**The Royal Victorian Eye and Ear Hospital**

**Guidelines for completing the Cover Sheet for New Research Project**

**and attachments (including Request for Extension)**

[Guidelines for completing the Cover Sheet 1](#_Toc49173152)

[Guidelines for completing Attachment A clinical trials form 12](#_Toc49173153)

[Guidelines for completing Attachment B Biospecimens and/or genetic and genomic research 14](#_Toc49173154)

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**Introduction**

This Cover Sheet is used by the Eye and Ear to assess site specific research governance obligations, including research ethics requirements.

The Cover Sheet is used by the following Eye and Ear departments:

|  |  |
| --- | --- |
| **Department** | **Purpose** |
| Research Office staff | 1. Assess review pathways
2. Ensure compliance with various regulatory requirements
3. Administrative application management - database
 |
| HREC secretariat and HREC members | 1. Obtain overview of project
2. Alert HREC to elements of the project that require additional attention
 |
| Supporting Departments | 1. Obtain overview of project to facilitate decision whether to support project or not
2. Alert Supporting Departments to elements that require additional attention
3. Ensure compliance with various regulatory requirements
 |

# Guidelines for completing the Cover Sheet

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| **SECTION A PROJECT INFORMATION** |

Complete **this section for all projects**

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| --- | --- | --- |
| **Field** | **Instructions** | **Additional notes** |
| **Date** | Date of submission of the form |  |
| **Project title** | The exact project title | This needs to be the same title on all documentationThe protocol is the primary source of the project title |
| **Site Principal Investigator** | Name of the Principal Investigator at the site. The site PI must be employed by the investigator site.The PI should be a senior member of the research team. | If the Eye and Ear is not a site, ie. For recruitment or services provision, please include an Eye and Ear contact person. |
| **Brief Description of the project** | The project is used by multiple departments and individuals.The project description should explain the project so they will understand why and how the study is being conducted and how participants are involved. |  |
| **Dates** | Indicate the expected start and completion dates | This assists with understanding the timeframe of the project and the expected completion date.Some projects are longitudinal – state longitudinal project – no completion date |
| **Responsible organisation (Sponsor)** | Indicate the organisation responsible for the research (who initiated the clinical investigation) | An organisation needs to be responsible for the project. This must be consistent across the documentation e.g. protocol, PICF, agreement (if required) and Head of Department (HoD) sign off.Further references on this can be found at:* Australian Clinical Trial Handbook
* NCTGF – Roles and Functions of Clinical Trial Sponsors
* FDA Elaboration of Definitions of Responsible Party
 |
| **Categories of research** | Broad Research CategorySee definition in [Appendix 1](#Appendix1)Australian Bureau of Statistics ReportingRefer to definition in [Appendix 1](#Appendix1) | This is used for reporting purposes* EAE Board
* ABS Reporting
 |
| **Authorisation pathway** | Identify which pathway relates to your projectComplete the sections of the cover Sheet as indicated.The new cover sheet is intended to restrict sections of the cover sheet for certain types of projects. | The Research Office receives applications from multiple organisations for multiple purposes so there are variable pathways for submission. Eye and Ear is considered to be a research site if for the purposes of the project Eye and Ear has responsibility for • The participants – ie patients; and• The site PI is an Eye and Ear employeeThere are 3 pathways for Research Governance Authorisation depending on whether1. The Eye and Ear HREC is the Reviewing HREC
2. The Eye and Ear is involved in the project at all, other than HREC review, therefore requiring an Eye and Ear Site Research Governance Assessment

The 3 pathways for authorisation are:**Eye and Ear HREC review only** Choose this option if the project is submitted to the Eye and Ear HREC for ethical review and approval and the Eye and Ear is not involved in the project in any other way.**Eye and Ear HREC review AND Eye and Ear Site Research Governance Assessment**Choose this option if the project is submitted to the Eye and Ear HREC for ethical review and approval and the Eye and Ear is involved in the project.**Eye and Ear Site Research Governance Assessment only**Choose this option if the project has or will have ethical approval from another HREC and will not be reviewed by the Eye and Ear HREC and the Eye and Ear is involved in the project so requires Eye and Ear Site Research Governance Assessment. |

