

# Researcher Qualifications and Credentials

## – Judging appropriateness

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**Abstract:** A gap in the body of knowledge and processes for HREC to assess researcher qualifications and credentials was identified. The current approach in Australia for HRECs making this assessment is via the information provided in various questions within the NEAF<sup>1</sup>, whereas in the UK a standardised process known as a “Research Passport”<sup>2</sup> is utilised.

**Aim:** To align researcher capacity to organisational goals and minimise risk. A tool was developed to support HREC to meet the requirement identified in both the National Statement (NS)<sup>3</sup> and the Australian Code<sup>4</sup> in advising HRECs to assess whether research is “justifiable by ... skill and expertise of researchers” (1.1a)<sup>3</sup> and “conducted or supervised ... with experience, qualifications and competence that are appropriate for the research” (1.1e)<sup>3</sup>.

  	
<b>Researcher / Investigator experience qualifications &amp; competency declaration</b> (NS 1.1e, 5.1.2). Please complete, print, sign and submit with ethics application. Electronic signatures are accepted.	
<b>Project Title</b>	
<b>NHMRC Field of Research*</b>	
<b>Type of Research</b>	<input type="checkbox"/> Clinical <input type="checkbox"/> Non Clinical <input type="checkbox"/> Combined
<b>Site</b>	<input type="checkbox"/> Multi-site <input type="checkbox"/> Single site
<b>Researcher / Investigator / Student</b>	<input type="checkbox"/> Researcher <input type="checkbox"/> Investigator Role <input type="checkbox"/> Coordinating Principal <input type="checkbox"/> Principal <input type="checkbox"/> Associate <input type="checkbox"/> Student Supervisor <input type="checkbox"/> Student
<b>Full Name and title</b>	
<b>Current job position</b>	
<b>Address</b>	
<b>Contact / mobile phone</b>	
<b>Email</b>	
<b>List Qualifications</b>	Research component <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Training</b> (accredited courses)	<input type="checkbox"/> ICH GCP <input type="checkbox"/> Research Ethics <input type="checkbox"/> Research Conduct Other (please list):
<b>List previous positions / employment / experience</b> (relevant to this project)	
<b>List previous experience in research / clinical trials</b>	<input type="checkbox"/> Protocol design <input type="checkbox"/> Recruitment <input type="checkbox"/> Consent <input type="checkbox"/> Data collection <input type="checkbox"/> Data management <input type="checkbox"/> Trial Procedures Other (please list):
<b>List current and past HREC project reference numbers</b>	
<b>List your publications with topics or methods that are relevant to this project</b>	
<b>Declaration:- I hereby declare that I have the experience qualifications &amp; competency to undertake this study in accordance with the National Statement on Ethical Conduct in Human Research and Australian Code for the Responsible Conduct of Research and that the information contained in this form is true and correct.</b>	
Name of Applicant	
Signature of Applicant	Date
<small>* <a href="http://www.nhmrc.gov.au/files/nhmrcfile/grants/policy/fields_of_research_nhmrc_111202.pdf">http://www.nhmrc.gov.au/files/nhmrcfile/grants/policy/fields_of_research_nhmrc_111202.pdf</a> BHSSJOG HREC Researcher Investigator Declaration Aug 2015</small>	

**Methods:** An analysis was conducted of the various questions asked within the NEAF<sup>1</sup> about researchers’ qualifications and credentials. A comparison was undertaken of the information provided within the NEAF<sup>1</sup> and that in the researchers’ Curriculum Vitae provided for all active research approved by Ballarat Health Services and St. John of God Hospital Ballarat (BHSSJOG) HREC in 2014.

**Results:** It is apparent that there is no clear accepted definition of a researcher and what qualifications and credentials are required to conduct research. Although Curriculum Vitae are provided, the requirement to demonstrate ‘capacity to undertake their role in the project’<sup>5</sup> was not always clear. Professional rather than research experience was detailed. Review of NEAF<sup>1</sup> (s2, Q6 & 7) and Curriculum Vitae is time consuming and subjective due to the

- Lack of specific guidance by regulators
- Lack of categorical options for selection in NEAF<sup>1</sup>
- Many different formats (free text)
- Varying information provided
- Generally clinical or job focused
- Little or no research focus

This analysis resulted in the development of a BHSSJOG HREC Researcher / Investigator Declaration to support the consideration of capacity to meet the requirements identified in both the National Statement (NS)<sup>3</sup> and the Australian Code<sup>4</sup>

**Conclusion:** The tool was accepted at the March 2015 BHSSJOG HREC meeting after which it was implemented and it has been a mandatory part of the application for HREC review since July 1, 2015.

Use of the tool allows both new and more experienced researchers to assess the research capacity of their team to identify and correct any gaps. Health services and organisations sponsoring research and HRECs reviewing research have a clear statement of the qualifications and credentials of researchers submitting projects and thus can minimise risk.

### References:

1. National Ethics Application Form <https://www.neaf.gov.au/>
2. <http://www.gcu.ac.uk/hls/ethics/researchpassports/>
3. National Statement on Ethical Conduct in Human Research (2007) - Updated March 2014 <https://www.nhmrc.gov.au/guidelines/publications/e72>
4. Australian Code for the Responsible Conduct of Research <https://www.nhmrc.gov.au/guidelines/publications/r39>
5. Research governance/site specific assessment - process and practice booklet <http://www.health.vic.gov.au/clinicaltrials/site-specific.htm>

Preliminary work was presented by Susan Shea and Frances Beaumont at the Australian Ethics Network Conference December 2014 “How to facilitate research and future challenges”