RESEARCH COMMITTEE

Subject: Final Report from the Ethics Processes Working Group (Sub-Committee established by Research Committee)

Origin: Peter Townsend, Director, Research Office

Executive Summary: Final report from the Ethics Processes Working Group detailing initial objectives, achievements/outcomes, recommendations and conclusions. It is recommended that a Change Management Project is established as soon as possible supported from both key School users, IT Services and the Research and Finance Offices to establish a revised workflow system. It would be the objective to provide an initial report/stage one business case by March 2016 for consideration by Operations Committee. In addition, the Research Office would undertake a further review of existing School based training and as part of the above mentioned Change Management Project would investigate the feasibility of providing a more coherent and clear set of training resources both centrally and within Schools.

Action Required: Research Committee are asked to note progress towards initial objectives and to approve the recommendations of the report.

1. Initial Objectives

The Ethics Processes Working Group was established to implement the recommendations of the external review of Loughborough University’s ethics processes which was undertaken during late 2013. At its first meeting the Working Group agreed the following objectives:

- Membership changes were required to the Ethics Approvals (Human Participants) Sub-Committee (HPSC). Specifically relating to the inclusion of lay members from outside the University.
- Formalisation and transparency of the HPSC ensuring clear decision making and alignment with national best practice.
- Establishing core competencies for HPSC members to ensure appropriate ethical review of proposals and provide specialist training to maintain those competencies.
- Establishing systems that support the capture and tracking of proposals that are submitted to HPSC, in order to deal with the expansion of the number and complexity of projects being carried out within the University.
- Alignment of insurance provisions, including a process for the recognition of studies approved by HPSC and NHS Research Ethics Committees so as to enable LU to be indemnified for all projects by the insurer.
- Working towards full adoption as an NHS REC sponsor for all NHS studies undertaken by the University.
• Consideration of the addition of Health and Safety issues within the HPSC checklist.

2. Achievements/Outcomes

The Ethics Processes Working Group met on 10 occasions and the following actions were completed:

Sub-Committee Membership

• Job descriptions and person specifications were prepared and approved by the Ethics Committee for lay and co-opted members of the HPSC. Three co-opted members had been recruited from SSEHS, Counselling Service and the Centre for Faith and Spirituality.
• Investigations into the recruitment of lay members culminated in a decision to source members with relevant experience from within the University but who were not involved in research.

System Improvements and Compliance

• Process mapping of ethics processes within Schools had been completed and a standardised process (Figure 1) had been developed showing the typical approval process for Schools, which could be used when developing procedures and potentially implementing a workflow system. This would not only enable greater transparency but also facilitate greater compliance and better record keeping as well as simplifying the process for applicants.
• As the current Sub-Committee processes are entirely paper based significant efficiency savings could be achieved both for applicants and School users if an on line workflow process was adopted.
• As a consequence two state of the art software systems were demonstrated to the Working Group (Propheris (Documas) and Infonetica (Ethics RM)).
Figure 1: Standard Ethical Approval Process within Schools

1. School contact e-mail staff advising of deadline for Committee.
2. Ethics checklist submitted to School contact.
3. School contact checks approval and then processes as appropriate.
4. Log form on database.
5. Pass checklists to signatory.
6. Signatory returns form to School contact confirming whether School approves the project.
7. School contact checks approval and then processes as appropriate.
8. Submit to Ethics Approvals (Human Participants) Sub Committee.
9. Confirmation of approval/refusal received from Sub-Committee.

- A risk if at this point the researcher does not apply for Ethical approval.
- A risk here if the research develops into areas not covered by initial clearance and amendments are not reported.
- Checks required on what is happening with research. A risk if research has started and approval not given.

EC15-P22
23 October 2015

All paperwork checked for missing signatures.
Check the Ethics checklist for symbols.
All paperwork checked for missing documents/information/signatures. Check investigators on generic protocols.
Further detail needed.
Refer back to researcher for missing information.
Decision logged on database and form retained. Confirmation of decision sent to staff member and student.
Decision recorded on database. Investigators informed that clearance is refused.

Approval
Declined

Approved and Symbol *, #, +
Approved and No symbol/ or # covered by Generic protocol

Figure 1: Standard Ethical Approval Process within Schools
NHS Ethics

- Loughborough has joined the Joint Research and Development Support Office Management Group with UHL and University of Leicester in order to facilitate sharing of best practice and to ensure efficient support for Loughborough staff. This will be of considerable benefit as the level of activity between LU, UHL and University of Leicester and other regional partners grows as the National Centre for Sport and Exercise Medicine and related activity develops both in terms of complexity and volume.

- As a consequence of the above Loughborough specific versions of the Standard Operating Procedures used by UHL and University of Leicester had been drafted so that Loughborough can act as sponsor and has externally recognised procedures for the approval and monitoring of projects.

- An informal Working Group had been established to review ethical and insurance requirements going forward with regard to research involving NHS Trust and Healthcare Partners and research within the National Centre for Sport and Exercise Medicine.

- A new workflow had been developed giving details of the process for NHS Passport applications. This had been discussed with relevant stakeholders and was now available on the HPSC website. This will enable the Research Office to facilitate NHS Research Passport applications and confirm that appropriate ethics approvals are obtained and records maintained of NHS research involving Loughborough researchers.