**Another way of viewing the instructions above is as follows:**

|  |  |
| --- | --- |
|  | **Is the Eye and Ear involved in the project?** |
| EAE is not involved in the research project | Eye and Ear is involved in the project  |
| **Which HREC is reviewing the project?** | EAE HREC or LRR | [ ]  Eye and Ear HREC review only | [ ]  Eye and Ear HREC review AND Eye and Ear Site Research Governance Assessment |
| Other HREC |  | [ ]  Eye and Ear Site Research Governance Assessment only |

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| **Research Methodology Category** | Compete the attachments as requiredThe Instructions for completing the attachments are in this document – see Content above or scroll down | Some types of research have specific regulatory requirementsFor more details refer to the Research website |

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| **SECTION B EYE AND EAR HREC REVIEW** |

**Review the background information on the Research website**

**Complete this section of the Cover Sheet if the Eye and Ear HREC is the Reviewing HREC for this project**

**If the project is not going to be reviewed by the Eye and Ear HREC then continue on to Section C.**

|  |  |  |
| --- | --- | --- |
| **Ethical Review Pathway** | Choose which type of project it is  | This is used for reporting purposesEAE BoardABSPrivacy Reporting |
| **Site names** | Tick the name of the research sites for the projectInclude the full legal entity name for Private clinics and any other sites  | The Eye and Ear reviews and approves research occurring at the Eye and Ear and at other sites.The name of the site is included in the HREC approval letter.List the legal entity name of the site. |

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| **SECTION C EYE AND EAR SITE SPECIFIC ASSESSMENT**  |

Complete this section if the Eye and Ear site is involved in the research

If the project requires HREC Review only then do not complete this section.

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| --- | --- | --- |
| **How is the Eye and Ear involved in the research project?**  | Tick all that apply  | This section relates to how the Eye and Ear as an organisation is involved in the research project. |
| **Site Governance Authorisation Pathway**  | Tick a single option  | This section relates to how the Eye and Ear as an organisation is involved in the research project.There are different pathways depending on whether the EAE is considered a research site or not.If the Principal Investigator is not clear which pathway is relevant, please complete the cover sheet and submit to the Research Office for a pre-review to facilitate a discussion prior to submission of any documentation. |
|  | Recruitment | Recruitment material includes PICFs brochures, posters |

**SECTION C1 EYE AND EAR PARTICIPANT RELATED INFORMATION**

|  |  |  |
| --- | --- | --- |
| **Recruitment procedures**  | Provide details of recruitment for the Eye and Ear site   | This section is reviewed by Specialist Clinics to understand the impact of recruitment on EAE services |
| **Is the Eye and Ear patient an inpatient or outpatient** | Complete for either or both options |
| **What is standard care at this site?** | Clearly explain the difference between standard care and the research proceduresUse a table or appendix if long detailed explanation required |
| **How does the research differ from standard care?** |
| **Who will cover the cost of the additional procedures?** | List the name of the organisation |
| **Participant Timeline/Flowchart** | Complete the table – please do not refer to Protocol as the Protocol does not list the location of the procedure | This table assists with understanding the roles of the EAE and location for each procedure |

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| **Eye and Ear Hospital Involvement and Impact on Departments/Services** | Tick all options that applyComplete and attach a separate Research Supporting Department Declaration Form for each service department/unit involved in this research project.  |  |
| **State number of participants to be recruited at the Eye and Ear site** | Provide a specific number or range (ie Minimum and maximum numbers) |  |
| **Who will be consulting/interacting with the participants for this research (eg: someone who is part of the normal clinic roster or someone who is supernumerary)?** |  |  |
| **Will there be an additional impact on Clinic (eg: additional appointments, longer appointments, extra tests)?** |  |  |
| **Detail any other additional requirements** | Add any other information required by hospital departments |  |

