Loughborough University Ethics Committee

Subject: External Review of Ethical Processes at Loughborough University

Origin: Dr Carl M Edwards PhD, Former Chair of NRES Committee East Midlands – Leicester and Zoe Stockdale, Research Office

Action Required: To consider and discuss the external review by Dr Edwards

Background

The University's Operations Committee requested that a Project Management Board (PMB) be established to look at research governance in human studies. One of the actions of the PMB was to request a review of the operation of the Ethics Approvals (Human Participants) Sub-Committee (HPSC). This review was undertaken, at the University's request, by Dr Carl Edwards.

Summary of findings

Dr Edwards found that "the current Human Participants Sub Committee (HPSC) and its procedures are appropriate for the current levels of work involving human participants. However, if the HPSC is to start to review more intense research with human participants and an increased numbers of proposals then there need to be some changes, which include:

- The HPSC requires membership changes, key of which is the inclusion of lay members from outside of the University
- The HPSC committee procedures require more formalisation to ensure transparency of decision making and alignment with national best practice
- Establish core competencies for HPSC members to ensure appropriate ethical review of proposals and provide specialist training to maintain those competencies
- The systems that support the capture and tracking of proposals put to HPSC require strengthening to allow for the expansion of the number and complexity of projects being carried out within the University
- There's a need to align the insurance provisions to include a process for the recognition of studies approved by HPSC and NHS Research Ethics Committees as being indemnified by the insurer"

Going forward

This review is to be considered by both the HPSC and Ethics Committee for comment and discussion before going forward to the PMB for approval. Once approved, the associated implementation plan (Appendix 3) will be implemented by staff in the Research Office, in collaboration with members of both the Ethics Committee and HPSC. The highlighted areas of the implementation plan are considered to be priority areas.

Review of Loughborough University Ethics processes

December 2013

Author: Dr Carl M Edwards PhD

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Summary

Loughborough University has an expanding number of research activities which include human participants through the growth of initiatives like the Exercise and Nutrition Biomedical Research Unit and the Centre for Sports and Exercise Medicine. In this changing environment it was decided to undertake a review of the current ethical framework within the University and the resources currently available to this activity.

The University requested a review of the currently available documentation, committee structure and indemnity provisions, the remit of which is available in Appendix 1. The review was carried out with reference to the current procedures recommended by Economic and Social Research Council and the NHS National Research Ethics Service to provide a national baseline of best practice.

The findings of the review are that the current Human Participants Sub Committee (HPSC) and its procedures are appropriate for the current levels of work involving human participants. However, if the HPSC is to start to review more intense research with human participants and an increased numbers of proposals then there need to be some changes, which include:

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- The HPSC committee procedures require more formalisation to ensure transparency of decision making and alignment with national best practice
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- The systems that support the capture and tracking of proposals put to HPSC require strengthening to allow for the expansion of the number and complexity of projects being carried out within the University
- There's a need to align the insurance provisions to include a process for the recognition of studies approved by HPSC and NHS Research Ethics Committees as being indemnified by the insurer

The alignment of the HPSC with national guidelines is part of an on-going process in the establishment of Loughborough University as an appropriate Sponsor for research with NHS patients. The development of capacity in the Research Office to provide support for HPSC will be a significant first step in the creation of systems which will enable the University to Sponsor a broad range of clinical research with NHS patients.

1.0 Ethics Approvals (Human Participants) Sub-committee Membership and meeting structure

1.1 Membership review

The current membership of Ethics Approvals (Human Participants) Sub-committee (HPSC) is listed in Appendix 2 and consists of 16 members drawn from University members of staff. This structure is based on drawing members from the individual Academic Schools of the University along with supporting expertise from the student body, health and safety, Counselling and Disability Service and Occupational Health. This composition provides a good technical and scientific base from which to make decisions on research protocols however, the structure may not meet the increasing needs for review of medically related research.

The membership models adopted by both the National Research Ethics Service (NRES) and the Economic and Social Research Council (ESRC) place less emphasis on ensuring complete expert representation within the committee and more on having a committee that reflects the makeup of the community it is serving. The details of the models are available in "Governance Arrangements for Research Ethics Committees" (Department of Health) and "ESRC Framework for Research Ethics" (ESRC) and these have been used in forming the recommendations for changes.

1.2 Membership recommendations

One of the main differences between the current committee membership and other nationally recognised models is that there is no explicit lay representation from outside of the University. Some revisions to the current Code of Practice are recommended drawing on these models:

- Establish a maximum of 18 members.
- Members of the Committee to be employed by the University – providing indemnity for actions and decisions whilst part of the HPSC for members from outside the University staff body.
- Consisting of both male and female members with an aim for an equal number
    - Where possible ensure a cultural mix reflecting that of the community within Leicestershire
- Establish Officers; Chair, Vice-Chair and Alternate Vice-Chair
    - Chair to be appointed by the University Ethics Committee after consultation with the HPSC
    - Vice-Chair roles to be agreed between the Chair and University Ethics Committee
- Create at least one Lay member post that is appointed from outside of the University body, the lay member can have a technical background and should be independent from the University
- Establish a Quorum of 7 members, to include:
    - a Chair or Vice-Chair
    - at least one expert member
    - one lay member (non-University Employee – 'lay plus' see 1.5 below)

The existing membership being drawn from a selection of representatives from the Ten Schools reflects expertise required to review the technical aspects of protocols however, to

strengthen the current composition it's recommended that it's made explicit that one member have recognised statistical expertise.

