

## Frequently Asked Questions

Category	Question	Answer
Consumer participation	Do I need to reference consumers and community participation in my research?	The WA Health Ethics application form section 4.5 requires you to state the involvement of any consumer or community groups in formulating your project. Please view resources available below to determine how this may apply to your research. If you do not feel that such involvement is required for your project please justify the reasons in your application. If you would like guidance please contact the ethics office.
Consumer participation resources	Where can I find information on consumers and community members and how to involve them in health and medical research?  What is the NHMRC website link for consumer participation?  What is the link to UWA and TKI community participation guidelines and resources?	Model Framework for Consumer and Community Participation in Health and Medical Research provides information and assistance to researchers and research organisations wanting to involve consumers and the community in their research. It can be accessed via the NHMRC website.  <a href="http://www.nhmrc.gov.au/guidelines-publications/r22-r23-r33-r34">http://www.nhmrc.gov.au/guidelines-publications/r22-r23-r33-r34</a>  <a href="http://www.sph.uwa.edu.au/community/consumer-and-community-participation/governance/consumers-policy">http://www.sph.uwa.edu.au/community/consumer-and-community-participation/governance/consumers-policy</a>
Contracts	Who should sign a research contract or agreement?	Any agreement requires review by The Research Governance Office ("RGO") and signature of the Executive Director of Medical Services ("EDMS"). A researcher should not sign an agreement on behalf of the institution. The RGO will organise the signature process by the EDMS. Please contact the RGO for guidance if you are not sure on 9340 7108.
Ethics Application	Which application form should I use, the WA Health application form or the NEAF?  Is there any help available to complete my application?  I've met the ethics submission deadline, what happens next?	If your research project is only being conducted in WA then you should use the WA Health Ethics Application Form. If your research is multi-centre and includes sites outside WA then a National Ethics Application Form ("NEAF") should be used. If a NEAF has already been submitted in the eastern states you can submit the same NEAF here but you need to make sure that PMH is referenced, the PMH HREC is referenced and the local PI is listed. This can be done by printing the additional pages with this detail to accompany the NEAF already used. Please also ensure the PMH Principal Investigator (PI) has signed the application. If you are using the NEAF you must also submit the WA Specific Module (Available from the website).  If you have questions or require assistance to complete your application please contact the ethics office or governance office. If you would like to make an appointment for more detailed assistance please e-mail <a href="mailto:helen.hughes@health.wa.gov.au">helen.hughes@health.wa.gov.au</a> Informal workshops to assist with completion of forms are held the week prior to the application deadline on Tuesday between 1-2pm in the CCRF seminar room.  Your application will be reviewed for completeness by the ethics secretary and if complete, added to the agenda for review at the next scheduled SASC meeting. If the SASC committee require further information or clarifications you will be notified and given time to answer any questions. If the SASC questions are answered satisfactorily and within the allotted time, your research will be added to the agenda for the next scheduled ethics meeting. If you do not answer the SASC queries to their satisfaction or if your research

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	<p>If I have approval under the National Mutual Acceptance scheme do I need to reapply to WA Health for ethics approval?</p> <p>What is the link to WA Health Research Governance and Single Ethical Review Standard Operating Procedures?</p>	<p>project requires more than minor amendments it will need to be re-submitted. If your project progresses for review by the ethics committee there are also occasions when they may require further information or clarification before your research can be approved. You will be advised of the outcome of the review and given the opportunity to address any issues raised.</p> <p>Yes, at this stage a single WA Health application is required for research to be undertaken at a WA Health facility. Please see question regarding which form to submit.</p> <p><a href="http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=12988">http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=12988</a></p>
<p>Ethics Application and Governance Application</p>	<p>How will I know what else is required?</p> <p>How will I know if I answered all the questions appropriately?</p> <p>What is the best way to avoid lots of follow up on my application?</p> <p>What Help is there that I can look up myself?</p> <p>Is WA Part of the single ethical review system?</p> <p>What approvals do I need to start my</p>	<p>You will be e-mailed (as the PI or contact person nominated in your application) confirming receipt of your application and advised of any clarifications required. You may get correspondence following the SASC meeting and following the HREC meeting requiring clarification before your project can be approved. You may also get an e-mail from the RGO requiring clarification.</p> <p>You will be notified if extra information is required and you will be notified when your application has been approved. You may not start your research until you have ethics and governance approval and institutional sign off.</p> <p>Take time to do a thorough submission. Ask for help before your submit your documents. You can get help from the Ethics Office, Governance Office and Biostatistician as well as from colleagues and supervisors before you submit your application. Ensure consistency between your protocol, ethics application form and SSA. Have a friend read your information sheet and make sure it is clear and easily understood at a 12-13 year old reading level. Check for grammatical and spelling errors particularly in your parent/participant information sheet and consent form. Handing in a rushed application is unlikely to result in approval of your application without delays. It is more time efficient for you and for the review committees to submit a thorough and complete application in the first instance.</p> <p>The website has many links to relevant documents including the National Statement on Ethical Conduct in Human Research under the heading "Important publications for researchers". Please also feel free to contact the ethics office if you have a particular question and would like to know where to find information and appropriate guidance.</p> <p>WA Health supports the concept of single ethical review for all multi-centre human research carried out in Australia. At this stage WA is <b>not</b> part of the national approach but there is a single ethical review process within WA Health. It is anticipated that WA will become part of the national mutual acceptance scheme once we have the IT platform in place to support this.(IT platform anticipated late 2015/early 2016)</p> <p>You need an HREC approval and an institutional approval to be able to commence your research. At PMH</p>

