GUIDE TO SUBMITTING RESEARCH FOR SITE AUTHORISATION

Please choose an appropriate option:

- If the research is to be conducted at multiple sites, has undergone single ethical review conducted by a full HREC (NEAF application form) which is a Lead HREC Certified by the NHMRC and an Adventist HealthCare site has been granted ethical approval as a participating site and an external entity agreement (or similar) exists between the Lead HREC and AHCL, follow Procedure 1.

- If the research is to be conducted at multiple sites, has undergone single ethical review of a LNR Application Form conducted by a Lead HREC Certified by the NHMRC and an Adventist HealthCare site has been granted ethical approval as a participating site and an external entity agreement (or similar) exists between the Lead HREC and AHCL, follow Procedure 2.

- If the research involves access to participants, their tissue or data at multiple sites and has undergone single ethical review of a LNR Application form conducted by a Lead HREC Certified by the NHMRC and an Adventist HealthCare site has been granted approval as a participating site and an external entity agreement (or similar) exists between the Lead HREC and AHCL, follow Procedure 3.

- If the research is to be conducted at multiple sites and has undergone single ethical review by a Lead HREC Certified by the NHMRC but an Adventist HealthCare site has **not** been granted approval as a participating site, then the research must be submitted to the Adventist HealthCare Limited HREC prior to submitting a request for site authorisation. Refer to the *Guide to Submitting Research for Review* on the HREC website http://www.sah.org.au/ethics-committee-forms.

- If the research has been reviewed by the Adventist HealthCare Limited HREC and an Adventist HealthCare site has been granted ethical approval, follow Procedure 4.

- If the research has not undergone single ethical review by a Lead HREC Certified by the NHMRC and an Adventist HealthCare site has not been granted approval as a participating site then ethical approval must be sought from the Adventist HealthCare Limited Human Research Ethics Committee prior to site authorisation. Refer to the *Guide to Submitting Research for Review* on the HREC website http://www.sah.org.au/ethics-committee-forms

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PROCEDURE 1

Step 1:
Complete the ***Site Specific Assessment (SSA) Form.*** The form is located at http://www.ethicsform.org/Au/SignIn.aspx.

Ensure that when completing **Point 9 Departments and Services involved in research** and **Point 10 Study Budget** on the *SSA Form* that all departments and/or services that will be utilised in conducting the research are listed and costed. This includes but is not limited to:

- Staff education or training
- Additional nursing care
- Investigations which are not part of routine care

The final budget must present a realistic cost of conducting the research and how these costs will be met. You must consult the Nursing Executive Officer, and/or other departmental directors or managers to obtain an accurate cost analysis.

The only signature required on the SSA Form is that of the Principal Investigator and Associate Investigator/s. No other signatures are required.

Step 2:
The following documents must be submitted electronically to the Research Governance Office ResearchGovernanceOffice@sah.org.au for site authorisation.

- Cover letter
- Copy of Lead NSW Health HREC or Lead NHMRC Certified HREC approval letter
- Copy of full HREC submission
- Site Specific Assessment Form (SSA)
- Site specific PICF documents based on approved Master and on site letterhead
- Site specific Radiation Safety Report if radiation exposure is over & above standard care
- Certificate of insurance, if a sponsored study
- Billing Information Form (see www.sah.org.au/research-governance-forms)
- TGA approval, if applicable

Step 3:
The following documents must be submitted in hard copy to the Research Office. For security, it is strongly recommended that documents be hand-delivered

Research Office
Adventist HealthCare Limited
Australasian Research Institute Building
185 Fox Valley Road
WAHROONGA NSW 2076

To ensure safe receipt of your documents please contact the Research Officer on 02-9487 9604 to advise when documents are to be hand delivered or delivered by courier.

To ensure that the documents are completed correctly, please refer to the *Research Documentation Checklist* on the Forms and Guidelines page http://www.sah.org.au/research-governance-forms. Forms which are not completed correctly will be returned.

- MA or MTAA Form of Indemnity for sponsored research
- MA Clinical Trial Research Agreement (CTRA) or MTAA Clinical Investigation Research Agreement for sponsored research
- Clinical Trial Notification (CTN), if applicable

Step 4:
Fees are payable to the Research Governance Office (RGO) for site review of a research submission. Where an application requires submission of a NEAF or LNR Form for HREC review, HREC review fees are payable in addition to RGO fees.

A Tax Invoice will be issued upon receipt of the submission. Fees are non-refundable, even if an application is unsuccessful or is withdrawn prior to consideration or determination by the HREC. The fees are outlined in the *Fee Schedule.*

Step 5:
Complete the *Billing Information* form and email it to ResearchGovernanceOffice@sah.org.au

If you wish to discuss your submission in person please phone the Research Governance Officer on 02-9487 9604.

