CHANGES TO AU RED IN PREPARATION FOR INTERSTATE MUTUAL ACCEPTANCE

OVERVIEW

AU RED will be offline from 5:30pm on Wednesday 19th October until 8.00am on Thursday 20th October 2011 when the changes will take effect.

IMPORTANT: These changes do not signal the commencement of Mutual Acceptance, which is currently expected to be in late November 2011. You will be advised when a definite implementation timeframe has been set.

Importantly, the URL for AU RED has changed and if you go to the old website you will be provided with the new URL which is:

https://nsw.ethicsdatabase.org/workarea/default.aspx
It is recommended you save the new URL as a Favourite or a Bookmark as soon as possible for easy future access.

Following is a summary of the changes:

For all applications:

1. EXPANDED LIST OF 'STUDY TYPES' – 'NEW APPLICATON' SCREEN AND 'REFERENCES' PAGE

The list of 'Study Types' has been expanded. A Definitions guide for the existing and the new Study Types (based on anticipated definitions to be used under HoMER) can be found at the end of this document. This change affects all applications registered in AU RED.

For full HREC applications, but not LNRs:

2. REMOVAL OF COMMERCIALLY SPONSORED TICKBOX – 'REFERENCES' PAGE

The 'Commercially Sponsored' field on the 'References' page has been removed for full HREC applications. This change does not apply to LNRs and you will still be required to make a selection for this field before you can start the clock for an LNR application.

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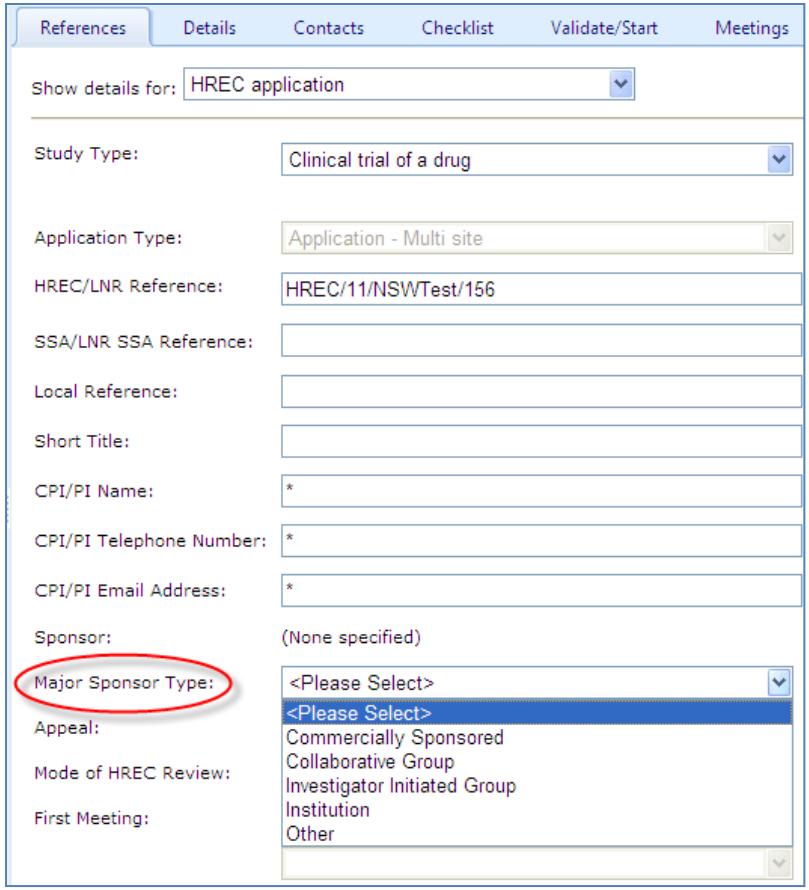
3. NEW FIELD – 'MAJOR SPONSOR TYPE' – 'REFERENCES' PAGE

A new field, 'Major Sponsor Type' has been created in place of the old 'Commercially Sponsored' tickbox for full HREC applications. A Sponsor has to be selected for all full HREC applications.

