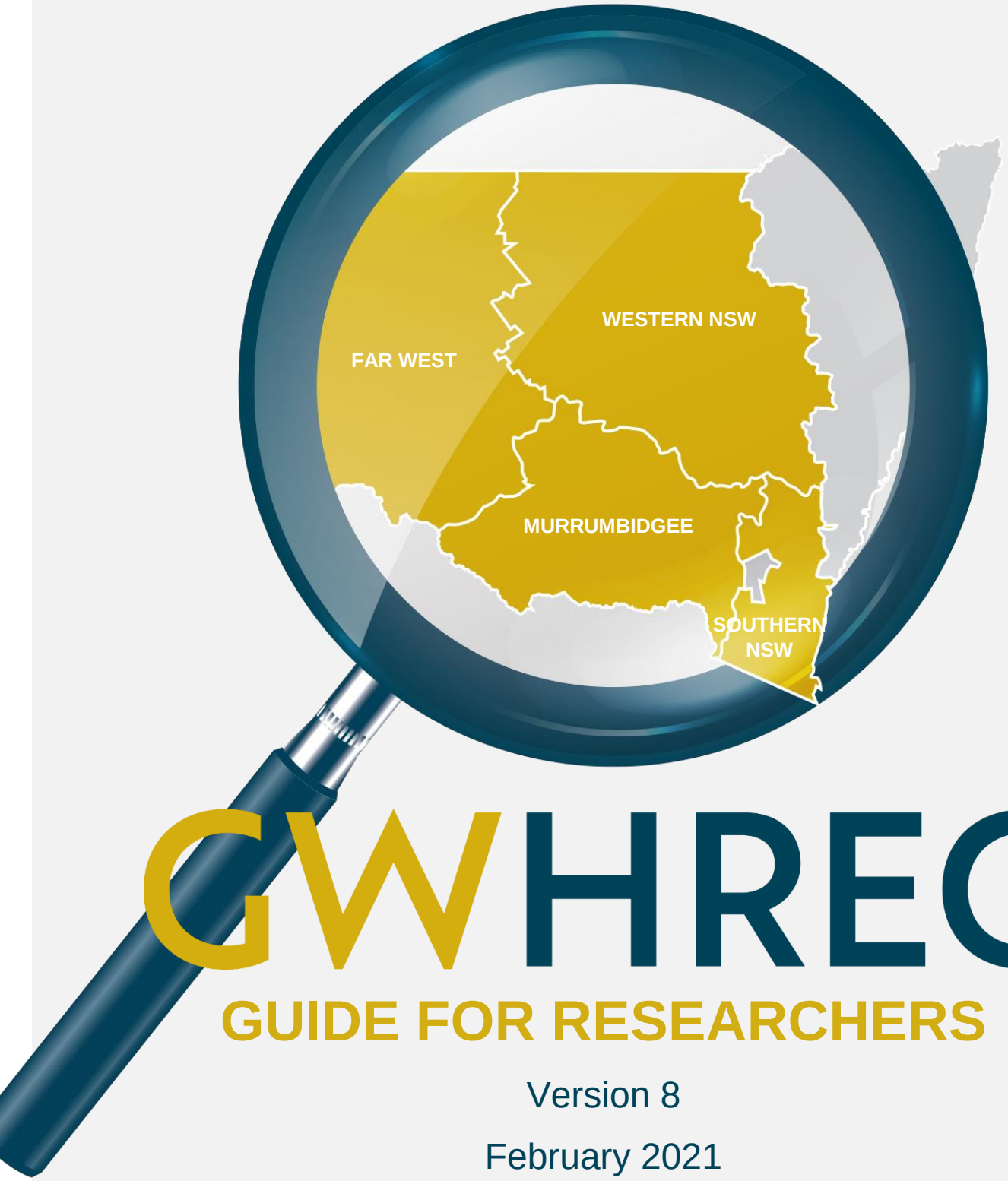

GWHREC

GUIDE FOR RESEARCHERS

Version 8

February 2021

Reviewing ethics applications for Western NSW LHD, Far West LHD, Murrumbidgee LHD and Southern NSW LHD

GREATER WESTERN HUMAN RESEARCH ETHICS COMMITTEE

incorporating **Western NSW, Far West, Southern NSW & Murrumbidgee Local Health Districts**

What is research?

A good question! There is no universally agreed definition of research and it can be difficult sometimes to find the point where quality improvement (QI) ends and research begins. However, within Western NSW, research is defined as: "a process of investigation, the outcomes of which leads to new knowledge or new or enhanced materials, products, devices, processes or services. It's where a research question or hypothesis is considered and the investigation represents original work."