The inclusion of members from the student body and from specialist backgrounds e.g. occupational health and, health and safety should be retained to support the HPSC in decision making. However, the use of co-opted members should be expanded to enable the HPSC to draw on other specific scientific or technical expertise in the review of specific projects where the HPSC has decided it needs assistance.

The terms of office for members in the Code of Practice appear entirely appropriate but perhaps should be amended to allow the co-option of expert advisers for single meetings. This would align with Section 7(c) in the Code of Practice (Seeking Expert Guidance).

1.3 Meetings review

The HPSC Code of Practice details the schedule of meetings (12 per year) and the types of decision that may be delivered by the committee. There are no detailed guidelines on committee discussion procedures or recommendations for the conduct of meetings which could be beneficial in supporting consistency of feedback to researchers and in capture of HPSC performance.

The provisions in the Code of Practice for delivery of decisions outside of the normal meeting schedule (Section 7(b) Obtaining Approval) are very helpful for researchers and this flexibility is welcome. However, there is a lack of detail on how members might input their opinions (e.g. email, teleconference or other virtual meeting space) and the probity of committee decisions would benefit from a more explicit framework for this activity.

1.4 Meetings recommendations

The Code of Practice should include a framework for the conduct of review meetings which sets out a standard agenda and responsibilities. As a minimum these should include provisions for:

- Agenda template
- Standards for provision of papers to members prior to the meeting (e.g. timing, maximum number of applications)
- Quorum (see 1.2 above)
- Explicit nomination of a person to record the proceedings of the meeting
- Process through which applications are reviewed e.g. by a single lead reviewer for comment by the other members
- Conduct of business guidelines e.g. responsibility for the meeting, responsibility for record keeping, process through which a decisions is reached
- Confidentiality provisions
- Template to provide feedback to applicants and minutes of the meeting

There are existing guidelines available from NRES and other HEI which can be adapted to match the resources and timetables of Loughborough. The provisions above cover a minimum standard but it's recommended that the Code of Practice also allow for future inclusion of items such as publically available minutes (redacted) and non-committee member observers.

The provision of a 'virtual' meeting service could be built on the template for the usual meetings with additional explicit provisions for:

- Standards for provision of papers to members prior to the meeting (e.g. timing, maximum number of applications)
- Standards for acceptable methods to feedback of opinions from members e.g. teleconference, email correspondence
- Explicit nomination of a lead to co-ordinate feedback
- Minimum and maximum time allowed to provide feedback
- Process through which a decision is made e.g. unaminity vs. Virtual ballot

The key in ensuring that the provision of 'virtual' meetings retain validity is the process for inclusion of members in the decision making process. Whilst the provision for remote interaction may be adequate within the University, it's important that external committee members have the same opportunity of access; this may require some additional ICT provision for external members for on-line review.

The process of ensuring the equivalence of virtual review with a full committee meeting is reliant on similar document standards e.g. standard electronic format. The provision of committee application documentation electronically is currently being implemented by NRES, with exceptions only for documents such as drug safety and efficacy documentation. The HPSC meeting process development should consider the standardisation of application documentation to electronic format, along with appropriate ICT support for making notes and commenting on application documents.

1.5 Lay membership recommendations - Definition and recruitment

The inclusion of lay members in an ethics committee is critical in aligning membership with national and international best practice in ethics. The definition of lay membership does vary between organisations, as one might expert where the type of 'expert' membership varies. One helpful description of lay membership can be derived from NRES guidance where a lay member is one who fails to meet the criteria for expert membership. In this case an expert member would be defined as a person

- Who has professional qualifications related to the conduct of research, or the statistical analysis of research (unless the research relates only to the ethics of research)
- Is not currently undertaking research, but has previously conducted research (at a level higher than Masters Qualification)

This means that professionals who manage research or monitor it may be regarded as lay members because they have not conducted or are not conducting research at a high level.

There then is the potential to define 'lay plus' as a category as a person with no experience of research in any form, but who still may be a technical expert in another field e.g. engineer, architect , etc. At least one member of the HPSC should qualify as being lay plus to maintain appropriate balance in decision making. Given the need for lay plus as part of the requirements of Quorum it would be prudent to have more than one member of this type on the committee at any one time.

