

		 St John first to care
>OMF 4.9.1	RESEARCH REGISTRATION FORM	

It is a requirement that all research and audit conducted within St John be registered with the St John Clinical Research Coordinator. By registering your project early on, the Clinical Research Coordinator can consider items that may need to be discussed such as design, contracts, funding and ethics approval. Once you have completed and submitted this registration form you will receive a copy of the relevant document checklist.

Use the TAB key to move between questions. Press the submit button to email your registration to St John. Research staff will endeavour to respond promptly to your registration. If you have not had a response and you have time constraints on your project please contact the Clinical Research Coordinator by email at clindevhelp@stjohn.org.nz Attn: Clinical Research Coordinator.

1 Registration Form

1.1 Investigator Details

Investigators - List all investigators involved in the study:

Principal Investigator (PI)

Name:

Position:

Organisation:

Address:

Email address:

Phone number:

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Nominate a primary contact person for this project: (forms will be emailed to this person)

Name:

Position:

Organisation:

Address:

Email address:

Phone number:

List all other co-investigators involved in the study

Name, position, email address, phone number:

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1.2 Project Details

Title of study:

Check the appropriate project type:

Audit or evaluation (retrospective)

- Undertaken to improve the delivery of the particular health or disability support service being studied or to control a threat to public health
- Done by people employed or contracted by the service provider holding the information
- Uses existing personal health data that is routinely gathered as provision of a service, or gathers non-sensitive additional information (if in doubt check with the St John Clinical Research Coordinator)
- Review of performance against evidence-based standards.

Observational research (prospective)

- Looks at the outcomes of standard treatment or at the properties or characteristic of groups of people (cohorts) with like problems, disorders or situations
- The investigator has no control over study variables and merely observes outcomes
- Differs from intervention or experimental studies, in that no intervention other than the recording, classifying, counting and analysing of data takes place
- Differs from audit in that significant new information may be gathered.

Clinical/Interventional

- Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes
- Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. (Reference: www.who.int).

Other

Timeline:

Expected project start date:

Anticipated project end date:

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Is this a multi-centre project?

- Not a multi-centre study
- Multi-centre, St John NZ-lead
- Multi-centre, St John NZ sub-site

Briefly outline your project:

Include the key objective(s) e.g. to compare treatment regimes, evaluate service provision etc.

Enter a list of key words:

These will be words that might be used in a 'search' for this project. These may or may not be words already in the project title.

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1.3 Ethics and Funding Details

What type of ethics approval will/has been sought?

To clarify ethics requirements please refer to the guidelines at www.ethics.health.govt.nz

- No ethics review is required
- Health and Disability Ethics Committee (HDEC) review
- Non-HDEC review (e.g. university ethics committee)
- Not sure

Will the project involve fund sources external to St John?

- No
- Yes

Enter name of fund source/organisation(s) providing funding:

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Will St John be a signatory for any contract(s) relating to this project?

St John legal review and approval of the entire contract is mandatory for all legal contractual agreements between St John and a research sponsor. The term 'contract' refers to the main body and all the schedules.

- No, contracts will not be signed by St John
- Yes, there will be St John contracts for this project

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