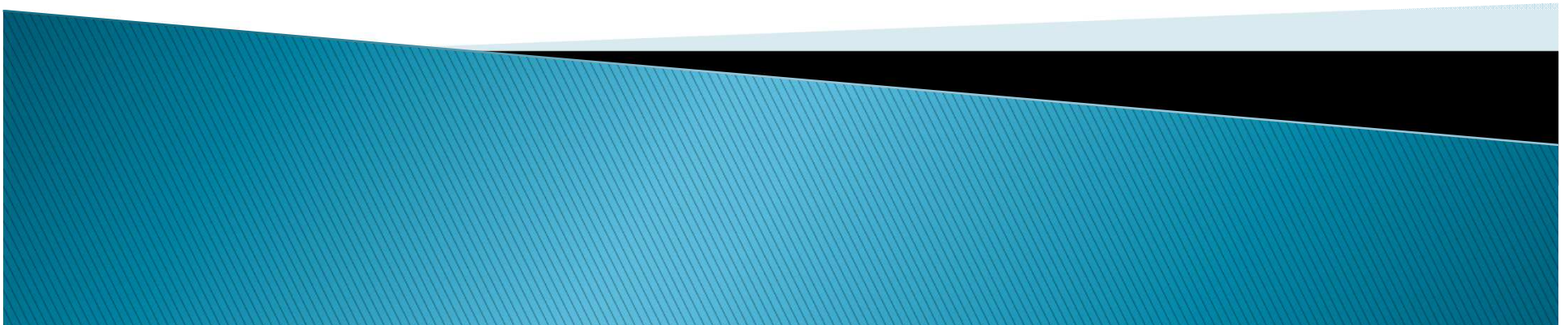


Experiences of embedding an online system for ethical approval of research projects

Aline Giordano & Sean Wellington
Southampton Solent University



QAA Institutional Audit Report December 2008

- ▶ Recommendation for action:
- ▶ ‘The audit team recommends that the University formalise the arrangements for faculty scrutiny and ethical approval of research projects and for reporting the outcomes to the University Ethics Committee.’
- ▶ Quality Assurance Agency, 2008. Institutional audit: Southampton Solent University [online]. Available at: <http://www.qaa.ac.uk/reviews/reports/institutional/Southampton09/RG415Southampton.pdf> [accessed 30 April 2011]



Outcome of the review of the implementation of the Ethics Policy

Must strengthen procedures taking into consideration the following :

- ▶ Some staff members were still not aware of the Ethics Policy
- ▶ There was a need to develop a protocol for all subject areas represented within the University
- ▶ Responsibilities and lines of reporting from the faculties to the University Ethics Committee would need to be strengthened
- ▶ It would need to be applicable to students and staff



Review of the ethics approval process

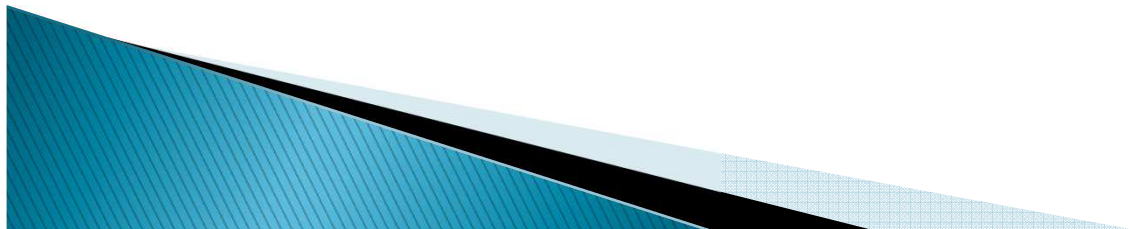
- ▶ Review of best practice
- ▶ Principles from the ESRC Research Ethics Framework (REF) and the British Educational Research Association (BERA) Guidelines
- ▶ The duty to protect participants' anonymity and their personal data and prevent damage to participants' health (mental or physical)
- ▶ The need to implement a systematic process that is robust and recognises the variations in ethical requirements across disciplines and services



Review of the ethics approval process

Issues encountered:

- ▶ Research only or applicable to enterprise too?
- ▶ Definition of key terms (e.g. project, gatekeepers...)
- ▶ Exemptions?
- ▶ How to deal with academic audit and service evaluation?
- ▶ From a laissez-faire approach to autocratic?



The revised procedures for the ethical approval of research/enterprise projects

Outline of process

Para. 8: ‘The principal investigator must secure ethical clearance before any research project or enterprise activity can commence and potential human participants can be approached’.

