Gavin Murnane – Senior Information Management Officer
- Ms Voula Phelagti – Project Officer, Finance
- Ms Kelly Roberts – Administrative Assistant

# Communications

Email: [Multisite.Ethics@dhs.vic.gov.au](mailto:Multisite.Ethics@dhs.vic.gov.au)

E-bulletin: *Streamline E-bulletin*

DHS website: [www.health.vic.gov.au/ethics/multi](http://www.health.vic.gov.au/ethics/multi)