**SECTION C2 EYE AND EAR CREDENTIALING REVIEW**

**The Research Office utilises this information to ensure that individuals who are involved in the project have been credentialed appropriately**

**For information about applying for an Honorary appointment, refer to Research website**

|  |  |  |
| --- | --- | --- |
| **Name** | List the full name of the individualList each member of the research teamIf there is a group of people with exactly the same role and requirements and appointment then you can list them together in a single box. See Appendix 2 for an example. |  |
| **Use of Eye and Ear resources** | Tick the box that applies for the individual named | None | This means that the individual is on the project team , possibly even the PI, and does not require access to the site, does not have patient contact and does not use EAE health informationIn this case, the individual does not need an Eye and Ear appointment of any type so tick[ ]  None required |
| Site access | This means that the individual requires on site accessNot all members of the research team need site access.If the individual does need site access then they will need an Eye and Ear appointment or Eye and Ear Honorary Researcher Appointment |
| Direct patient contact | This means that the individual will have direct in person contact with Eye and Ear patients |
| EAE health information | This means that the individual will have direct use of identifiable information of Eye and Ear patients |
| Other | Other use of EAE resources not identified above |
| **Current Eye and Ear appointment status****Tick the box that applies for the individual named** | None required | This means that an EAE appointment is not required.Examples:* PI and does not require use of any EAE resources
* Statistician and only analysis deidenitfiable EAE data

  |
| Eye and Ear employee | This means that the staff member is undertaking this role in their capacity as an Eye and Ear employee |
| Eye and Ear Honorary Researcher Appointment (HRA) | This means that the individual has a current Honorary Researcher appointment |
| Pending EAE appointment | This means that the individual is waiting to receive EAE appointment. Provide additional details in the section below. |
| Pending / will apply for HRA | This means that the individual needs an Honorary Researcher appointment and has either submitted an application or will submit an application. Provide additional details in the section below. |
| **Additional appointment status information** | Provide additional details in this section |  |
| **Scope of Practice** | All members of the research team must have a scope of practice that meets their employment role.The Principal Investigator should confirm that this is the case  |  |

**SECTION C3 MULTI-SITE PROJECT INFORMATION**

Review the information on the Research website

Complete this section if there are multiple research sites involved.

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| **Is the Eye and Ear the Reviewing HREC** | If no, state the name of the Reviewing HREC  |  |
| **Is the project a Collaborative Project?** |  | If the project is collaborative the Eye and Ear will own a portion of the IP.Collaborative project does not mean that EAE is providing services. If the project is a collaborative project then a Collaboration agreement may be required. Please indicate this in section C4 and the Research Office will review and contact the PI.  |
| **Eye and Ear site Principal Investigator Details if different from Project PI** |  |  |
| **List the sites involved** |  | This information assists the Research Office to understand the project and ensure the correct HREC is providing ethical approval and to communicate with other sites if required. |
| **Coordinating PI details** |  | The CPI has specific responsibilities for a multi-site project under the streamlining procedures |
| **Eye and Ear site Principal Investigator Details if different from Project PI**  |  | If the EAE is a site then an eye and Ear employee must be allocated Principal Investigator. If that person is not the applicant, please list the name in this section |

**SECTION C4 Agreements**

**Review the information on the Research website**

[Research Agreements – The Royal Victorian Eye and Ear Hospital](https://eyeandear.org.au/research-overview/research-ethics-and-governance/researcher-resources/research-agreements/)

|  |  |  |
| --- | --- | --- |
| Intellectual property |  |  |
| Agreement type | Tick the relevant box  |  |

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| **SECTION D FEE SCHEDULE** |

