

POLICY 08:01:02

Original: 07.07.92
Revision: 01.07.09

STANDARD: 08 – SERVICE MANAGEMENT

SUBJECT: RESEARCH AND ETHICS

SUMMARY PAGE

What is...?

This policy is designed to ensure that all research undertaken and supported by the organisation is ethical and in line with the Research Agenda.

What are...?

Research and Ethics

- **Research** provides a means of generating, testing and validating new knowledge.
- **Ethics Committees** protect the rights of the participants and ensure that the researcher is doing research that is not in any way illegal or damaging – thus Ethics Committees protect the interests of both researcher and participants.

Why is this Policy needed?

To ensure that all research undertaken by staff at The Spastic Centre and other institutions collaborating with The Spastic Centre has followed the guidelines set out in this policy, and protect both Spastic Centre clients and staff.

Whom does it affect?

Clients, staff at The Spastic Centre and researchers seeking to involve clients/families of The Spastic Centre as research participants.

How will it affect the organisation?

All research undertaken within The Spastic Centre will be relevant to the Research Agenda, will be of a high standard and will conform with approved ethical standards.

Expected Results/Outcome

The Spastic Centre will encourage participation in high quality, ethically sound research that will add to the body of available knowledge and will shape and inform practice. In addition, links will be encouraged with other organisations - i.e. Universities and hospitals, and information from research will be disseminated both internally and externally, raising the profile of the organisation as a Centre of Excellence in Cerebral Palsy.

POLICY STATEMENT

The Spastic Centre is committed to **participating** in high quality and ethically sound research to shape and inform practice and increase knowledge relevant to cerebral palsy. It achieves this in several ways, including its support of the Cerebral Palsy Institute by supporting selected employees to undertake approved research projects and by assisting other researchers to recruit Spastic Centre and NSW CP Register clients and families to participate in approved research projects.

It is mindful, however, of participant burden and will ensure that Spastic Centre and NSW CP Register clients and families are not approached more than three times in any given year to participate in research projects approved by The Spastic Centre.

These participatory objectives are supported by a governance structure comprising of the Board of Directors and its two subcommittees – the Research Committee and the Ethics Committee.

In addition to the above, The Spastic Centre is committed to **funding** and building research capacity in the field of cerebral palsy on a national and international basis. Through the work of its Cerebral Palsy Foundation, it selects and funds research projects via an annual application process managed by its Cerebral Palsy Institute.

It achieves these funding objectives through the governance structure of the Cerebral Palsy Foundation and draws upon external expertise when required. The Cerebral Palsy Foundation's mandate is to fund research projects that are of high quality; are ethically sound and match the priorities of its research agenda as defined by its mission¹ and the results of the Delphi Study².

Any research undertaken within The Spastic Centre must be:

- Approved by The Spastic Centre's Research Committee (**Attachment 1**)
- Approved by The Spastic Centre's Ethics Committee (**Attachment 2**)
- Endorsed by the Board.

Any research project funded by the Cerebral Palsy Foundation must be endorsed by the Directors of the Foundation

Any research project funded by the Cerebral Palsy Foundation and involving Spastic Centre/CP Register clients/families as participants must be:

- Approved by The Spastic Centre's Ethics Committee (**Attachment 2**)
- Endorsed by the Board

¹ To prevent and cure cerebral palsy

² 2008 (S. McIntyre) Consensus Research Priorities

The Spastic Centre's Ethics Committee is a recognised National Health and Medical Research Council (NHRMC) Human Research Ethics Committee (HREC) and will comply with the National Statement 2007.

Requests to promote and or publicise research studies being conducted by other institutions will be directed, in the first instance, to the Chief Executive Officer (CEO). Depending on the nature of the request, promotion of these activities may be approved by the CEO using the various communication channels within the organisation such as the web site, electronic newsletters and/or print media. The Board will be advised on these approvals in the Board papers. The CEO will direct all other requests to the Chair of the Research Committee for consideration. The Chair may request review by the Ethics Committee.

PROCEDURES

See **Attachment 3** – Flowchart

All research proposals must be in electronic format and submitted to ethics@tscnsw.org.au. Contact with one of The Spastic Centre's Cerebral Palsy Institute representatives is welcomed.

Spastic Centre staff and health professionals are not considered a vulnerable population. Therefore research and ethical approval is not required when the study participant is a staff member or a health professional.

All research proposals will be tabled concurrently with the Research Committee and the Ethics Committee as an agenda item. Should a proposal not be approved by the Research Committee, that proposal would be withdrawn from the agenda of the Ethics Committee.

Each Ethics Committee member is able to seek advice and support prior to making a final recommendation. This may result in a final decision not being made when first tabled at the Ethics Committee. In these circumstances discussion will be held over until the next meeting, and deliberations will continue until a final recommendation can be reached to approve or not approve a proposal.

1. For new researchers

All persons embarking on a research project for the first time can seek the support of a Spastic Centre's Cerebral Palsy Institute representative and may want to consider submitting a Research Expression of Interest (EOI) – (**Attachment 4**) for consideration before embarking on a formal Research proposal.

Staff must seek advice from an approved university course supervisor or appropriate person with recognised research experience – e.g. Cerebral Palsy Institute staff in preparing the research proposal to ensure design methodology and academic value are sound.

