

Getting started - NEAF

ICONS

- Navigate
- Print draft
- Export - Downloading NEAF - xml

***Key Identifier**
From CAS booking (multi-site trial)
OR
Once logged on AU RED

ICONS

- Save
- Undo
- Previous
- Next

Dr Suzanne Hawthorne
Clinical Researcher
MELBOURNE
20/03/2010 11:39:52

Form Section: 1 TITLE and SUMMARY of Project

Status: In Progress

Created On: 20/03/2010

Last Modified On: 20/03/2010 11:39:52

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Where is the nearest site of this research project?

Investigator details

Go to Section 5 of NEAF
Select 'Clinical research'
'Chief Investigator' details appear in Section 2

Dr Suzanne Hawthorne
Clinical Researcher
MELBOURNE
20/03/2010 12:10:13

Form Section: 2 RESEARCHERS / INVESTIGATORS

Status: In Progress

Created On: 20/03/2010

Last Modified On: 20/03/2010 12:10:13

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Chief researcher: Dr

Title: []

Research details: []

Surname: []

Mailing Address: []

Phone (Bsp): []

Phone (AM): []

Mobile: []

Page: []

Fax: []

Suburb/Town: []

State: []

Postcode: []

Country: AUSTRALIA

NEAF - Section 5

Department of Health - Research Form 5 - NEAF

Search: [Project] [Go]

Project: 5. PROJECT

Status: In Progress
Created: 20/09/2010
Last Modified: 23/09/2010 12:10:17

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1. Type of Research

Not as many of the following types of research as apply to this project. Your answers will use of HREDCs in considering your response. If tick in some of these boxes the HREDCs will be populated in your proposal form for the HREDCs. Statement requires additional ethical matters to be considered. Answer will appear in Section 4 of NEAF.

The project involves:

- Research using quantitative methods [HS.2.1](#)
- Research using qualitative methods, population level data or databases, e.g. survey research, epidemiological research [HS.2.2](#)
- Clinical research [HS.2.3](#)
- Research involving the collection and/or use of human samples [HS.2.4](#)
- Genetic testing research [HS.2.5](#)
- A cellular therapy [HS.2.6](#)
- Research on workplace practices or processes impacting on workplace relationships [HS.2.7](#)
- Research conducted overseas involving participants [HS.2.8](#)
- Research involving animal radiation [HS.2.9](#)
- Research involving gametes or use or creation of embryos - ART guidelines
- None of the above

Does the research involve limited disclosure to participants? [HS.2.10](#)

Department of Health - Research Form 5 - NEAF

Section 4 - Prior reviews

Site names are populated in further NEAF questions.

Department of Health - Research Form 5 - NEAF

Search: [Project] [Go]

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4. Ethical Review

Some HREDCs may require researchers to provide information additional to that contained in a NEAF proposal. For this reason, it is prudent to check whether the HREDCs to whom you propose to submit this proposal require additional information.

4.1. In how many Australian sites, or site types, will the research be conducted?

1/20

4.2. In how many overseas sites, or site types, will the research be conducted?

1/20

4.3. Provide the following information for each site or site type (Australian and overseas, if applicable) at which the research is to be conducted.

Site / Site Type Name	Site / Site Type Location	Site / Site Type Details
1	Site / Site Type Name	Site / Site Type Location
2	Site / Site Type Name	Site / Site Type Location

Department of Health - Research Form 5 - NEAF

Section 4 – Prior reviews

6. To how many Association HRECs (representing site organisations of the researcher's / investigator's organisation) is it intended that this research proposal be submitted?

4. List of HREC registered Human Research Ethics Committees (HRECs) along with their jurisdictional approvals and contact details is available on the HREC website at the following web address:

HRECs

1. Name of HREC:

Provide the start and finish dates for the research for which this HREC is providing ethical review:

Anticipated start date or date range: (dd/mm/yyyy)

Anticipated finish date or date range: (dd/mm/yyyy)

For how many sites in which the research is to be conducted will this HREC provide ethical review?

Site 1

Name of Site:

Principal Researcher 1

Principal Researcher Name:

Site details appear in the drop-down list

Section 9 – Project specific

Type of research/trial

1. The study involves:

The administration of a drug / medicine (includes a complementary / alternative medicine)

The use of a medical device

The administration of human somatic cell gene therapy

The use of a xenograft/implant

The use of stem cells (adult or embryonic) as therapy

Other

2. The project will be conducted as follows:

Under the Clinical Trial Notification Scheme (CTN): Yes No

3. Provide the following details for the clinical trial protocol:

Protocol name:

Protocol version number: (dd/mm/yyyy)

Protocol version date: (dd/mm/yyyy)

If the protocol has been registered this trial on a publicly accessible register, please include the details of where to find it:

4. Provide the following details for the investigator's how-to-reporting information (see instructions):

Drug / medicine

Medical device

Manage the NEAF online

- Return to 'Navigate' page
- Select 'Documents' in menu
- The 'list' of documents will appear
- Select 'Upload'

NEAF Supporting Documents - Upload

The screenshot shows the 'Documents' page in the NEAF Online Forms system. The page has a navigation menu at the top with 'Documents' selected. Below the menu, there are several tabs: 'Documents', 'Links', 'Authentication', and 'Support'. The 'Documents' tab is active, showing a 'List' section with an 'Upload' button circled in red. Below the 'List' section, there is a 'Document Type' dropdown menu set to 'Document', a 'Version' field, and a 'Description' field. A 'Choose file to upload' button is also visible. A note at the bottom of the form states: '* Please note that the same Version and Description will be visible in the supporting registration'. A 'Submit' button is at the bottom of the form.