**Review the information on the Research website**

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| --- | --- | --- |
| **Fee type** | Tick the relevant box | There is no fee for * EAE investigator initiated projects
* Research Partner projects

Fees are charged for * Projects initiated by and funded by commercial organisations
* Organisations that are not research partners
 |
| **Contact person for invoices** | Provide details |  |

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| **SECTION E OTHER**  |

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| **Other relevant information** |  | Do not include an additional cover letter.Provide any other information that you would like to communicate in this section. |

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| **SECTION F DECLARATIONS**  |

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| **Principal Investigator declaration** |  |  |
| **Head of Department declaration** |  | For Eye and Ear research projects onlyThis declaration ensures that the Head of Department is aware of and supports research being conducted in the department they are responsible for. |

# Guidelines for completing Attachment A clinical trials form

Review the information on the Research website related to Clinical Trials

<https://www.eyeandear.org.au/page/Research/Conducting_research_at_the_Eye_and_Ear_Hospital/Essential_information/Types_of_research/>

|  |  |  |
| --- | --- | --- |
| **Project title** | The exact project title | This needs to be the same title on all documentationThe protocol is the primary source of the project title |
| **Protocol** | List the* Number
* Version
* Date
 | If this project has been reviewed by another HREC then the supplied details and Protocol version must match the version approved by the Reviewing HREC. |
| **Investigational Product details** |  | Review the information on the Research websiteThis is important for Biologicals as there are specific requirements for Class 4 Biologicals. |
| **Project Sponsor type** | Tick the relevant option |  |
| **DSMB** | Tick the type of DSMB that will be reviewing the data.If no independent data monitoring committee has been established, please detail the reason why it is not needed. | Clinical Trials must have a DSMB or equivalent.This information must be included in the protocol. |
| **Good Clinical Practice**  | List * name of each member of the research team
* Role in this project
* GCP training expiry date
 | Review the research website for EAE site specific requirements for GCP trainingIf GCP training not complete add expected completion date |
| **Research governance documentation** |  | IndemnityEye and Ear HREC will often conduct the ethical review for clinical trials being conducted at other research sites. Use the HREC Review Only Form of IndemnityThis information is available at [Eye and Ear Indemnity webpage](https://www.eyeandear.org.au/page/Research/Conducting_research_at_the_Eye_and_Ear_Hospital/Essential_information/Indemnity/)CTN FormIf Eye and Ear is a research site for the clinical trial, the CTN Form details are available at [Eye and Ear CTN form details webpage](https://www.eyeandear.org.au/page/Research/Conducting_research_at_the_Eye_and_Ear_Hospital/Essential_information/Clinical_Trials_and_TGA_requirements/)   |
| **Eye and Ear Declaration**  | Attachment A (this form) must be signed by Eye and Ear Executive Director Medical Services Submit the * Protocol
* Completed Cover Sheet
* Completed Attachments

to Research Office who will facilitate EDMS signing documentation | This section relates to projects where the Eye and Ear is the Sponsor of the Clinical Trial.There are significant considerations related to being a Sponsor of a clinical trial therefore Executive approval is required.Please contact the research Manager if you would like to discuss your project prior to submission to EDMS. |

# Guidelines for completing Attachment B Biospecimens and/or genetic and genomic research

|  |  |  |
| --- | --- | --- |
| Project title | The exact project title | This needs to be the same title on all documentationThe protocol is the primary source of the project title |
| Use of Human Biospecimens |  | Members of the research team should be familiar with National Statement Chapter 3.2. |
| Name of Biobank and HREC Ref Number |  | Provide details of the HREC approved Biobank. Include name and HREC reference number. |
| Genetic ResearchGenomic Research |  | Review the definitions of genetic and genomic research and list which genes are included / excluded |
| Please confirm the Principal Investigator has reviewed Chapter 3.3 (Genomic Research) of the National Statement? |  | Members of the research team should be familiar with National Statement Chapter 3.3. |
| Returning individual research findings to the participant? |  | The National Statement requires an ethically defensible plan for the potential return of findings and individual results from genomic research.This must be included in the Protocol. |
| Will the genetic testing be completed in a NATA approved facility? |  | This issue is included in the DHHS Genetic PICF template.The template should be amended to reflect the Protocol.  |