Recruitment of lay and lay plus members should be by an open process, drawing from the community in which the University operates. This would imply people from Leicestershire or the broader East Midlands that reflect the views of the local population. Advertisements in local press are effective in raising awareness and have been used by other Universities and the NHS research ethics service to recruit to ethics committees.

- It may be possible to raise awareness of the opportunity to work with Loughborough University through the regional NHS ethics service. There is a 'pool' of potential members waiting to join NHS ethics committees that may wish to work with Loughborough University; this could be done through contacting the NRES administrative centre located in Nottingham.

The selection panel for lay members should also reflect views from outside of the University, with representation from an external organisation e.g. charity or other HEI to provide balance. This selection process should align with existing University recruitment policies as any external members will need to be employed as members of the HPSC to provide them appropriate indemnity for their actions as part of the committee.

2.0 Training of committee members

The HPSC should have a framework of member competencies from which it can demonstrate its ability to provide acceptable opinions on research proposals. These competencies can be evidenced through participation in workshop type events, on-line learning and self-directed learning. An important aspect of learning is to ensure there is a shared experience for the committee, ethics committees should operate through achieving unanimous decisions, this is best achieved by making sure there is a common level of understanding of ethics and technical issues.

2.1 General ethical training (including lay members)

The ethics of research in relation to human subjects has a number of key aspects which should form the basis of the core competencies for review of research proposals. These include both statutory obligations to consider and also general ethical principles under pinning ethical review. The basic elements of training should as a minimum include:

- Legislation in relation to research involving human participants:
  - Nuremberg Code (1947)
  - Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013)
- Research and society
  - Societal impacts of research
  - Research in pursuit of knowledge
- Ethical approaches to research
  - Consequence vs Principles based approach

The training of an ethics committee should involve a core basic set of technical/ethics knowledge which is then applied in group work on specific ethical issues. The process of debate through examples of ethical debates from elsewhere improves the cohesion of the committee and leads to more consistent service to the research community.

The current Code of practice sets aside 3 meetings per annum to include discussion of 'ethical issues' in addition to the review of projects. This provides an existing mechanism through which examples of ethical issues taken from elsewhere could be used to improve the performance of the committee and also provide a continuous process that will help integrate new members to the committee after their basic training.

2.2 Specific topic training recommendations

The remit of the committee in respect of the research carried out at Loughborough will have specific aspects where it would be beneficial to have one or more members have specific expertise in relation to legislation in relation to research being carried out within the University. The greater involvement with the Exercise and Nutrition Biomedical Research Unit and the Centre for Sports and Exercise Medicine would indicate that the key areas for expert knowledge will be:

- Research using human tissues – Human Tissue Act (2004)
- Research data and confidentiality – Data Protection Act (1998)
- Research using ionising radiation – imaging and administration of radioactive substances

In the context of the current research carried out within Loughborough University there is no explicit need for expertise in the review of studies utilising pharmaceuticals or adults lacking capacity to consent. These studies would need to be reviewed by an NHS REC, however, in the future the HPSC could form the core of support structures to enable Loughborough University researchers to apply to carry out such studies.

2.3 Training resources

Loughborough University doesn't currently provide specialist training in research ethics and in the first instance using external suppliers will provide the University with a validated training provision that could be provided in a timely manner.

The provision of training in the core ethical principles and legislation is available from a number of providers, a network of which is available through the Association for Research Ethics (AfRE) (http://www.arec.org.uk/) an organisation which could advise on providers. As an example in the local area, Keele University provide bespoke training courses in research ethics.

Training in specialist aspects of research ethics is available through AfRE and also in association with NRES, who provide regular courses dealing with all aspects of research with human participants. (http://www.hra.nhs.uk/hra-training/)

One practical issue of ensuring appropriate training for the HPSC will be the interaction with other ethics review organisations outside the University. The effective functioning of an ethics review committee is critically dependent on its ability to learn and adapt to the changing community environment and also technical innovations. In working with external bodies in training and potentially in sharing membership the HPSC will have demonstrable competence in delivering appropriate ethical opinions.

3.0 Approvals process and documentation

3.1 Background

The current Code of Practice provides a relatively flexible system for review of research involving human participants with a substantial responsibility for ensuring successful completion of the approvals process falling on the HPSC itself. In order to present a more transparent and equitable

3.1.1 Processes

As detailed in previous sections (e.g. 1.4) the process for how a meeting shall be conducted requires documentation to provide consistency of the review process. There is a lack of clarity in the HPSC's expected performance in terms of the speed and number of reviews carried out, and in the interaction with other University structures such as those involved in investigation of research misconduct.

