Gaining NHS ethical approval: A biomedical engineering team perspective

Gaining NHS ethical approval from the perspective of a biomedical engineering team

Hannah Jones and Kianoush Nazarpour

ABSTRACT

Gaining ethical approval to conduct collaborative research in the NHS is transitioning. The process of gaining ethical approval from a Research Ethics Committee was viewed as cumbersome within the UK. This viewpoint fuelled continuous improvement of the approval system, most recently implemented by the Health Research Authority. This paper documents an 8-month process of gaining ethical approval, under Proportionate Review, to recruit NHS patients, by an academic biomedical engineering laboratory. Within the field of prosthetic healthcare technology, the multidisciplinary laboratory adopted co-design principles to establish an effective relationship with clinicians to collaboratively gain approval. The challenges and recommendations of acquiring such approval are presented in this paper, including time commitment, project management, strategic networks and stakeholder engagement. The authors believe that academic biomedical engineering research is ideally situated to collaborate with the healthcare sector. By forging a collaborative approach, biomedical engineering can lead in the translation of technology from early stage research to clinical adoption. This vision will be facilitated by gaining an understanding of the NHS ethical approval process. The paper provides insight to this regard, with the aim of informing academic, research management and healthcare domains of this transitioning field of work.

Key words: ethics ■ biomedical engineering ■ project management ■ early career researcher ■ stakeholder engagement

The healthcare industry is experiencing an accelerated pace of innovation. This development is increasingly seen to materialise from private organisations, as opposed to the public sector (Young, 2017). One perspective may identify how industry is market driven, which can result in speed-to-market being one of many critical success factors. In comparison, university laboratories may work towards longer time horizons in order for technology to be transitioned into the healthcare market. To enable the pace of innovation to increase in public sector organisations, there needs to be an active culture of collaborative research that engages stakeholders throughout the project lifecycle. This can be addressed by academic collaborations with the NHS, especially in the

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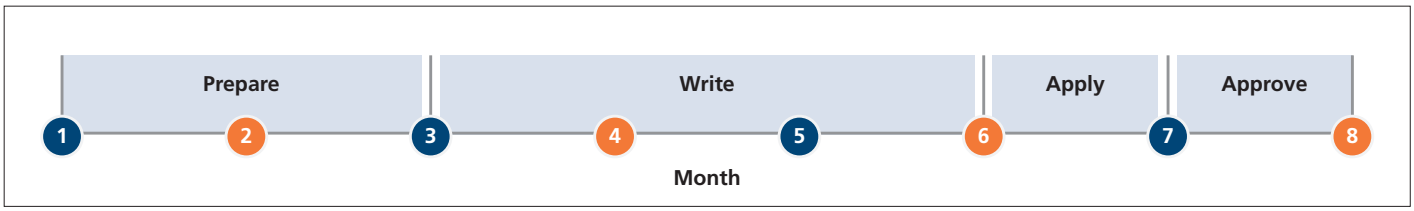

Figure 1. Project timeline

context of early stage research, where time can be more accommodating.

This paper documents an experience of gaining ethical approval by an Engineering and Physical Sciences Research Council (EPSRC), funded biomedical engineering laboratory at Newcastle University's School of Engineering.

The focus of the research is biomedical engineering, in the context of prosthetic healthcare technology for people who have limb loss or limb deficiency. This paper provides insights for the research management field and biomedical engineering Early Career Researchers; by presenting a firsthand experience of the key themes that were evident throughout the process: time commitment, project management, strategic networks and stakeholder engagement.

From a procedural viewpoint, the experience was driven by information sourced from the Health Research Authority (HRA), along with internal university ethics advisors. From an academic perspective, the laboratory used the EPSRC Impact and Translational Toolkit for Healthcare Technologies, as a frame of reference (EPSRC, 2017).

Theme one: time commitment

The research team prepared an application by establishing a thorough understanding of the processes and the interactions between stakeholders. Once prepared, the chief investigator wrote the application (in collaboration with stakeholders), which required detailed work and involved many revisions before the final submission. Post submission, the HRA and a Research Ethics Committee (REC) requested further information and clarification on aspects of the application within a set time-frame. Consequently, the approval phases accumulated to 8 months of dedicated time from all members of the research team, especially the chief investigator (*Figure 1*). Without gaining an understanding of the process in the preparation phase, the application would have inevitably taken longer to complete, with potential post-submission amendments, leading to a prolonged approval period.

