


Research Teaching and Ethics

Steven Vogel, Vice Principal
Sam Keeping, Research Administrator,
Secretary BSO Research Ethics Committee




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Aims

- Describe research teaching and assessment
- Discuss research governance
- Share ethics review and process (*see hand out of forms*)
- Describe common problems
- Discuss other models and experiences




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Critical analysis and Enquiry

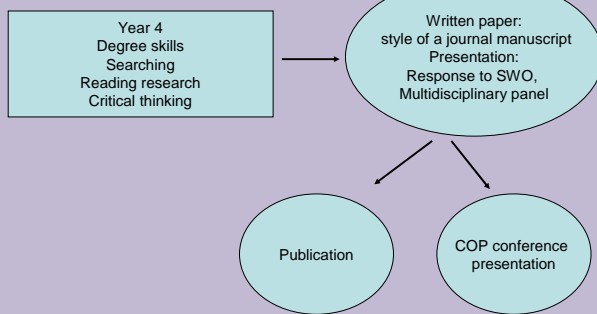
<div> <p>Year 1</p> <p>Degree skills Searching Reading research Critical thinking</p> </div>	→	<div> <p>3 papers Essay Personal Development Portfolio Presentation skills</p> </div>
<div> <p>Year 2</p> <p>Statistics Research Methodology</p> </div>	→	<div> <p>Statistics paper/ work book Critical evaluation essay</p> </div>
<div> <p>Year 3</p> <p>Identification of topic supervisor Proposal – Ethics application</p> </div>	→	<div> <p>Literature review Ethics application (Reviewed by REC marked by CAE team)</p> </div>



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Critical analysis and Enquiry



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Research Governance

❖ Aim: Improve quality of research and safeguard key stakeholders e.g. profession, patients, students.

❖ Achieved through:

- suitable risk assessment and management.
- developing appropriate research questions.
- using appropriate research methodology; data gathering and interpretation.
- Responsibility? BSO



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Research Governance at the BSO

❖ foster accountability in research at the BSO.

❖ number of key stakeholders in student research process to include:

- ❖ researcher/ student.
- ❖ participants.
- ❖ sponsor of the research (BSO).
- ❖ approving ethics committee (BSO REC).
- ❖ supervisor.



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Responsibility of Supervisor in Governance Process

- ❖ research is of sound quality and clinical relevance.
- ❖ submission of proposal to BSO REC.
- ❖ BSO REC informed of changes to protocol/procedure.
- ❖ adequate supervision and support throughout the process (use of personal diary?).
- ❖ student is aware of and complies to CAE guidelines for submission (both proposal and paper).



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BSO REC

BSO Research and Ethics Committee

- ❖ currently meets twice per year to consider undergraduate and postgraduate research applications.
- ❖ all students required to submit application, signed by supervisor as part of CAE Unit.
- ❖ signing the application signifies your agreement with respect to quality and continued supervision.

Application

- ❖ form and guidance.
- ❖ database of applications to trace progress and recommendations made by the committee.



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Dear XXXX,

BSO Research Ethics committee

Further to your volunteer work as a member of the BSO Research Ethics Committee, I am happy to agree this arrangement until such time as you feel the need to step down from the committee.

The intention of this arrangement is that you will be a member of the School's Research Ethics Committee, and the School will benefit from your support on the committee. There is no obligation on you to attend for any meeting. Sam Keeping, (Research Administrator and Secretary to the Committee) will liaise with you directly about the Schedule of meetings and will supply papers for the meeting. Personal liability for work completed as a member of the committee is insured under the School's insurance policy.

Actual expenses relating to travel to and from the BSO will be paid on the production of receipts, to the value of a second class return ticket. Please note that travel expenses, where paid, will not include travel using taxis or first class fares, and should reflect that the best price has been sought for the journey. Please liaise with Sam Keeping in order to process your travel expenses.

This agreement reflects the hopes and intentions of the volunteer and the BSO, and is not contractually binding in any way on either party.

Thank you for your contributions to date and for all that you bring to the Ethics Committee, it is a valuable and generous contribution of your time to the School.

Yours sincerely

Nina Waters

Head of HR & Business Development

Tel: 020 7089 5308

E-mail: n.waters@bso.ac.uk

Terms of Reference

- To be responsible to Academic Council:
- To protect and safeguard the welfare of patients and all research participants
- Examine undergraduate, postgraduate and other research proposals regarding ethical suitability to be undertaken under the auspices of the institution and in related osteopathic contexts
- To keep up-to-date with research ethics and the broader research environment, developing and amending strategy and policy for research proposal approval
- To report any concerns regarding patterns of issues to the Senior Management Team and Academic Council
- Provide ethical advice for researchers as required or requested
- To produce an annual report



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Membership

- Dr Jo Zamani (Chair), Research and Development Manager*
- Penny Conway (Vice Chair), Clinic representative, Osteopath
- Will Podmore, Librarian
- Steven Vogel, Vice Principal, Researcher, Osteopath
- Hilary Abbey, CAE team, Clinic representative, Osteopath
- Alan Ruben Chair NHS REC, Retired GP*
- Carol Reid Patient representative, Trustee*
- Stuart Walker (Recently Retired External)
- Margaret Wolff, Lay member, Lecturer in Ethics
- Paul Grant, Solicitor, Non-practising Osteopath
- Donna Clift-Williams, POS lecturer, Osteopath

Sam Keeping BSO REC Secretary



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BSO REC Outcomes

Outcome	2008		2009	
	N	% of total	N	% of total
Supervisor/ Chair Amendments	19	36.5	35	48.6
Resubmit to Chair or designated REC member	12	23.1	16	22.2
Resubmit to BSO REC	17	32.7	15	20.8
Accepted with student amendments	4	7.7	6	8.3
Total	52		72	



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Reasons to Amend or Reject

- ❖ Lack of scientific/ clinical value.
- ❖ Lack of academic validity. Poor use of research principles and methods.
- ❖ Unfair/ inappropriate participant selection. Evidence of coercion.
- ❖ Risk – benefit ratio. Risks to the participant outweigh benefits to all.
- ❖ Lack of informed consent.
- ❖ Lack of respect for participant – no provision to maintain confidentiality; no process for withdrawal from study; no dissemination strategy.



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Ethics Checklist

- ❖ Question relevance and academic quality of proposal.
- ❖ Appropriate use of methodology, statistics. Is the questionnaire well designed? Will it collect meaningful data?
- ❖ Participant selection. Reliance on participants already known to student?
- ❖ Harm minimisation. Benefits outweigh potential risks.
- ❖ Informed consent using standard BSO pro forma.
- ❖ Protect confidentiality, data protection and storage, permission given to withdraw from study, clear dissemination strategy.



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Problems

- Time and effort
- Resentment from applicants
- Limited scope for RCTs
- Skills and resources



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Questions

- How do other institutions deal with these issues?
- Payment and arrangements for ethics committee members?
- Cost benefits – is it worth all the work?



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Useful Resources

- ❖ BSO REC Application Form and Guidance.
- ❖ NCOR Research Governance Framework
http://www.brighton.ac.uk/ncor/rgf/RGF_6.pdf
- ❖ DH Research and Governance Framework for Health and Social Care (2005).
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962
- ❖ The NHS R&D Forum – specifically Research Governance Documentation and Information Guide.
<http://www.rdforum.nhs.uk/045.asp>



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Thank you for your attention!

s.vogel@bso.ac.uk



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