It is recommended that the current Code of Practice should also include:

- Explicit timelines for review and feedback of opinion
- Process for appeals against HPSC decisions
    - Role of the University Ethics Committee as appellate body
- Process through which audit is carried out and reported needs to be clarified and aligned with current University misconduct procedures:
    - Role of the University Ethics Committee in investigation of irregularities
    - Role of HPSC in determining breach of approvals
    - Distinction between audit of HPSC function (i.e. performance metrics) and the audit of research conduct (i.e. professional standards and practice)
- Process to allow for changes to proposals
    - Changes to recruitment procedures
    - Changes to interventions

The role of the HPSC in the current Code of Practice is not clear in respect of how to deal with appeals against its decisions and also in cases where there have been breaches of the procedures approved by it. The institution of an appeals procedure should include the University Ethics Committee in the role of arbiter of appeals; this role in provision of support to the HPSC aligns with its role in selection of Officers of the HPSC.

The requirement for audit of projects by HPSC is not defined within the current Code of Practice with a general statement that the HPSC should provide and audit of all projects. The audit of the performance of the HPSC in carrying out its functions e.g. accepting and reviewing proposals and collection of final reports should be a separate activity to audit of research conduct. The reporting of the performance of the HPSC should take the form of:

- Monthly update to the University Ethics Committee
    - Proposals submitted
    - Proposals reviewed
    - Time to provide an opinion from date of submission
    - Titles of final reports submitted
    - Membership changes

- Annual report to the University Ethics Committee
    - Annual activity data
    - Maintenance of core competency training
    - Membership summary and recruitment activity

The audit of research conduct should be a process aligned with current University structures with the role of the HPSC defined in relation to that. The personnel and resources required to audit every research proposal is likely to be substantial and it's recommended that the current University structures examine the feasibility of this. It is usual, even in the case of inspection by authorities such as the Medicines Healthcare Regulatory Agency, that only a proportion of projects are audited in relation to the conduct of the research and this is a model that should be considered an appropriate use of resources.

The current recommendation for the role of HPSC in potential incidences of research misconduct would be in determining the ethical implications of any potential misconduct in relation to potential harm to participants. For instance misconduct relating to finances or research staff would likely not be a matter that the HPSC would provide a view upon, whereas failure to follow proper consent procedures would be specifically reviewed by the HPSC.

- The views of the HPSC would be provided to the University structures that carry out research misconduct investigation, the HPSC should not be expected to lead investigation or review of misconduct.

The communication of decisions in relation to potential misconduct should be passed to the University Ethics Committee as part of normal monthly reporting procedures. The communication with other University Committees is current achieved through the inclusion of members from other committees within the HPSC e.g. Health and Safety Committee. However, this should be formalised to ensure that information is consistently shared; it is recommended that the other Committee's receive the same summary data provided to the University Ethics Committee on a monthly basis for information.

The provision of an HPSC opinion on the conduct of a research proposal including human participants should be considered by all other University Committees (apart from the University Ethics Committee) to be the final decision on all of the ethical aspects of the study e.g. recruitment procedures, participant information. This final opinion also includes the appropriateness of the potential risk to participants, use of personal data and other research procedures; this is recommended to ensure that there is a minimisation of duplication of effort and also reducing the ability of researchers to 'fish' for the ethical opinion they would like.

The current Code of Practice has no explicit provision for researchers to change the research procedures during the life of the project. The implementation of an 'amendments' procedure should align with the current information procedures currently in place that deal with 'generic' applications. The ability to track amendments to protocols and the obligation on researchers to ensure any changes are notified to the HPSC will improve project tracking and provide researchers with an opportunity to adapt protocols more easily. The decision on what constitutes a change to an already approved project and what is a new project is important and the Chair should lead on any discussions where this is unclear.

3.1.2 Documentation

The application documentation provided for researchers on the current website demonstrates a high level of consistency and quality. It provides researchers with a structured way to consider their proposal in relation to the ethical and legislative framework. It is recommended (Section 4.1) that the existing application documentation be adapted to provide an entirely on-line application system so there will be no detailed comment on application documentation.

The University provides a suite of documentation providing advice to researchers on what to consider when working with human participants, most of which deal (very effectively) with the legislative provisions for research involving the use of drugs or specific vulnerable groups. However, one set of documentation is important in relation to HPSC and the broader governance of research with human participants and that is the template consent forms.

The provision of example consent forms is very helpful for researchers in considering the issues in communicating with participants. However, aligning the format with current national standards would be helpful e.g. initial boxes provided for participants to acknowledge each statement. There is a new set of standard consent forms being developed by NRES and in the future these may provide a useful reference to align to; though often NRES documentation is very focused on providing documentation to support Clinical Trials of Investigative Medicinal Products and as such may not be appropriate for the broad range of research within the University.

The Code of Practice has explicit provisions for the HPSC to provide an opinion on alternatives to written consent for participants and this is important to retain in the development of the role of HPSC and the inclusion of people in research. There is also a helpful document on the inclusion of children and young people in research which supports the use of the Assent form provided by the University. There are however, some discrepancies which should be addressed as the documentation is updated.