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	<p>research?</p> <p>Which WA Health HREC should I submit my application too?</p>	<p>these are issued together (as 2 separate approval letters) if your HREC approval was also through PMH.</p> <p>WA Health HREC's categories of expertise are listed in the WA Health Research Governance and Single Ethical Review Standard Operating procedures available via the link below. A Governance application (SSA form) should be submitted to each institution where you will be conducting research.</p>
General	<p>What is the difference between ethical review and governance review and why do I need to submit different but similar documents?</p>	<p>The Ethics office handles the process of scientific and ethical review of your research project. There is a subcommittee of the Princess Margaret Hospital for Children ("PMH") HREC called the Scientific Advisory Sub Committee ("SASC"). The SASC meets to review the scientific validity of your research and looks at your hypotheses and research aims as well as trial design, safety aspects, sample size and statistical requirements to answer your research aims. The Ethics Committee looks at the research merit and integrity, justice, beneficence and respect components of your application. The Research Governance Office ("RGO") reviews any institutional risks associated with your research project including looking at detail of contracts, insurance, budgeting and support from relevant hospital departments.</p>
General and Safety	<p>Where do I find the WA Health Research Governance and Single Ethical review Standard Operating Procedures?</p>	<p><a href="http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=12988">http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=12988</a></p>
Governance application	<p>Who do I need to get to sign off?</p> <p>What happens with my SSA?</p>	<p>The Site specific Assessment Form ("SSA") form requires sign off by the PI, Head of Department, Business Manager and Divisional Director. Please take note of the guidance on the SSA form at 18.3 which explains that investigators must not approve their own research on behalf of their department. There are 3 finance managers, please select the most appropriate one to review and provide signature on your SSA form: for surgical (Lamison Tan), paediatric medicine (Fiona Baxter) and medical services (Thisanka Fernando)</p> <p>The Research Governance Office will review your application for completeness and to ensure it meets requirements. If further information or clarifications are required you will be informed. Once your application is approved you will be issued with an approval letter.</p>
Information sheet and ethics application	<p>How do I put scientific language in lay terms?</p> <p>Where is the website for converting medical terminology into layman's terms?</p>	<p>There is a website that provides guidance on converting medical and scientific terminology into lay terms. The link is provided below.</p> <p><a href="http://www.grouphealthresearch.org/about-us/capabilities/research-communications/prism">http://www.grouphealthresearch.org/about-us/capabilities/research-communications/prism</a></p>
Safety	<p>What are the requirements of safety reporting to the HREC?</p>	<p>According to the WA Health requirements the reporting timeline is 24 hours if there is a material impact on the ethical acceptability of the study or the event requires a change to the protocol. If there is no material impact as considered by the Principal Investigator ("PI") the event must be notified to the Human Research</p>

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		Ethics Committee ("HREC") within 72 Hours. Details of safety reporting requirements are detailed in the WA Health Research Governance and Single Ethical review Standard Operating Procedures (Link available under heading of "General and safety") .
Submissions	<p>What do I need to submit to the Ethics Office for a new application?</p> <p>Do I need to submit a hard copy or can I just e-mail you the documents?</p> <p>What do I need to submit to the Governance Office for a new application?</p> <p>Who is responsible for the ethics and governance application?</p>	<p>You need to submit your protocol, ethics application form, information sheets and consent forms and documents such as an Investigator brochure or product information and advertising or promotion material, diary cards and questionnaires. All documents used in recruiting potential research participants should be approved by the review body. Each document submitted must have a version number and date in the footer (e.g. Version1, dated 19May15).</p> <p>The current process is to provide a single hard copy of all documents as well as a USB drive or CD with each document saved in PDF format. The USB or CD can be collected from the ethics office 2 weeks after submission.</p> <p>You need to submit the SSA form or Health Access Request form (available from the website) as well as any contracts or agreements, insurance/indemnity documentation, declarations of confidentiality and any declarations of conflict of interest. If you are using a CTN form this should also be submitted to Governance for review. The governance office will provide it to the ethics office for HREC signature once review is complete. The governance office does not require copies of other study documents submitted to ethics, these documents can be accessed internally when your project is reviewed. If approval has already been granted by another WA Health HREC then a copy of the approval letter as well as the documents approved by that HREC (protocol, information sheet etc.) will need to be submitted with the SSA form.</p> <p>The PI who signs off on the application is responsible for its content. If completion of submission forms is delegated it is highly recommended that the completed submission is reviewed by the responsible person prior to submission. Incomplete application forms and submission packages may result in a delay to the review of your project. Please ensure that an appropriate contact person is listed in your application. This is the person that correspondence regarding your application will be directed to. This should be the person with the best knowledge and availability to respond to any queries in relation to the application. If you have questions or require assistance to ensure your submission is complete please e-mail <a href="mailto:helen.hughes@health.wa.gov.au">helen.hughes@health.wa.gov.au</a>.</p>