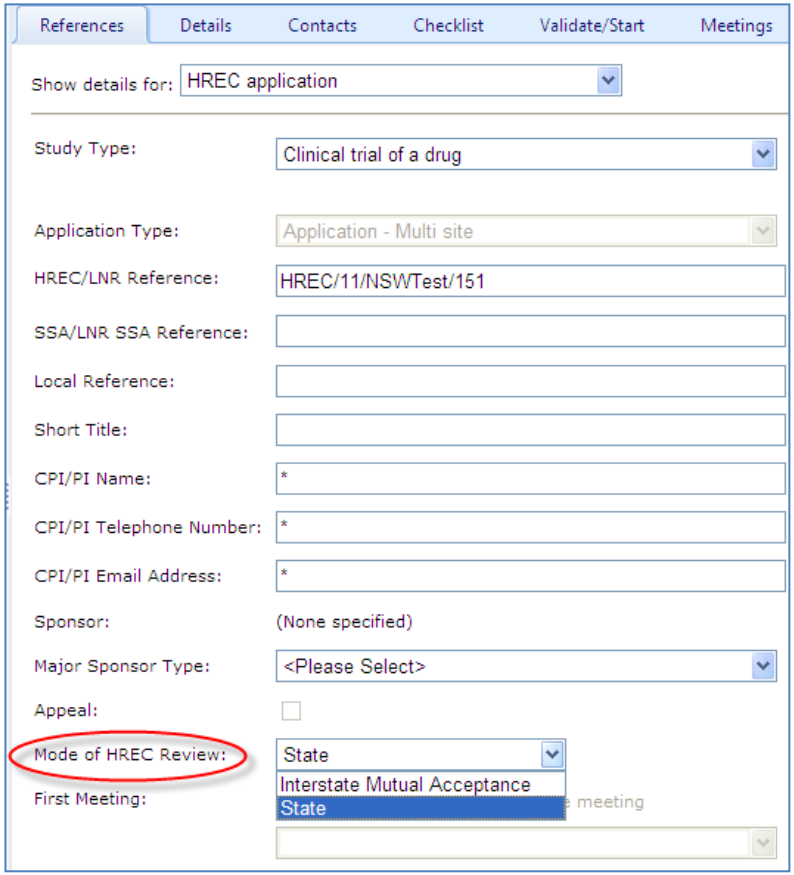
A Definitions guide for the selectable values can be found at the end of this document.



4. NEW FIELD – 'MODE OF HREC REVIEW' - 'REFERENCES' PAGE

A new field, 'Mode of HREC Review' has been created. <u>IMPORTANT: YOU SHOULD NOT CHANGE THE DEFAULT VALUE OF 'STATE' PRIOR TO THE IMPLEMENTATION OF MUTUAL ACCEPTANCE.</u>

A Definitions guide for the selectable values can be found at the end of this document.



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5. ‘DEPENDENT SSAs’ INFORMATION – ‘DETAILS’ PAGE FOR HREC

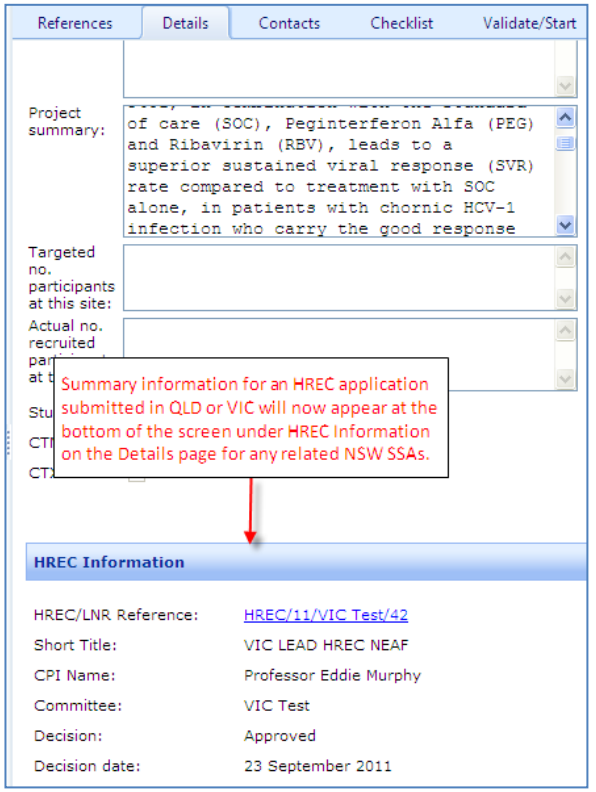
The *Dependent SSAs* section at the bottom of the ‘Details’ page for an HREC application will now display summary data relating to any interstate (Mutual Acceptance) related SSAs.

Changes made to any of the summary details fields for the related SSA applications (such as PI details or the recording of a decision) will immediately be updated in the Dependent SSAs tab for the NSW HREC.

6. ‘HREC INFORMATION ‘– ‘DETAILS’ PAGE FOR SSA

The *HREC Information* section at the bottom of the ‘Details’ page for a NSW SSA will now display interstate (Mutual Acceptance) HREC application summary data where the HREC application was submitted in QLD or VIC under Mutual Acceptance.