It's recommended that the "Additional Information: Working with Children and Young People" and the consent form templates are changed to reflect the content of the Code of Practice. In the Code there is an explicit statement "In the cases of participants under the age of 18, or with some other potentially vulnerable groups, it may be necessary to obtain consent from the parent/guardian or carer. " This is entirely appropriate and reflects best practice in inclusion of young people and children in research, where there is the acknowledgment that they may be able to consent to participate research independently of their parents or guardians. However, there is no provision for a template consent by a younger person which may lead researchers to conclude that this isn't an option available to them. It is also the case in the additional information document (section 3.1) that the text doesn't encourage the researcher to consider consent from the participant "Consent from a parent, guardian or responsible adult should be obtained for all studies (including demonstration of procedures and techniques) involving people under the age of 18." It's recommended that they be amended and researchers also refer to the MRC publication "Medical Research Involving Children" which has extensive information on when children and young people should be asked to consent to research, rather than assent.

4.0 Supporting structures and infrastructure

4.1 Support staff

The membership indicates that there is a Secretary in attendance at HPSC meetings but the role of this individual is not made explicit. As mentioned earlier (Section 1.4) the responsibility for accurate record keeping and actions arising from HPSC meetings needs to be clarified. The recommendation is that there is an individual, the Secretary, with responsibility for ensuring the appropriate performance of the HPSC with sufficient administrative support to deliver the HPSC workload. This workload is likely to increase over time and the HPSC and University Ethics Committee should be responsible of ensuring that the resource provided is sufficient to deliver appropriate performance. As a means of ensuring adequate resources the report of HPSC performance to the University Ethics Committee should include a statement on the current staff available and any need for change.

4.2 Systems

The current system of on-line MS Word documents that are then submitted to the Research Office currently works well. However, it is unlikely to prove sufficiently robust to deal with the increasing numbers of applications to the HPSC as a result of the changing research within the University. This paper based system will also impact the ability of the HPSC to effectively audit performance and workloads, without the need for substantial administrative support.

Conversion of the current application and checklist forms to an on-line system that will allow central project tracking should be seen as a priority for the HPSC. This would allow easier performance audit, faster identification of proposals failing to deliver appropriate reports and allow better resource planning. This type of system would establish an ability to track amendments to existing approved projects and to monitor the use of 'generic' approved procedures. There is no national template for the development of an ethics tracking system and Universities locally have used in-house designed systems to implement on-line application systems. It should be noted that the system should be developed with a view to the future role of the research Office Sponsoring research protocols as part of the legislation in the Research Governance Framework for Health and Social Care (see section 6.3).

4.3 Storage

There are no explicit national guidelines specifically in relation to the storage of information by research ethics committees in relation to their business except in relation to Clinical Trials of investigational Medicinal Products (CTIMP). The minimum standard in this case is that all documentation held by the committee is retained for 3 years after the end of the project after termination. There are a number of statutory obligations covering the need for researchers to retain information in relation to research with human participants, especially in relation to Clinical Trials and evaluation of medical devices but these do not apply to the ethics committee itself. It is recommended that to align storage requirements with the current national standards then the NRES standard operating procedures should be adopted (page 222 Research Ethics Committee SOPs). These summarise the timeframe to store data and paper records (usually 3 years) and the minimum dataset to be stored (allows for disposal of interim reports and non-essential documentation).

5.0 Insurance and indemnity

5.1 Background

A review of documentation from typical sponsoring organisations demonstrated a broadly similar pattern of generic research insurance:

- Insurance coverage of costs up to a total £10m
- Coverage of research in adults with the capacity to consent only (excluding women who were pregnant)

There are specific items that can then be included if appropriate:

- No fault indemnity insurance – necessary for organisations Sponsoring clinical trials of medicinal products (or a commitment to cover any no fault claims)
- Project specific permission for research in 'other groups' – e.g. pregnant women, children, or vulnerable adults

In practical terms the historical incidence of insurance claims related to research related mishaps is very small. The events at Northwick Park where patients suffered severe side effects from an experimental drug administered as part of a clinical trial, were a one-off incident, with many large research active pharmaceutical companies reporting very little need to use insurance policies. Notably one large multinational pharmaceutical company does not carry insurance for costs incurred through mishaps in research, but commits to cover any no fault claims. This is entirely appropriate given the size of the organisation and in keeping with the Association of British Pharmaceutical Industry Code of Practice, where there's an obligation to indemnify against the cost of all claims but no explicit prescribed method of doing so.

5.2 Recommendations

The insurance coverage of the University research should provide coverage appropriate to the University's research activities, which would presently exclude the need to provide for no fault insurance, for instance.

The insurer will want assurances of the governance of the research within the University and assurances that all research involving human volunteers has been approved by the University HPSC. It is important that this assurance also recognises that a favourable opinion from an NHS Research Ethics Committee is equivalent to the HPSC approval. This will avoid researchers needing to have both NHS and Loughborough University Ethics Committee approval to comply with the insurance provisions. This will avoid a significant amount of duplication and avoid any incidences of conflicting advice from different ethics committees.