There are two choices for submission of research proposals.

2. For experienced researchers

Option 1: Using the National Ethics Application Form (NEAF)

As a result of The Spastic Centre's NHMRC HREC recognition, researchers can download and use the NEAF located at <https://www.neaf.gov.au/Default.aspx>

This form is ideal for researchers who are required to submit their proposals to multiple HREC as the NEAF allows researchers to identify more than one HREC on their submission, removing the need to prepare multiple application forms.

This one form will go to both the Research and Ethics committees. No further forms are required. Please submit completed form to ethics@tscnsw.org.au

Option 2: Using The Spastic Centre's standard Research and Ethics process

1. All persons wishing to conduct research within The Spastic Centre must submit the following forms to the committees via ethics@tscnsw.org.au who will submit these in turn to the Research Committee and Ethics Committee to be considered concurrently.

As preparation researchers must read "Guidelines for Ethical Approval to Undertake Projects" – (**Attachment 6**).

List of forms to be completed

(**Attachment 5**) Application for Research Approval (electronic only)

(**Attachment 7**) Application for Ethical Approval of a Project (electronic only)

2. The outcome of the Research Committee's and the Ethic Committee's consideration (Conditional Approval/Approval or Disapproval is confirmed in writing to the researcher within five (5) working days from the date of the committee meeting.

3. Final Approval

If conditional approval is granted, The Spastic Centre must be satisfied with the researcher's response to the conditions outlined in the letter of "Conditional Approval". A final letter of approval from the Ethics Committee will then be issued. Once ethical approval has been finalised, the research project is tabled at the next Board meeting for endorsement. No project is to be commenced until Board endorsement has been granted.

In situations where the Ethics Committee's approval has not been granted, the Board should be advised prior to notification to the researcher of the outcome.

4. Handling Complaints

Any complaint raised about researchers or the conduct of research or about the conduct of the Research Committee or Ethics Committee will be handled promptly and sensitively.

These complaints should be directed in writing to the Chief Executive Officer, who will manage the complaint in line with the Spastic Centre's policy on Good Working Relations - S08:03:36

5. Consent Forms

Guidelines for the preparation of information and consent forms and a template for an appropriate Consent Form can be found in **Attachments 10a and 10b**.

*It should be noted that consent forms developed by external researchers are permitted and it is not necessary to use the template **Attachment 10b** as long as the consent form demonstrates that it meets the requirements outlined in the guidelines set out in **Attachment 10a**.*

6. Research Project Completion

As a condition of approval, staff will be expected to disseminate the findings of their research – for example: internal education forums; external conference/s and/or by journal submissions. A copy of the completed research report must also be forwarded to the Ethics Committee.

Any research conducted during Spastic Centre working hours, utilising Spastic Centre resources must acknowledge The Spastic Centre in the final report.

LIST OF ATTACHMENTS/FORMS

- Attachment 1 – Research Committee
- Attachment 2 – Ethics Committee
- Attachment 3 – Flowchart
- Attachment 4 – Research Expression of Interest
- Attachment 5 – Application for Research Approval (*electronic only*)
- Attachment 6 – Ethical Guidelines for Approval to Undertake Projects
- Attachment 7 – Application for Ethical Approval of a Project (*electronic only*)
- Attachment 10a – Guidelines for the Preparation of Information and Consent Form
- Attachment 10b – Template for a Information and Consent Form

RELATED POLICIES AND FURTHER READING

Policy S08:03:36 Good Working Relations



SIGNATURE OF CEO: _____
DATED: ____/____/____

REVISION SCHEDULE

Policy 08:01:02 – Research and Ethics

Review Date	Outcome	Comment on revised/review details
21.09.00	<input checked="" type="checkbox"/> revised	Incorporated Research into the current Ethics Committee policy. Attachments 1 to 8 have been added. Further info can be found on the Internet.
18.05.04	<input checked="" type="checkbox"/> revised	Reviewed and revised in consultation with the Board in line with standards with the National Health and Medical Research Council.
18.04.05	<input checked="" type="checkbox"/> revised	Combined Research and Ethics procedures flowchart into one Designed new attachments accordingly – 1-11
07.06.05	<input checked="" type="checkbox"/> revised	Timeframes have been included once submissions have been forwarded to the Ethics and Board Committees re Approval/Disapproval - avoiding any potential misunderstandings.
20.06.05	<input checked="" type="checkbox"/> revised	Appendix 9 expanded to include a section to be completed when the proposed research is a clinical trial involving drugs.
27.03.07	<input checked="" type="checkbox"/> revised	<ul style="list-style-type: none"> • Change in procedures to review research projects concurrently by the Research Committee and the Ethics Committee • Introduction of a second option for application submission – NEAF • Rearrangement of forms naming to suit the new procedure
27.08.07	<input checked="" type="checkbox"/> revised	<ul style="list-style-type: none"> • Insertion of statement about request to promote research studies of others • Change in the composition of the Ethics Committee to be in line with the new National Statement 2007 • Attachment 8 and 9 made obsolete as a personalised letter is sent to the researcher indicating the outcome of committee's recommendation
01.07.09	<input checked="" type="checkbox"/> revised	Inclusion in the policy of the funding of research projects through the CP Foundation. General review.