School of Informatics

Research Committee

Proposal to Establish a School of Informatics Ethics Committee
&
Revision of Ethics Assessment Processes

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Background

The number and variety of research projects being undertaken in the School at UG4/MInf., MSc. and PhD. levels as well as grant funded and personal research projects has grown rapidly in recent years. An increasing number of these require formal ethical assessment. In parallel, the regulatory framework for ethical research including specific recent provisions relating to data protection has become more complex. There are now additional legal requirements associated with the justification for the use of personal data and tight controls on what it can be used for.

Most importantly, the legal basis for research studies is now no longer just participants' informed consent, it is whether the proposed research can be said to be in the public good. An increasing amount of research data is being made publicly available upon publication, reused and re-analysed in ways that could have profound implications for privacy and compliance with data protection regulations.

Establishing that research is in the public good and that the collection, storage, analysis and release of data is adequately assessed is currently the role of the Informatics Ethics Panel. The existing processes for ethical assessment in the School need to be significantly

strengthened to ensure that the research conducted in the School is properly vetted and ethically sound.

We propose the establishment of a **School of Informatics Ethics Committee** and the replacement of the existing **School of Informatics Ethics Procedure** to enable us to fulfill these obligations.

School of Informatics Ethics Committee

The motivations for the proposed change from an Ethics Panel to a formal Ethics Committee reflects the increased burden, need for greater prominence and the requirement to adapt effectively to changes both in research and regulation. We believe that by constituting a Committee we can:

1. visibly elevate our commitment to Ethical Research

2. create a grouping that has the necessary expertise to ensure we maintain an ethical review procedure that is fit-for-purpose and that can respond to changes in a timely fashion.

3. co-ordinate and develop longer-term strategic pieces of work such as ethics training, support systems and relationships with equivalent bodies across the University

4. create a high-level School point of contact for Ethics

5. mirror administrative support arrangements in line with other School Committees.

We believe that it is important, if possible, to ensure that a core number of the Committee (we suggest 3) at any given time have successfully led at least one Ethics application to a committee with strict regulations, such as NHS Ethics Boards, or at least two Ethics applications to local University Ethics boards (not counting Informatics self-certification). The remaining members (we suggest up to 4) should have experience of applying for permission to use sensitive data, and/or in creating and enforcing data management plans for sensitive data (e.g. have obtained Caldecott Approval for accessing NHS data). In our experience, these are the minimum qualifications required for being able to give advice to others on Ethics-related matters. The mixture of the committee at any given time should allow for knowledge transfer from more to less experienced members who would in time then be suitably knowledgeable to satisfy the more stringent membership requirement.

Appointment of staff to Committees is decided by the Senior Management Team. During our consultations with Ethics Committees at other Schools in the University we learned that their adopted practice was to make new appointments in consultation with the Committee's existing membership. We would recommend that we adopt the same process in the School of Informatics.

We envisage that the structure and operation of any newly established **School of Informatics Ethics Committee** would mirror that of existing School Committees.

School of Informatics Ethics Review Procedure

The details of a replacement Ethics Review Procedure should be developed by the Committee and tabled as a separate paper for a forthcoming Research Committee meeting. We have, however, already consulted with colleagues at Linguistics, Clinical Psychology, and Geosciences, with a view to learning from their best practice in the development of our refined process. The two main objectives are:-

1. Help those who do research with human participants and on sensitive or personal data think through the implications of their work

2. Protect participants and those who have generated the potentially sensitive data from potential abuse and harm.

The process will, as a by product, help shield the School from disrepute and ensure our research is ethical and has the appropriate legal foundation. Furthermore, many journals now require evidence of clearance by an Ethics Board for publication.

Replacement Ethics Review Procedure

Of the self-certification instances seen by the Ethics Panel in recent years it is estimated that at least three quarters raise cause for concern. These have ranged from simple omissions, such as failing to name the supervisor of an MSc / UG4 project, to serious errors such as using the self-certification mechanism to apply for a study of NHS patients on NHS premises. The majority of these issues could be addressed with feedback from somebody who is experienced and knowledgeable about the practical ethical issues.

Preliminary Recommendations

We recommend that:-

1. The current Self-Certification mechanism is abolished, and that researchers are instead required to obtain approval from an Ethics Committee for research that is not Level 0 under the current system. A web-form based system will be developed that guides applicants through the process.

2. If Ethical Approval has been granted by another institution with a functioning Ethics Board, this will be accepted automatically, provided the letter confirming approval and the full original Ethics application in PDF are submitted.

3. There is an escalation procedure within the system depending on the level of the ethics application.

4. There is a published response timescale based on the level of the application.

5. Guidance material will be made available to all staff in an updated Ethics section (http://web.inf.ed.ac.uk/infweb/research/ethics-and-integrity)

6. Training resources and opportunities be identified for Staff to help them develop their understanding of Ethical Research and use of the School Ethics Review Procedure.

7. In addition to the established Committee membership, we propose that an advisory pool be established to assist the Committee with its deliberations as needed comprising; Head of School, Director of Equality & Diversity, Director of Research, Head of Research Services, Student Representatives (x3) UG4, PGR & PGT.

Timescale

There is a pressing need to make changes in time for the 2019/20 academic session. As such we propose a two stage approach as the University is currently developing additional support for Ethics Review across the University.

- By June 1st, establish an internal School of Informatics ethical review process that operates using the Qualtrics infrastructure (https://www.qualtrics.com/uk/). This is a form-based compliant system that will allow for tightly controlled entry of applications and their subsequent monitoring through the review process. The School already has a licence for this and the forms are currently being developed.

- Ideally by the start of the Academic session, migrate the Informatics system into the Infonetica Ethics Management Tool that is being procured by the University (https://www.infonetica.net). We are not in control of the timeline for when this will be available but it is expected to be so in the Summer.

Actions asked of the Committee

1. Support the establishment a formal **School of Informatics Ethics Committee** to replace the current **School of Informatics Ethics Panel**.

2. Support the removal of the existing **School Ethics Review Procedure**.

3. If the new Committee is approved, request that they bring a technical paper to Research Committee proposing the detail of a replacement **School Ethics Review Procedure**.

Equality & Diversity

The Ethics Committee will work closely with the Equality and Diversity team to monitor relevant implications of research. We will strive to ensure representation of minorities on at least the wider Ethics committee as much as possible.

Resource Implications

The current Ethics panel consists of five members of staff, including the Convenor. The proposed new structure is intended to be largely resource-neutral comprising 3 experienced members (including Convenor) and 2-4 other members.

Streamlining of the Ethics Review Procedure as outlined above using first Qualtrics and then Infonetica tools will improve consistency, accountability and, once established, lead to significant time savings for member of the Committee responsible for reviewing applications. We are also preparing revised participant information sheet and consent form templates.

The Committee would require some administrative support for minute taking, meeting organisation and possibly for other defined project tasks that will arise as the system is being developed, but once established would likely require minimal intervention.