Insurance

- The Working Group had investigated issues regarding the interpretation of studies and legislation as to what the insurers defined as a clinical trial in terms of their cover as well as to ensure that the dual elements of both Public Liability and Professional Indemnity were fully addressed. As a consequence the University has now obtained clinical trial cover for studies which are within defined limits and not which do not involve vulnerable participants or clinical trials of experimental medicinal products. A revised Insurance Flowchart has been produced which enables a clearer decision making process by academic PIs and other School users. This also minimises the risk of breaching/exceeding our insurance cover by undertaking uninsured activities.

Health and Safety

- The Ethics Committee has now approved the proposal to request completed Risk Assessments along with ethical clearance applications. A revised checklist has been produced and has been made available along with template risk assessments for common activities including interviews, questionnaires and on line data collection.
3. Recommendations

- **Workflow System for Ethics Approvals Processes** – There is an increasing requirement to ensure compliance with all the regulatory and audit protocols in the context of the NHS Research Governance Framework and other associated areas including Human Tissue Authority licence requirements. Although the University has received a positive report from our recent HTA audit, the Working Group is strongly of the opinion that there are still significant potential risks both in terms of reputation, audit and compliance requirements regarding our human participants ethical approvals system. There is still strong reliance on inefficient paper-based processing which does not easily lend itself to effective monitoring, processing and systematic recording of information. Consequently the Working Group was strongly in favour of undertaking a change management project in order to improve our processing system as well as ensuring greater compliance and better monitoring of investigations involving human participants. This would be beneficial to both ethics applicants and School support staff as well as for the HPSC. This would enable greater clarity of the requirements and processes, remove dependence on Word based documentation and drive greater efficiency particularly in terms of staff time in Schools and within the HPSC. A further key benefit would be the ability to deal more efficiently with complaints or adverse incidents. This would allow speedier investigations to determine the most appropriate course of action including where interactions are required with our insurance providers (as has recently been experienced with a Health and Safety incident). Such an approach would improve our ability to access archived information and related project documentation that could otherwise be difficult to obtain in the situation where a PI may have left the University since the project was completed.

A revised workflow system would also facilitate the simplification of the process within Schools and remove the need for them to maintain separate paper records, databases and inefficiency of processing within Schools.

**Recommendation:** The Working Group therefore recommend that a Change Management Project is established as soon as possible supported from both key School users, IT services and the Research and Finance Offices to establish a revised workflow system. It would be the objective to provide an initial report/stage one business case by March 2016 for consideration by Operations Committee.

- **Improved training provision for staff/students**
  From its initial review of current arrangements the Working Group was clear in its recommendation that further serious consideration should be given to the implementation of a mandatory high level, University-wide, training and awareness resource synonymous with Fire Safety etc. The expectation would
be that completion of a high level on line training module would provide sufficient awareness of key issues and requirements and would then signpost colleagues to more specific discipline based training which is it is recognised is currently being offered by Schools. Another key area that the Working Group identified was around the provision of mandatory on-line training in informed consent for all investigators carrying out research involving human participants.

Recommendation: The Research Office would undertake a further review of existing School based training and as part of the above mentioned Change Management Project would investigate the feasibility of providing a more coherent and clear set of training resources both centrally and within Schools.

4. Conclusion and Future Activity

It is pleasing to note that the Working Group has achieved the original objectives and tasks which it was set by the Research Committee and the PVC(R). It has been clear to the Working Group throughout its activity that there has been a welcome increase in the level of activity and joint working which requires ethical approval of one type or another. There has been a particular step change in the activity undertaken in the broad context of the establishment of the National Centre for Sport and Exercise Medicine with collaborators from within the NHS. In addition many other areas of the University outside SSEHS are also increasing their research activity with colleagues in the NHS and health services including from within Chemistry and from within Engineering areas including the Centre for Biological Engineering. Many of the initial potential barriers to effective interaction as outlined above have now been addressed. These include the fact that we hold our own HTA Licence, can now act as an NHS research governance sponsor and that Loughborough University is now a formal member of the joint R&D office management group with UHL and University of Leicester. Under the latter we have been able to adopt the relevant standard operating procedures mirroring those of our healthcare partners.

However, to enable Loughborough to continue to grow this strategic research activity it is now important that LU reviews the underpinning workflow, systems and processes to enable it to continue to operate effectively and efficiently and to continue to be perceived as a partner of choice by University and NHS collaborators. An example where this will be particularly relevant will be around the imminent rebidding for the high profile renewal of the Biomedical Research Unit in Diet, Lifestyle and Physical Activity jointly with UHL and University of Leicester towards the end of 2015/early 2016.

Finally, members of the Working Group have acknowledged the benefit of this forum to discuss and address issues which were not as a matter of course discussed by the Ethics Committee or the Ethics Approvals (Human Participants) Sub-Committee.
Consequently members have established an NHS Trust and Healthcare Partners Working Group, initially comprising representatives from Finance (Srinivasan), Research Office (Townsend/Green), SSEHS (Casey/Goodall/Bentley/King/Clements). This group has consequently been able to expedite and address arising strategic and operational matters which has facilitated and supported initial research activities that are taking place within the National Centre for Sport and Exercise Medicine. This will continue to be important as activity grows with all our partners and membership of this group may widen.

**Members of the Ethics Processes Working Group**

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Dr Victoria Haines, Design School

Dr Karen Coopman, Chemical Engineering

Professor Mark Lewis, Dean of School of Sport, Exercise and Health Sciences

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