6.0 Future development of governance structures

6.1 Applications through the Integrated Research Application System (IRAS)

The current gateway through which applications can be made to carry out research with NHS patients is the IRAS application form (www.myresearchproject.org.uk). This is a tool which has evolved over time from a form for providing information to NHS Research Ethics Committees to a tool to enable researchers to eliminate duplication of effort in providing study information not only for ethical approval but NHS R&D, MHRA and a number of other bodies.

The complexity of the form, and the variants of it that are generated when selecting the type of research being carried out, lead to wide variations in the quality of applications throughout the system. This variation is not always a reflection of the scientific quality of a proposal but of misunderstanding the form and lack of experience of using the form.

It is usual for Sponsor research offices to provide feedback to researchers and final quality control of IRAS applications, as they bear responsibility for the performance and outcomes of the research. This relies on a level of expertise within the Sponsor research office, usually gained over a substantial amount of time.

In the case of Loughborough University there is the opportunity to build on the existing experience of research staff and the proposed increase in research involving the NHS to develop a core expertise to support applications through IRAS. The creation of internal capacity to support researchers with the IRAS process can be developed organically through creation of peer groups and introduction of training for staff and postgraduates in the IRAS process. Some suggested development steps are given below with an emphasis on ensuring the current expertise in this field is shared efficiently:

- Identification of staff with previous experience of IRAS applications
  - Create a IRAS support forum
  - Build FAQs to support IRAS applicants

- Core training for staff and students on IRAS structure and function
  - Presentations from HRA/REC Members and NHS R&D Leads
  - Provision of best practice examples

- Establish Research Office quality control procedures and resources
  - Set up to run in 'shadow' form with Research Office assessments compared to final outcomes from REC and Trust R&D
  - Roll out Research Office quality control with establishment of Loughborough as a research Sponsor

The development of links to HRA and Trust R&D offices through invitation to peak with researchers should be exploited to broaden Loughborough's engagement with NHS organisations. Inviting representatives from different Trusts in the region will enable researchers to find out about the different internal Trust review processes, which will improve their ability to deliver applications appropriate for NHS Trust approval.

6.2 NHS Sponsor requirements

The role of the Sponsor in research involving NHS patients is defined as:

"The sponsor is the individual, or organisation (or group of individuals or organisations) that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study."

The sponsor requirements are detailed in the Research Governance Framework (DH 2005) and the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031), which should be consulted for further information. However, the primary needs are that the Sponsor have:

- Explicitly allocated resources to track and support research projects being undertaken
- Established roles and responsibilities for execution of the statutory duties involved in research sponsorship
- Systems for audit and governance of projects with established procedures for detection and rectification of poor compliance with the research protocol or statutory duties
- Ability to comply with external audit and monitoring from statutory bodies e.g. MHRA
- Financial capacity to provide adequate compensation for any research participants harmed as a result of participation in research projects

The requirements for Sponsorship rely heavily on the existence of a robust research project management system and suite of standard documents which detail the Standard Operating Procedures of the research governance process and also standard agreements which the University will use with research partners when it is acting as Sponsor.

In reviewing Loughborough as a Sponsor for NHS studies any NHS Trust R&D department that it is working with will want assurances about the systems and indemnities that are in place. The form of the assurance process varies between Trust R&D offices and depends on the complexity of the study e.g. Sponsorship of a non-interventional questionnaire study would raise fewer concerns than a CTIMP.

The potential to increase the tracking and resources in response to the type of research being carried out does mean that the development of Loughborough University as a Sponsor could be carried out in a stepped fashion. This would entail developing individual research studies of increasingly complexity in conjunction with a partner NHS R&D Office; each of which would demonstrate the capacity for Loughborough to act as an appropriate Sponsor.

It is usual for Sponsors to retain an external auditor, to review a selection of historical and on-going studies; this is usually to help organisations ensure they are ready for other

external statutory inspections e.g. MHRA. The results of external audit can also act as assurance credentials when proposing to be a Sponsor of research and as such external audits should be incorporated into the Research Office systems at the earliest opportunity.

The ability to Sponsor research projects in the NHS is critically dependent on the ability to demonstrate that there is current and accurate information all projects being carried out. Once Loughborough University starts to Sponsor CTIMPs there are a number of statutory duties including identifying and reporting adverse events, ensuring documentation and patient information is consistent and appropriate closure of trials. Breaches of the 'Medicines for Human Use (Clinical Trials) Regulations' are considered criminal acts and as such ensuring that there are appropriate systems in place for monitoring and reporting is of the highest importance for the University.

6.3 Further development

The establishment of new systems that will enable Loughborough University to act as Sponsor of clinical studies including CTIMPs will require significant changes to the current capacity of the research office. ICT systems and project tracking compliant to Good Clinical Practice standards as well as the capacity to monitor, detect and rectify any breaches of research protocol. As emphasised earlier a significant part of the assurance process to enable Sponsorship of NHS research is in the systems' capacity to deliver accurate and timely information about research projects as they are carried out. Suggestions on potential nest steps on the two key areas of systems and process are below:

ICT systems

All NHS Trusts and other research Sponsors have developed software based systems to enable tracking of projects, these systems have evolved over time and are often bespoke to the individual organisation. The fact that Loughborough University has an opportunity to adopt a system to use 'as is' as it starts to develop its Sponsorship capacity means that purchasing an off-the-shelf solution would be a good option over adapting systems already in place.