Proposals which need ethical review and approval

The GWHREC should review any proposal for research within its boundaries involving humans or impacting on humans where:

- Research is conducted within public health facilities;
- Participants are clients, visitors or health service staff;
- Participants are recruited through public health facilities; and/or
- Research is being undertaken by health service employees.

Generally speaking, it's expected that the outcomes of the research would be made public through formal peer-reviewed journal publications or other forms of written or oral presentation. The GWHREC is only accredited to review general research. This includes:

- epidemiological research
- population health research
- health service research
- qualitative research
- quantitative research
- clinical research of a non-interventional nature
- other general categories of research

Interventional studies will need to be reviewed by an appropriately accredited HREC. A list of NSW Ethics committees and their accreditations can be found here.

An ethics committee cannot provide retrospective approval for a study which has commenced or been completed.

Low and negligible risk research

Low and negligible risk (LNR) research can be reviewed through an expedited process by a sub-committee of the GWHREC, or reviewed at the first available meeting whether it be the full committee or the sub-committee.

Low risk research is where the only foreseeable risk is that of discomfort. This could be, for example, the minor side-effects of medication, the risks associated with taking a blood sample, the anxiety of an impending interview.

Negligible risk research is where any foreseeable risk is no more than an inconvenience to participants. This could include filling in a questionnaire or participating in a survey.

Please note that the following are **not eligible** for LNR review:

- Interventions and therapies including clinical and non-clinical trials and innovations or new treatment modalities;
- Active concealment or planned deception of participants;
- Exposure of illegal activities; or
- Research specifically targeting Aboriginal or Torres Strait Islander people.

Research involving the following are only eligible for LNR review where the research involves the collection of non-identifiable data and carries only a negligible risk:

- Human genetics
- Human stem cells
- Women who are pregnant and the human foetus
- People who are highly dependent on medical care who may be unable to give consent
- People with cognitive impairment
- People with an intellectual disability or a mental illness
- People who may be involved in illegal activities

Current National Health and Medical Research Council (NHMRC) Guidelines as to what constitutes LNR research can be found here. If in doubt, researchers should contact the Research Office.

The Ethics Committee

Public Health Ethics Committees are composed of volunteers who freely give of their time to review research proposals. The GWHREC is constituted, and operates in accordance with, the National Statement on Ethical Conduct in Human Research (see page 6) and the CPMP/ICH Note for Guidance on Good Clinical Practice.

The GWHREC is composed as per the guidelines in the National Statement with members appointed in various categories in order to provide a broad spectrum of knowledge and experience. As of February 2021 the GWHREC comprises the following members

A/Professor Tony Brown	Chair - Dubbo
Professor David Lyle	Research Experience – Broken Hill
Dr Jannine Bailey	Research Experience – Bathurst
Dr Ellie Gresham	Research Experience – Bathurst
Dr Georgia Wingfield	Research Experience – Orange

Dr Nicole Sugden	Research Experience – Bathurst
Dr Emily Saurman	Research Experience – Broken Hill
Dr Tim McCrossin	Professional Care Experience – Bathurst
Ms Jane North	Lawyer – Dubbo
Fr Edwin Byford	Minister of Religion – Mulwala
Mr Philip Worrad	Layman – Orange
Mr Neil Moon	Layman - Orange
Ms Sally Spence	Laywoman – Orange
Mr David Burke	Minister of Religion – Bathurst
Ms Miriam Dayhew	Professional Care Experience - Bega
Mr Phil Sanders	Executive Officer – Bathurst
Ms Teesta Saksena	Research Administration Officer - Bathurst

The Committee meets on the first Wednesday of each month, except for January. There is also a sub-committee which meets in between full committee meetings to review LNR research proposals. In 2020, the average length of time for a full ethics review was 29 days and for an LNR review 20.5 days.

Multi-site studies

Lead HRECs are accredited to conduct a single ethical and scientific review on behalf of all sites within the public health system thereby eliminating the need for each local HREC to conduct a review. This can also apply across state borders where a project is submitted for review under the National Mutual Acceptance (NMA) scheme.

However, the GWHREC is only accredited to carry out multi-site reviews for sites within NSW. If researchers wish to utilise sites in other states they should consider submitting to a Lead HREC accredited under the NMA scheme. A list of NSW Ethics committees and their accreditations can be found here.