# Guidelines for completing Attachment C Privacy Reporting

|  |  |  |
| --- | --- | --- |
| Project title | The exact project title | This needs to be the same title on all documentationThe protocol is the primary source of the project title |
| Commonwealth agency |  | If answered Yes, please complete relevant section |
| Private Sector Organisation |  | If answered Yes, please complete relevant section |
| Public Health Organisation |  | If answered Yes, please complete relevant section |

**Appendix 1 - Broad Research Category**

We use Broad Research Category in internal reporting

|  |  |  |
| --- | --- | --- |
| BROAD CATEGORIESSource: NHMRC | Description and source | Notes |
| Basic Science | Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view.Source: ABS definition<https://www.nhmrc.gov.au/about-us/resources/australian-standard-research-classifications-and-research-keywords> | Lab basedUse of human cells / biospecimens* Collect
* Use
 |
| Clinical Medicine and Science | Clinical Trial |  |  |
| Clinical Research |  |
| Genomic Research |  |
| Epidemiological |  |
| Other |  |
| Health Services | Health Services Research (HSR) is a multi-disciplinary research activity with an implicit objective of improving the health services patients receive. Thus it is an area of applied rather than 'basic' research - it uses theories of human behaviour from contributing disciplines, along with evidence from the medical sciences, to generate and test hypotheses about the delivery of health care.Source: HSRAANZ<http://www.hsraanz.org/> |  |
| Public Health  | The World Health Organization defines public health as 'the art and science of preventing disease, prolonging life and promoting health through the organized efforts of society'.Source: NHMRCPublic Health - Term variously referring to the level of health in the population, to actions that improve that level or to related study. Activities that aim to benefit a population tend to emphasis prevention, protection and health promotion as distinct from treatment tailored to individuals with symptoms. Examples include provision of a clean water supply and good sewerage, conduct of anti-smoking education campaigns and screening for diseases such as cancer of the breast and cervix.Source: Department of Health <https://www.nhmrc.gov.au/health-advice/public-health><https://www1.health.gov.au/internet/main/publishing.nsf/Content/Glossary#p> |  |

**ABS Reporting**

<https://www.nhmrc.gov.au/about-us/resources/australian-standard-research-classifications-and-research-keywords>

|  |  |
| --- | --- |
| ABS reporting |  |
| Basic research | Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view. |
| Pure Basic Research | Pure basic research is carried out for the advancement of knowledge, without seeking economic or social benefits or making an active effort to apply the results to practical problems or to transfer the results to sectors responsible for their application. |
| Oriented research | Oriented basic research is carried out with the expectation that it will produce a broad base of knowledge likely to form the basis of a solution to a recognised or anticipated problems or possibilities. |
| Applied research | Applied research is an original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific, practical aim or objective (including a client-driven purpose). |
| Experimental development | Experimental development is systematic work, drawing on knowledge gained from research and practical experience and producing additional knowledge, which is directed to producing new products or processes or to improving existing products or processes. |

**Appendix 2**

Example of grouping individuals in a single

|  |  |  |
| --- | --- | --- |
| Name | Use of Eye and Ear (EAE) resources for role in this projectSelect all that apply | Current Eye and Ear appointment status |
| Research Co-ordinatorsMr Alpha BetaMs Gamma DeltaMr Epsilon Zeta | [ ]  None[x]  Site access[x]  Direct patient contact [x]  EAE health information  (medical records)[ ]  Other | [ ]  Eye and Ear employee[x]  Eye and Ear Honorary Researcher (HRA)[ ]  Pending/ Will apply for HRA[ ]  Do not need an HRA |