An example of a system developed to manage NHS research is 'Documas', produced by Propheris for Nottingham University Hospitals as a replacement for previous systems. A summary of the system is attached, it has been successfully adopted by Imperial College to manage its research governance processes and as such represents a good example of the type of system that Loughborough will need. The company is happy to demonstrate the system for Loughborough University the contact details for them are:

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Systems development

The process of assembling document flows and lines of responsibility that align with the requirements of both NHS R&D governance and the Clinical Trials Regulations is a significant task. Whilst the systems in place at the present time are appropriate for the current research portfolio it is unlikely that they will be capable of scaling up to be able to manage the challenge of more complex clinical trials. The recommendation is that Loughborough University obtain further advice on the structure of research governance systems to enable the development to be appropriately costed and resourced.

There are a large number of regulatory consultancies however, they usually focus on the audit and monitoring of existing systems than the design of new systems. A suggested source of advice is below, former Head of Research Operations at the University of Nottingham, familiar with the requirements of Sponsor organisations and the interactions between University and NHS R&D offices.

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Appendix 1 – Remit

Remit

Stage 1: Internal Governance and Processes

1.1 To review and make recommendations on the remit, membership and meeting structure of the Human Participants Sub Committee, with particular regard given to the developing areas of health-related research across the University (e.g. the Biomedical Research Unit, Centre for Sport and Exercise Medicine etc.).

1.2 To review and make recommendations on the current processes for ensuring appropriate training for the HPSC members.

1.3 To review and make recommendations on the way in which the HPSC communicates and co-ordinates with other committees at the University, including the positioning of HPSC within the University governance structure.

1.4 To review and make recommendations on how best lay-members could be approached to join the HPSC, including appropriate training, expenses payments and insurance cover, where not considered elsewhere.

1.5 To review and make recommendations on the research ethics approvals processes for research outside the scope of the Research Governance Framework for Health and Social Care.

1.6 To review and make recommendations on existing Codes of Practice and guidance materials.

1.7 To review and make recommendations on the support structures underpinning research ethics approval processes at Loughborough University.

1.8 To review and make recommendations on the processing and storing of research ethics approval applications.

Stage 2. Insurance and Indemnity

2.1 To advise on any issues presented by the current insurance cover and levels of indemnity at the University, and the need for any immediate or future adjustments given the emerging health-related research focus at Loughborough including participation in the working group meeting on insurance matters (22 October 2013).

Stage 3: Sponsorship in NHS studies

3.1 To review and make recommendations on the research ethics approvals processes for research under the scope of the Research Governance Framework for Health and Social Care, with particular focus on the growing health-related research portfolio at Loughborough, and including processes for (i) applications to NREC (ii) the acquiring of Research Passports and (iii) NHS R&D approval

3.2 To make recommendations on how the University can ensure it complies with all required criteria to act as Sponsor in NHS studies.

Outcome of the Review

The findings will be presented in a final, written report and presentation to the Working Group on Governance for Current and Future Health Research at Loughborough.

Timetable

Start Date: 7th October 2013
Final Report Submission: 30th November 2013
Presentation of Final Report to the Working Group (Chair – DVC): December 2013

Appendix 2 – Current Loughborough Ethics Approvals (Human Participants) Sub-Committee Membership

Position	Member
Chair - appointed by Ethics Committee	Sarabjit Mastana
Secretary	Zoe Stockdale
Six representatives from the Ten Schools of the University	
School of Social, Political and Geographical Sciences (Social Sciences)	Carly Butler/Cristian Tileaga
Wolfson School of Mechanical and Manufacturing Engineering	Amit Chandra
School of Sport, Exercise and Health Sciences	Richard Ferguson
School of Civil and Building Engineering	Ashraf El-Hamalawi
School of Science (MEC)	Matthew Inglis
Loughborough Design School	Samantha Porter
Ethical and Environmental Officer, Students Union	Yara Al Wazir
Health, Safety & Environmental Office	Cathy Moore
Up to 4 co-opted members (to include one external occupational health expert)	
Counselling and Disability Service	Manuel Alonso
Occupational Health	Tim Ellis
Regularly in attendance: a member of the Research Office or Research Team	