All documents referred to can be located at http://www.sah.org.au/research-governance-forms

PROCEDURE 2

Step 1:
Complete the ***Site Specific Assessment Form for Low and Negligible Risk Research (LNR SSA).*** The form is located at http://www.ethicsform.org/Au/SignIn.aspx.

Ensure that when completing **Point 9 Departments and Services involved in research** and **Point 10 Study Budget** on the *SSA Form* that all departments and/or services that will be utilised in conducting the research are listed and costed. This includes but is not limited to:

- Staff education or training
- Additional nursing care
- Investigations which are not part of routine care

The final budget must present a realistic cost of conducting the research and how these costs will be met. You must consult the Nursing Executive Officer and/or other departmental directors or managers to obtain an accurate cost analysis.

The only signature required on the SSA Form is that of the Principal Investigator and Associate Investigator/s. No other signatures are required.

Step 2:
The following documents must be submitted electronically to the Research Governance Office ResearchGovernanceOffice@sah.org.au for site authorisation.

- Cover letter
- Copy of Lead NSW Health HREC or NHMRC Certified HREC approval letter
- Copy of full HREC submission
- Site Specific Assessment Form (LNR SSA)
- Site specific PICF documents based on approved Master and on site letterhead, as applicable
- Billing Information Form

Step 3:
The following documents must be submitted in hard copy to the Research Office. For security, it is strongly recommended that documents be hand-delivered

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A Tax Invoice will be issued upon receipt of the submission. Fees are non-refundable, even if an application is unsuccessful or is withdrawn prior to consideration or determination by the HREC. The fees are outlined in the *Fee Schedule.*

Step 5:
Complete the *Billing Information* form and email it to ResearchGovernanceOffice@sah.org.au

If you wish to discuss your submission in person please phone the Research Governance Officer on 02-9487 9604.

All documents referred to can be located at http://www.sah.org.au/research-governance-forms

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Procedure 3

Step 1:
Complete the ***Access Request Form - NSW.*** The form is located at http://www.ethicsform.org/Au/SignIn.aspx.

Step 2:
The following documents must be submitted electronically to the Research Governance Office ResearchGovernanceOffice@sah.org.au for site authorisation.

- Cover letter
- Copy of Lead NSW Health HREC or NHMRC Certified HREC approval letter
- Copy of full HREC submission
- Access Request Form
- Site specific PICF documents based on approved Master and on site letterhead, as applicable
- Billing Information Form

Step 3:
Fees are payable to the Research Governance Office (RGO) for site review of a research submission. Where an application requires submission of a NEAF or LNR Application Form for ethical review, HREC review fees are payable in addition to RGO fees.

A Tax Invoice will be issued upon receipt of the submission. Fees are non-refundable, even if an application is unsuccessful or is withdrawn prior to consideration or determination by the HREC. The fees are outlined in the *Fee Schedule.*

Step 4:
Complete the *Billing Information* form and email it to ResearchGovernanceOffice@sah.org.au

If you wish to discuss your submission in person please phone the Research Governance Officer on 02-9487 9604.

All documents referred to can be located at http://www.sah.org.au/research-governance-forms

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Procedure 4

Step 1:
Complete the ***Site Specific Assessment (SSA) Form or Site Specific Assessment Form for Low and Negligible Risk Research (LNR SSA) or Access Request Form, as appropriate.*** The forms are located at http://www.ethicsform.org/Au/SignIn.aspx.

Ensure that when completing **Point 9 Departments and Services involved in research** and **Point 10 Study Budget** on the *SSA Form* that all departments and/or services that will be utilised in conducting the research are listed and costed. This includes but is not limited to:

- Staff education or training
- Additional nursing care
- Investigations which are not part of routine care

The final budget must present a realistic cost of conducting the research and how these costs will be met. You must consult the Nursing Executive Officer and/or other departmental directors or managers to obtain an accurate cost analysis.

The only signature required on the SSA Form is that of the Principal Investigator and Associate Investigator/s. No other signatures are required.

Step 2:
The following documents must be submitted electronically to the Research Governance Office ResearchGovernanceOffice@sah.org.au for site authorisation.

- Cover letter
- Copy of AHCL HREC approval letter
- Site Specific Assessment Form (SSA)
- Site specific PICF documents based on approved Master and on site letterhead
- Site specific Radiation Safety Report if radiation exposure is over & above standard care
- Certificate of insurance, as applicable
- Billing Information Form
- TGA approval, as applicable

Step 3:
The following documents must be submitted in hard copy to the Research Office. For security, it is strongly recommended that documents be hand-delivered

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- MA Clinical Trial Research Agreement (CTRA) or MTAA Clinical Investigation Research Agreement for sponsored research
- Clinical Trial Notification (CTN), as applicable MTAA

Step 4:
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All documents referred to can be located at http://www.sah.org.au/research-governance-forms