1. Fast tracking Ethical Approval [Ethics Release]
2. Full Ethical Review




Full ethical review

- ▶ Request for ethical approval (REAF)
- ▶ Application is then reviewed by the Chair of the Ethics Standing Panel + two members of the panel



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Ethics Release Checklist (ERC)

Southampton Solent University's Ethics Committee has agreed that there is no need for full ethical scrutiny of projects that include students with a disability or a declared mental health issue in the research sample. This is with the proviso that their inclusion enables a representative cross-section of the population to be surveyed.

In practical terms, this means that if you wish to include in your surveyed sample students with a disability or a declared mental health issues - with the proviso that their inclusion enables a representative cross-section of the population to be surveyed - you may tick [NO] to Q1a below.

Personal:

Project Name:

Principal Investigator:

Other Investigator(s):

Faculty:

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Ethics Release Checklist (ERC)

Questions:

Q1. Will the project involve human participants other than the investigator(s)? Yes No

Q1a. Will the project involve vulnerable participants such as children, young people, disabled people, the elderly, people with declared mental health issues, prisoners, people in health or social care settings, addicts, or those with learning difficulties or cognitive impairment either contacted directly or via a **gatekeeper**? (for example a professional who runs an organisation through which participants are accessed; a service provider; a care-giver; a relative or a guardian) Yes No

Q1b. Will the project involve the user of control groups or the use of deception? Yes No

Q1c. Will the project involve any risk to the participants' health (e.g. intrusive intervention such as the administration of drugs or other substances, or vigorous physical exercise), or involve psychological stress, anxiety, humiliation, physical pain or discomfort to the investigator(s) and/or the participants? Yes No

Q1d. Will the project involve financial inducement offered to participants other than reasonable expenses and compensation for time? Yes No

Q1e. Will the project be carried out by individuals unconnected with the University but who wish to use staff and/or students of the University as participants? Yes No

Q1f. Will personal data OTHER THAN gender, age and address of participants be collected as part of the project? (For monitoring and data analysis purposes only. When asking for age, use age brackets, such as 18-24, 25-39, 40-49, 50-59, 60+) Yes No

Q2. Will the project involve sensitive materials or topics that might be considered offensive, distressing, politically or socially sensitive, deeply personal or in breach of the law? (for example criminal activities, sexual behaviour, ethnic status, personal appearance, experience of violence, addiction, religion, or financial circumstances) Yes No

Q3. Will the project have detrimental impact on the environment, habitat or species? Yes No

Q4. Will the project involve living animal subjects? Yes No

Q5. Will the project involve the development for export of 'controlled' goods regulated by the Export Control Organisation (ECO)? Yes No

"This specifically means military goods, so called dual-use goods (which are civilian goods but with a potential military use or application), products used for torture and repression, radioactive sources."
(for further information <http://www.berr.gov.uk/whatwedo/europeandtrade/strategic-export-control/index.html>)

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In this section

- Ethics
- Forms

Confirmations:

I/we, the investigator(s), confirm that:

- The information given is correct.
- I/we have assessed the ethical consideration in relation to the project in line with the University Ethics Policy.
- I/we understand that the ethical considerations of the project will need to be re-assessed if there are any changes to it.
- I/we will endeavour to preserve the reputation of the University and protect the health and safety of all those involved when conducting this research/enterprise project.

Previous Submit

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Feedback & Comment

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Thank you for completing the ERC (Ethics Release Checklist) form.

You can now self-certificate your Ethics Release by printing and signing the checklist.

What to do next

1. [Print your ERC](#)
2. [Sign the ERC](#)
3. [Keep a copy for your records and submit a copy with your project](#)

[If you wish to complete another ERC form please click here.](#)

In this section

- Ethics
- Forms**

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Implementing the University Ethics Policy

»» Faculty of Technology

Faculty of Technology

- ▶ 3,400 student
- ▶ Three academic schools:
 - Computing & Communications
 - Design
 - Engineering, Construction & Maritime
- ▶ Research Centre
- ▶ Enterprise Centre



Ethics Standing Panel

- ▶ Chair – Professor Sean Wellington
- ▶ Two members of academic staff from each school – experienced in research
- ▶ Head of Faculty Enterprise Centre
- ▶ Faculty Ethics Advisor



Implementation

- ▶ Establish Faculty Ethics Standing Panel
- ▶ Produce briefing material
- ▶ Development session held for members of Ethics Standing Panel, subsequently offered to all staff
- ▶ Faculty Standard for Supervision of Final Year Projects and Dissertations
- ▶ Appropriate reference to ethical approval process included in student project/dissertation handbooks



Experience

- ▶ Two stage (risk-based) process is effective, with attention focused on stage two proposal (REAF)
- ▶ Some variability in the quality of submissions from students, suggesting a need to strengthen treatment of ethical issues in some subject areas
- ▶ In some cases the REAF submission led to a dialogue about the purpose of the study (and appropriateness of methodology)
- ▶ Promoted a greater understanding and discussion of research ethics amongst staff and students



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