Changes made to any of the summary details fields for the HREC application (such as the recording of a decision) will immediately be updated in the HREC Information tab for any related NSW SSAs.



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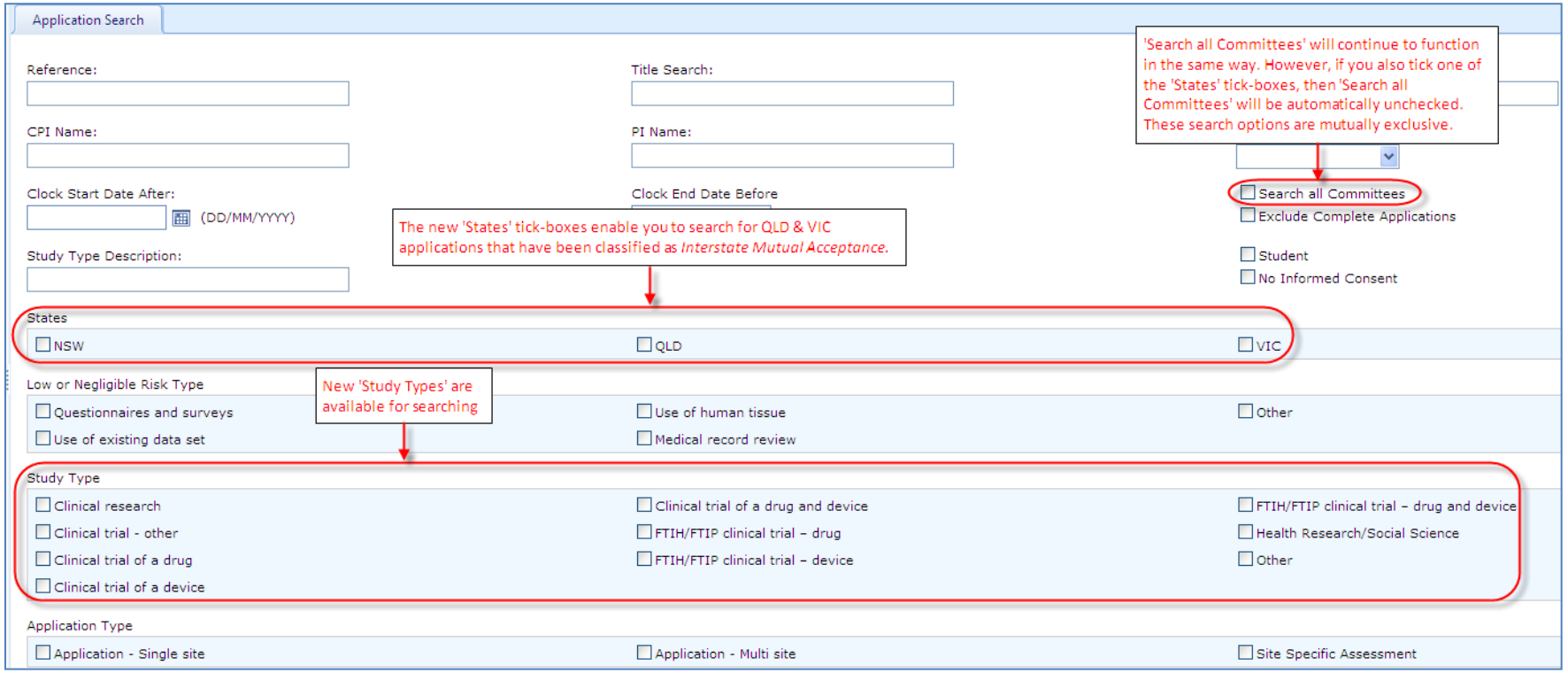
7. NEW SEARCH OPTIONS – 'APPLICATION SEARCH' PAGE

New functionality will enable you to search for interstate applications from QLD and VIC, for which the 'Mode of HREC Review' has been classified as *Interstate Mutual Acceptance.* Note: there should be no applications classified as *Interstate Mutual Acceptance* prior to the announcement that Mutual Acceptance has been implemented.

Once Mutual Acceptance has been implemented, you can search for interstate applications by clicking in one or more of the 'State' tickboxes, NSW, QLD or VIC.You must also as a minimum, select 'Application Type' *Multi-site* or *Site Specific Assessment*, in conjunction with a 'State' selection.

To search for applications within NSW, you should click in the tick-box 'Search all Committees', as previously. Whether searching for NSW applications or interstate applications, only summary data will be displayed.



The additional Study Types have also been added to the 'Application Search' page.