Appendix 3: Implementation Plan

Action	To complete	Cost
1. Membership		
1.1 Establish a maximum of 18 members	Ethics Committee and HPSC	
1.2 Aim to ensure an equal male/female split and a cultural mix reflecting the community	Ethics Committee and HPSC	
1.3 Establish Officers: Chair, Vice-Chair and Alternate Vice Chair	Ethics Committee	
1.4 Recruit lay-persons to the Sub-Committee	HPSC	Advertising cost to be established
1.5 Establish a quorum of at least 7 members to include: - a Chair or Vice-Chair - at least one expert member - at least one lay member	Ethics Committee and HPSC	
2. Meetings		
2.1 Update Code of Conduct to include a framework for the conduct of review meetings. This Framework should include: - Agenda, feedback and minutes templates - Standards for provision of papers (e.g. timing, maximum number of applications) - Quorum - Explicit nomination of a recorder of meetings - Process through which applications are reviewed (e.g. single lead reviewer, for comment by other members) - Conduct of business guidelines (e.g. responsibility for the meeting, record keeping, decision process) - Confidentiality provisions	Updates: HPSC Secretary Approval: HPSC and Ethics Committee	
2.2 Establishment of 'virtual' meetings: - Standards for provision of papers (e.g. timing, maximum number of applications) - Standards for acceptable methods to feedback opinions from members (e.g. teleconference, email correspondence) - Explicit nomination of a lead to co-ordinate feedback - Minimum and maximum time allowed to provide feedback - Process through which a decision is made (e.g. unaminity vs. virtual ballot)	Updates: HPSC Secretary Approval: HPSC and Ethics Committee	
3. Training of Committee Members		
3.1 General ethical training (including lay members) - Legislation in relation to research involving human participants - Research and Society - Ethical approaches to research	Keele University: Professional Ethics at Keele or Association for Research Ethics	Cost to be established.
3.2 Specific topic training - Research using human tissues (HTA) - Research data and confidentiality (DPA) - Research using ionising radiation	HRA Data Protection Agency	Cost to be established.
4. Approvals Process		
4.1 Update Code of Conduct to include: - Explicit timelines for review and feedback of opinion - Process of appeals - Audit process - Amendment process	Updates: HPSC Secretary Approval: HPSC and Ethics Committee	
4.2 Establish monthly update to University Ethics Committee	HPSC Secretary	
4.3 Establish annual report to University Ethics Committee	HPSC Secretary	
5. Documentation		
5.1 Align Consent Form format with current national standards	HPSC Secretary	
5.2 Update all guidance documents to accurately reflect current national guidance	HPSC Secretary	
5.3 Add Young Person Consent Form to templates	HPSC Secretary	
6. Supporting Structures and Infrastructure		
6.1 Annual Report to University Ethics Committee should include statement on current support staff available and any need for change	Report: HPSC Staff recommendations: Ethics Committee	
6.2 Move to an on-line system for applications and tracking This should be developed with a view to the future role of the Research Office as Sponsor for NHS research protocols	Research Office	Cost to be established.
6.3 Align time period of storage for ethics information to the NRES standard operating procedures: - Store data and paper records for 3 years - Minimum dataset to be stored (interim reports and non-essential documentation can be disposed of)	HPSC Secretary	
7. Insurance and indemnity		
7.2 Ensure the University insurance coverage is appropriate to the University's research activities.	University Insurance Office	Additional cover being sought if required
7.3 Insurer will assurances that: - There is governance of research within the University - All research involving human volunteers at the University has been approved by HPSC - That an NHS REC favourable opinion is equivalent to HPSC approval, therefore avoiding the need for duplicate applications for the same study	University Insurance Office HPSC Ethics Committee	

Action	To complete	Cost
8. Future development of governance structures		
8.1 Develop a core expertise to support applications via IRAS: Identification of staff with previous experience of IRAS - Create a IRAS support forum - Build FAQs for IRAS applications Core training for staff and students on IRAS structure and function - Presentations from HRA/REC members and NHS R&D leads - Provision of best practice examples Establish Res.Office quality control procedures and resources - Set up to run 'in shadow' form with Res.Office assessments compared to final outcomes from REC and Trust R&D - Roll our Res.Office quality control with establishment of Loughborough as research Sponsor	Research Office University Schools NHS REC members NHS R&D leads	Costs associated with hosting meetings/forums/training sessions
8.2 Broaden Loughborough's engagement with NHS organisations	Research Office HPSC Secretary	
9. NHS Sponsor requirements		
9.1 Establish infrastructure and support to ensure Loughborough complies with requirements to act as research Sponsor. To include: - Explicitly allocated resources to track and support research projects being undertaken - Established roles and responsibilities for execution of the statutory roles involved in research sponsorship - Systems for audit and governance of projects with established procedures for detection and rectification of poor compliance with research protocol - Ability to comply with external audit and monitoring from statutory bodies - Financial capacity to provide adequate compensation for any harm to research participants	Research Office	Cost to be established.
9.2 External Auditors External audits should be incorporated into the Research Office systems at the earliest opportunity. It is usual for Sponsor's to retain an external auditor, to review historical and on-going studies; External audits can act as assurance credentials when proposing to be a Sponsor.	Research Office	Cost to be established.