Research Governance

An HREC only reviews the scientific and ethical aspects of a study. Each Public Health Organisation (PHO) is responsible for undertaking a Site Specific Assessment (SSA) in order to decide whether or not it has the capacity to conduct the research at its facility. The SSA application can be submitted at the same time as the ethics application to allow the Research Governance Officer (RGO) to review its

validity. However, it cannot be approved until the ethics application has been reviewed and approved. We recommend researchers discuss their study with all the proposed sites at an early stage of their research planning to streamline this process. In 2020, the average time for an SSA approval in WNSWLHD and FWLHD was 1.3 days.

Quality Improvement

Quality improvement (QI) is an activity where the primary purpose is to monitor or improve a process, program or system delivered by an institution. QI activities are sometimes called 'quality assurance' or 'clinical audit'.

QI activities involve the systematic evaluation of health care practices in order to improve patient care. This is usually achieved by analysing routinely obtained data to capture current practice and comparing this to existing best practice standards. QI activities do not involve extra interventions or clinical assessments.

QI activities ask whether we are doing the things we have agreed we should be doing or achieving the outcomes we have agreed we should be achieving. Types of QI activities can include:

Clinical Audit:	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit standards and the implementation of changes in practice if needed.
Practice Review:	The systematic assessment of current practice, without comparison against set criteria or of one therapy against another and may also be known as a baseline assessment.
Satisfaction / Knowledge Survey:	The systematic collection of data from a sample of patients or staff to determine levels of satisfaction or knowledge about a service.
Service Improvement:	Implementing an initiative to promote change or maintain good practice in order to enhance care and may be known as practice development.
Program Evaluation:	Evaluation is the systematic collection and analysis of information about a specific program or intervention in order to allow is critical.

The National Statement on Ethical Conduct in Human Research

The ethical conduct of research in Australia is governed by the National Statement on Ethical Conduct in Human Research. All researchers should familiarise themselves with the contents of this document, a copy of which can be found here.

The National Statement is a set of guidelines to be followed by researchers when preparing their research and the ethics committee when reviewing it. It is divided into the following sections:

Section 1: Values and Principles of ethical conduct

Section 2: Themes in research ethics: risk, benefit and consent

Section 3: Ethical considerations specific to research methods or fields

Section 4: Ethical consideration specific to participants

Section 5: Processes of research governance and ethical review

Ethical Considerations in Research

When planning and conducting research, the following principles should be followed:

- **Research merit and integrity:** A commitment to the recognised principles of research conduct.
- **Justice:** ensuring that within a population, and for every research participant, there is a fair distribution of the benefits and burdens of participation in research.
- **Beneficence:** the minimisation of risks and harms to participants. Respect for the dignity and well-being of participants must take precedence over the expected increase in knowledge.
- **Respect:** having regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage, individually and collectively, of research participants.

An ethics committee is concerned with protecting the welfare and rights of research participants and in facilitating research that will be of benefit to the community. A committee will, therefore, take into consideration the scientific validity of a research proposal as it is unethical to ask people to participate in research that is poorly designed and unlikely to be of benefit.

Potential for infringing basic ethical principles exists where the research could:

- cause harm to the well-being of participants physically, emotionally, spiritually or psychologically;
- lead to the exploitation of cultural knowledge or property;
- lead to the infringement of privacy or confidentiality; or
- impose burdens with little benefit,

Consent

Consent to participate in research must be freely given and not be subject to any coercion, inducement or influence which could affect its voluntary nature. A person may decide not to participate in research without having to give a reason. If they decide to take part in research and later change their mind they should be free to withdraw without having to give a reason.

If there are consequences to withdrawal (e.g. in a clinical drug trial) advice should be given to participants when they give their consent to take part in the study.

Where a person lacks competence to consent, someone with lawful authority to decide for that person must be provided with sufficient information to make the decision on their behalf.

Research involving children

If a study is primarily aimed at children, researchers are advised to contact the Sydney Children's Hospital Network Human Research Ethics Committee.

Research involving the Aboriginal community

Research involving the Aboriginal community may, in addition to review by the GWHREC, need consent from community representatives and review by the Aboriginal Health and Medical Research Council's (AH&MRC) HREC. The AH&MRC HREC aims to not only ensure that research is conducted in an ethical manner, but that research is also undertaken with Aboriginal people in a culturally appropriate manner. This means that there is community consultation at all levels and that the project is designed with the Aboriginal community. Research applications that require AH&MRC HREC review include projects where:

- Aboriginality is a key determinant
- Data collected is explicitly directed at Aboriginal people
- Aboriginal people, as a group or a community, are explicitly or incidentally identified or identifiable in the results
- Use of the data has an impact or potential impact on an Aboriginal person or community
- Aboriginal health funds are a source of funding.