Definitions

1. Study Type

Study Type	Definition
Clinical research	Studies, including observation studies in the clinical setting, which are designed to understand, find and treat illnesses and other health issues. These studies involve a wide range of activities from genetics to assisting medical staff and patients communicate better. Examples include finding how genetics leads to disease or finding the best ways to counsel people who have a genetic mutation that predisposes them to a certain disease such as cancer; the relationship between smoking and heart attacks.
Clinical trial (other)	Is an interventional study that do not fall under the broad definitions of drug or device trials. Examples may include interventions such as exercise, physiotherapy, cognitive therapy, special diets, methods of surgery, radiation therapy methods and dosage etc.
Clinical trial of a drug	Is an interventional study designed to assess the effect(s) of one or more chemical or biological agents (drugs, medicines, vaccines).
Clinical trial of a device	Is an interventional study designed to evaluate the use of any physical item used in medical treatment whether it be an instrument, piece of equipment, machine, apparatus, appliance, material or other article, and whether it is used alone or in combination with the intention of preventing, diagnosing, treating, and curing a disease or condition. Examples include: artificial limbs, contact lenses, ventilators, catheters, implants, vibration therapy machines.
Clinical trial of a drug and device	Is an interventional study designed to assess the effect(s) of one or more chemical or biological agents and the evaluation of the use of any physical item used in medical treatment whether it be an instrument, piece of equipment, machine, apparatus, appliance, material or other article, and whether it is used alone or in combination with the intention of preventing, diagnosing, treating, and curing a disease or condition
First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – drug	Is an interventional study involving the first administration of the drug to humans (healthy volunteers) or patients.
First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – device	Is an interventional study involving the first administration of the device to humans (healthy volunteers) or patients.
First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – drug and device	Is an interventional study involving the first administration of the drug and device to humans (healthy volunteers) or patients.
Health Research/Social Science	Health Research studies are designed to gain information and understanding about health.The goal is to find ways to improve human health. Social science studies seek to understand social behaviour through (a) the measurement

Study Type	Definition
	of social phenomena, (b) the discovery of social regularities, and (c) the creation of social theories. Examples include interviews involving one or more participants, focus groups discussing a specific set of topics, observing the participant in his/her own environment or in the environment being studied.
Other (please state)	Is a study that does not fall into the above categories. For example: Population and Public Health studies: The purpose of research within this category is to develop or contribute to generalizable knowledge to improve public health practice; intended benefits of the project can include study participants, but always extend beyond the study participants, usually to society; and data collected exceed requirements for care of the study participants or extend beyond the scope of the activity. Research activities include the collection and analysis of qualitative and quantitative survey data, the analysis of administrative datasets, economic evaluation of health care interventions, health care financing priority, evaluation of health services and health policy, GIS studies and knowledge translation. It includes population-level and health-system research, but not clinical or biomedical research.

Note: A clinical trial is the name commonly given to research in which a therapeutic, preventive or diagnostic intervention is tested. It is a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures (radiation therapy) and devices, a preventive procedure, or a diagnostic device or procedure. Often a clinical trial will involve a new therapeutic drug or device i.e. a 'therapeutic good' which is subject to the Therapeutic Goods Act, administered by the Therapeutic Goods Administration (TGA) under the CTN or CTX scheme.

According to the World Health Organisation (WHO), a clinical trial is ' *Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.*'

2. Major Sponsor Type

Major Sponsor Type	Definition
Commercially Sponsored	Is where a company (pharmaceutical company or corporate entity) takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial and provides the indemnity for the trial.
Collaborative Group	Is where an academic or non-commercial collaborative research group takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial and provides the indemnity for the trial.
Investigator Initiated Group	Is where an individual, such as a private medical practitioner, takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial and provides the indemnity for the trial. Where the Coordinating Principal Investigator is an employee of a NSW Health Public Health Organisation (PHO), and is conducting the trial as part of his/her employment, the

Major Sponsor Type	Definition
	sponsor is usually the PHO and the sponsor type 'Institution' should be ticked.
Institution	Is where an organisation such as a Local Health District or non government organisation or private research organisation takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial and provides indemnity for the trial.
Other	Is a sponsor that does not fall into the above classifications or where a study does not have a sponsor.

3. Mode of HREC Review

Mode of HREC Review	Definition
State	Is the default value for the field and indicates that the application is not an Interstate Mutual Acceptance application.
Interstate Mutual Acceptance	Should only be selected when the application relates to a multi-centre clinical trial to be conducted in two or more states (i.e. NSW, QLD,VIC), for which only one HREC review is required. This single ethical review is facilitated under the Memorandum of Understanding for Mutual Acceptance between NSW, QLD & VIC.