TIP
Enter site or identifying details in 'Version' box
It is then visible in the documents 'list'

Select 'Upload' - document will be listed

Transfer NEAF to another person

Email address required & Online Forms must account

Transfer history

Electronic authorisation (signature) - CPI can request

Email address is required & an Online Forms account

CPI can request PI signature
More PI fields appear as a request is made

Submission code – NEAF

Mandatory – must have this for lodging NEAF to the reviewing HREC

The screenshot shows the 'Australia Online Forms' web interface. On the left, there is a navigation menu with 'My Project' selected. The main content area displays a submission form for 'HREC Reference Form Request - NFA'. A table at the top right shows the submission status: 'Status: In Progress', 'Owner: G. S. S. S.', 'Created On: 22/03/2010', and 'Last Modified On: 29/03/2010'. Below the table, there are several tabs: 'Links', 'Documents', 'Timeline', 'Authorisation', 'Submission', and 'Stats'. The 'Submission' tab is active, showing a 'Generate Submission Code' button circled in red. A message box below the button states: 'Due to the upgrade, applicants who generated a LONR, DCDE, plus to the 12th March 2010 and in the process of submitting their form to the HREC or RGO will need to re-do the HREC, RGO or the correct submission code. If required, generate another RFA where you have the correct code in the bottom right hand corner. Click Back for step-by-step instructions.' At the bottom, there is a footer with 'No Grids Found - version 8.0 Build 17332 - 19/03/2010'.

Submission – NEAF

- Generate the 'Submission code'
- Print the NEAF and supporting 'Documents'
- Attach the 'Ethics Checklist' and indicate attached documents as required for HREC review
- Send documents to the reviewing HREC Coordinator

'Submission code' allows changes to NEAF or SSA after review

The 'hourglass' hover shows a text history window lists as new text, old text, ~~deleted text~~

Printing and generating a pdf an option allows the last 3 saved text changes to print

SSA Forms

The screenshot shows the 'Australia Online Forms for Research' interface. On the left, there is a sidebar with 'My Project' and 'SSA Forms'. The main area displays a table of SSA forms. A callout box on the left points to the 'SSA' column header in the table.

Message	Comments	Status	Authorisation	Submission	SSAs
Message SSA - 27112 (In Progress) (Research Administration Form)		In Progress			Create
Message SSA - 27112 (In Progress) (Research Administration Form)		In Progress			Create
Message SSA - 27112 (In Progress) (Research Administration Form)		In Progress			Create

At the bottom of the table, there is a text input field and a note: "Please type the number of forms you wish to create in the box. You may select the form type for which to create SSA forms on page 1 of each form after the forms have been created."

Create SSA Forms

This screenshot is identical to the one above, showing the 'Australia Online Forms for Research' interface. The callout box on the left now points to the 'Create' button in the 'SSAs' column of the table, indicating the next step in the process.

SSA Location - Victoria

Big Tox trial
 HREC Reference: Form Number: NSA
 Status: In Progress
 Created On: 25/03/2010
 Last Modified On: 15/04/2010

Location: **Victoria**
 New South Wales
 Queensland
 Victoria

* Please note that changing the location and/or form type will update this form to the latest version if available.

All Online Forms Version: Version 2.0.0.42 17/03/2010

SSA Location

Big Tox trial
 HREC Reference: Form Number: NSA
 Status: In Progress
 Created On: 25/03/2010
 Last Modified On: 14/01/2010

Location: **Victoria**
 New South Wales
 Queensland
 Victoria

* Please note that changing the location and/or form type will update this form to the latest version if available.

All Online Forms Version: Version 2.0.0.42 17/03/2010

SSA – supporting 'Documents' uploaded from NEAF

(PI to update as required re site specific documents)

The screenshot displays the 'Documents' section of the NEAF system. A callout box on the left contains the following text:

Documents uploaded on the NEAF will appear here.
 Upload any site documents here.
 In 'Version' put key information/identification of the document

The main interface shows a list of documents with columns for 'Location', 'Status', 'Version', and 'Upload Date'. The 'Version' column is highlighted with a red circle. Below the list, there is a section for 'Upload Documents' with a 'Browse' button and a 'Upload' button. The 'Upload' button is also highlighted with a red circle.

SSA – authorisations (electronic using Online Forms account)

The screenshot displays the 'Authorisations' section of the NEAF system. The 'Authorisation' tab is selected and highlighted with a red circle. The main content area shows a table of electronic authorisation options for the Victorian SSA form. The table has two columns: 'Role' and 'Status'. The 'Status' column is highlighted with a red circle.

Role	Status
Principal Investigator	Not requested
Associate Investigator	Not requested
Head of Department	Not requested
Head of Supporting Department	Not requested
Authority for Data Transfer	Not requested

Below the table, there is a section for 'Electronic Authorisations History' which currently shows 'No Electronic Authorisations to display'.

Keeping informed

Email: Multisite.Ethics@health.vic.gov.au

E-bulletin: *Streamline E-bulletin*

CCHRE website: www.health.vic.gov.au/cchre