Community consent requires the involvement of, and negotiation with, the relevant Aboriginal Community Representatives before consent is sought for individual participation. If in doubt about whether an application needs review by the AH&MRC HREC, researchers should contact the AH&MRC Executive Officer to clarify.

TIP
A submission can be made to the AH&MRC HREC at the same time as an application is made to the GWHREC. If the GWHREC approves a study prior to a decision being made by the AH&MRC HREC, the commencement of research will be subject to also obtaining their approval.

Executive Officer: Ms Tania Skerry

AH&MRC Ethics Committee
PO Box 193, Matraville NSW 2012
Phone: (02) 9212 4777
Fax: (02) 9212 7211
Email: ethics@ahmrc.org.au

Submitting a proposal

All research proposals need to be submitted to the Research Office via the Research Ethics and Governance Information System (REGIS).Via REGIS, researchers can:

- Set up a User Account
- Register a project
- Download and complete the Human Research Ethics Application (HREA)
- Submit it to the Research Office along with the related project documents
- Receive feedback from the Research Office
- Respond to requests for further information
- Complete and submit SSA for Research Governance review

TIP
The REGIS website contains Quick Reference Guides for all stages of the ethics review process.

There are two mandatory documents to include with an ethics application:

1. The completed Human Research Ethics Application (HREA)
2. A research protocol or research plan

Other documents to upload into REGIS will depend on the type of study, but may include:

- Participant Information Sheets and Consent Forms (PISCF)
- Data collections tools
- Questionnaires, letters to participants, phone scripts

- Advertising material

It's important to give all documents version numbers and dates and to include tracked changes when submitting updated versions.

Researchers are encouraged to contact the Research Office for help and guidance at any time during the preparation of their submission.

Human Research Ethics Application (HREA)

The HREA is used for submitting both full ethics applications and LNR ethics applications. When the HREA form has been completed, researchers will be asked which pathway (Greater Than Low risk or Low or Negligible Risk) they wish their application to be considered under. If in doubt about the appropriate pathway, researchers are encouraged to contact the Research Office for advice during the preparation of their HREA.

Research Protocol

The research protocol is a document that describes the background, rationale, objectives, design, methodology, statistical consideration and the organisation of a research project. The HREA cannot be commenced without first attaching a research protocol.

TIP
The Project Summary should be written in plain language so that the aims and intentions of the study can be understood by lay people on the committee and also by clinicians who may not be experts in the field being investigated.

The HREA contains guidance on what should be included in a research protocol, but the following websites may also be useful:

- http://www.who.int/rpc/research_ethics/format_rp/en/
- https://www.nbt.nhs.uk/sites/default/files/attachments/How_to_write_a_research_proposal.pdf
- https://www.caresearch.com.au/caresearch/Portals/0/Documents/PROFESSIONAL-GROUPS/Nurses%20Hub/NH_EBP_ResearchProtocol_Mar2013.pdf

Participant Information Sheet and Consent Form (PISCF)

"The guiding principle for researchers is that a person's decision to participate is voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it."

Given the above, a Participant Information Sheet (PIS) should be written in plain English in an easy to follow format that gives potential participants all the information they need to know in order to make an informed decision as to whether to participate or not. It should clearly state:

- Who is carrying out the research
- The purpose of the research
- What is required of a participant
- The risks and potential benefits of taking part in the research

The NHMRC website contains templates relevant to different types of research, which you can access here.

If the study includes more than one participant group (e.g. clinicians and patients), there should be a separate PICF for each of the groups

Multi-site studies – if a study is taking place at multiple-sites, then the PISCF should be a Master Version from which each site can then prepare a local version for submission to the Research Governance Officer for each site. This is simply done by making the legend in the footer: *Master Version x dated xx xxx xxxx.*

The PISCF should also contain the following statement:

"This study has been approved by the Greater Western Human Research Ethics Committee. If you have any concerns or complaints about the conduct of the research study, you may contact the Executive Officer of the Ethics Committee, on (02) 6330 5948 and quote: (Insert REGIS reference)."

Accessing patient data - waivers of consent

Routinely collected patient data is for clinical purposes only. If access to this data is required for research purposes, then the permission of the patient is required or a waiver of consent sought from the HREC.

The HREC will review a request to access patient data in line with the following legislation:

- **The NSW State Privacy Commissioner's Guidelines under the Health Records and Information Privacy Act 2002 –** for information held by a state department or agency e.g. a public hospital. For a full version, please visit this website.
- **Section 95A pf the Commonwealth Privacy Act 1988 –** for information held in the private sector e.g. private hospital, GP or specialists' rooms. For more information, click here.
- **Section 95 of the Commonwealth Privacy act 1988 –** information held by a Commonwealth Agency e.g. Australian Institute of Health and Welfare. For more information, click here.

It is important for researchers to remember that a waiver is required even if data is immediately de-identified, as it's the accessing of personal information that is the key.

If a waiver is required, researchers will be asked to complete the **NSW Ministry of Health Privacy Questionnaire** and give the reasons why it is impractical to seek permission from individuals. These reasons can be:

- The size of the population involved in the research
- The proportion of individuals who are likely to have moved or died since the health information was originally collected
- The risk of introducing potential bias into the research thereby affecting the generalisability and validity of the results
- The risk of creating additional threats to privacy by having to link information in order to locate and contact individuals to seek their consent
- The risk of inflicting psychological, social or other harm by contacting individuals with particular conditions in certain circumstances
- The difficulty of contacting individuals directly when there is not existing or continual relationship between the organisation and the individuals
- The difficulty of contacting individuals indirectly through public means such as advertisements and notices

The Committee will weigh the right to privacy of individuals against the benefits to the community of carrying out the research.
For a copy of the Privacy Questionnaire contact the Research Office of click here:

HREC decisions

Researchers will be informed of the HREC's decision within 10 working days of the meeting. The decision can be one of the following options:

- Approved
- Approved with conditions
- Approved subject to further information and clarification
- Decision pending further information and clarification
- Rejected

If further information is required, the proposal may be referred back to the next available meeting or, if the information is minor in nature, be reviewed by the HREC Executive Office who has been delegated to make a decision on behalf of the HREC.

Approval is given for 5 years subject to the receipt of Annual Reports.
After 5 years, researchers can apply for an extension of approval.

Site Specific Approval

When a researcher registers a project and names the proposed sites, REGIS will automatically create and pre-populate an SSA for each site. Details on how to complete the SSA can be found on the REGIS website.

The SSA can be submitted to the relevant Research Governance Officer (RGO) while the ethics application is being considered, but approval cannot be granted until the project has ethics approval.

As the SSA will require a Declaration of Support from appropriate Heads of Department (HOD) it is important that researchers contact them when they're preparing their submission to get in-principle support. Researchers should also check that the HODs are registered in this role in REGIS as the SSA will be circulated to them via REGIS. If registration as a HOD is required, details should be sent to the Research Office for forwarding to REGIS.

In Western NSW, Far West, Southern NSW and Murrumbidgee Local Health Districts, the RGOs are:

Western NSW LHD and Far West LHD:

Name: Mr Phil Sanders
Email: Phil.Sanders@health.nsw.gov.au
Phone: 02 6330 5948

Murrumbidgee LHD:

Name: Ms Janelle Thomas
Email: Janelle.Thomas@health.nsw.gov.au
Phone: 02 5943 2014

Southern NSW LHD:

Name: Ms Dot Hughes
Email: Dot.Hughes@health.nsw.gov.au
Phone: 02 6150 7574

Contact details for other NSW RGOs can be found here.

Access Requests

When a research project requires support from a Public Health Organisation (site) in the form of access to participants, data or tissue but does not involve direct recruitment or research at that site, then an Access Request Form may be submitted for Governance Review instead of an SSA.

An Access Request should be used when a project involves one or more of the following:

- Participant recruitment through posters, leaflets, handouts or letters of invitation but not through direct contact with participants or enrolment at the site.
- The distribution of surveys to staff at the site but not the collation and analysis of the responses.
- Access to data or tissues held at the site but not the processing or analysis of the data or tissue.

Access Requests are managed external to REGIS and should be made using the NSW Health Access Request Form. This is available via the Research Office or:

https://www.medicalresearch.nsw.gov.au/site-authorisation/

Post-approval

Ethics Amendments

Any amendments to the study protocol, changes to the Coordinating Principal Investigator/site Principal Investigator, the addition of new sites or a request for an extension of approval should be submitted via REGIS to the Research Office for review.

Please make sure that changes to the protocol and associated documents (e.g. PISCFs) are tracked and the documents given new version numbers and dates.

Governance Amendments

Amendments which only affect a particular site e.g. addition of a site investigator/ adding an administration contact can be completed by the site Principal Investigator and submitted via REGIS for Governance Review.

Annual Reports

It is a requirement of the NHMRC that an Annual Report is completed for all approved studies. The researchers will receive email reminders via REGIS for completion on the anniversary of the approval date.