Recommendation one: preparing

The preparation stage is integral to the success of the application process; however, there is potential to minimise the time it takes to understand the requirements. The authors acknowledge that the HRA is currently in the second year of operating this process and is beginning to provide a wider spectrum of tools, such as the Approval Animation (brought about by the HRA to 'bring approval to life') (HRA, 2017b) and the Twitter community (HRA @HRA_Latest, 2017). Going forward, the authors will find it encouraging to see the HRA implement different educational approaches, such as training days for academics and research managers, as well as private user forums. These additional resources have the potential to facilitate an invaluably quicker learning experience, thus minimising the preparation phase.

Theme two: project management

The task of gaining ethical approval was varied, especially in regards to the multidisciplinary nature of the work and the range of stakeholders involved. In addition, this was the first time a research laboratory at the University's School of Engineering had applied for NHS ethical approval, which created an unfamiliar scenario. Therefore, the laboratory's research project manager (RPM) was assigned the task

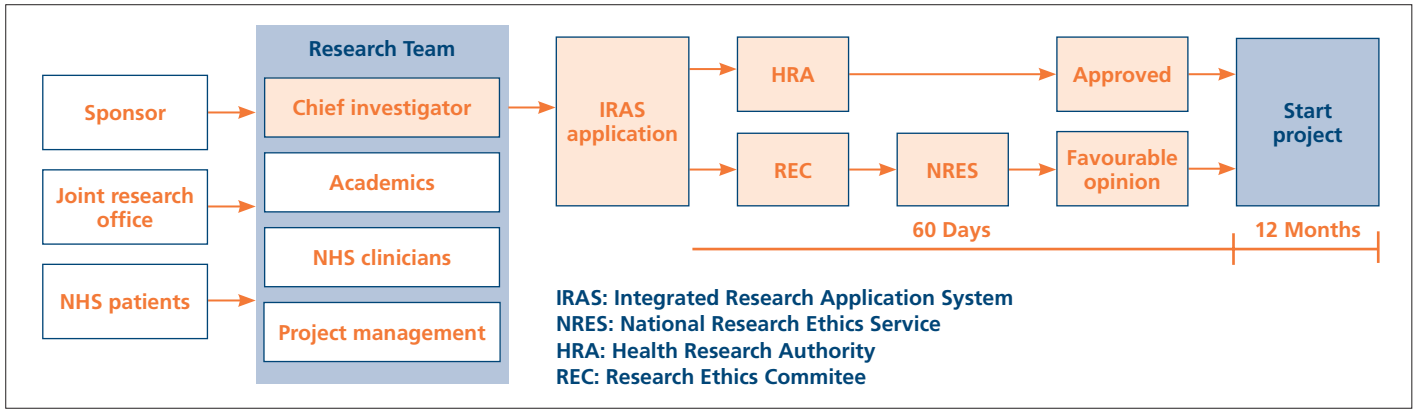

Figure 2. Project map

of managing the approval process, from the preparation phase through to final approval notification. The appointment of the RPM was possible with funding from EPSRC, justified in line with EPSRC Impact and Translation toolkit.

The key role that the RPM adopted was centred on coordinating internal and external project stakeholders. Coordination was achieved by implementing co-design principles to the management of the project, which engaged all members in the creation of the proposed research study. This was facilitated by the RPM holding regular face-to-face team sessions that discussed topics, such as research participation and protocol. By adopting an inclusive approach, the RPM was in a strong position to request valuable information (and corresponding time) from members to meet the application milestones, which was set independently by the RPM and chief investigator, and agreed by all members.

Recommendation two: communication methods

During the project, the RPM communicated a range of information with varying degrees of complexity to different stakeholders. Not all stakeholders learned from one form of communication e.g. visual, audio and kinesthetic. Therefore, it was beneficial to implement a number of different styles of communication to ensure maximum impact upon the audience. For example the RPM studied websites, such as HRA and Integrated Research Application System's (IRAS) online tutorials, to create a comprehensive understanding of the application process. However, the vast majority of content was text-based. In response, the RPM communicated the information using visual tools, for instance with process diagrams (*Figure 2*). This approach enabled the RPM to communicate in a rich array of styles, which facilitated the articulation and awareness of the process.

Theme three: strategic networks

Parallel to the core project stakeholders, the research team maintained a strategic network that was coordinated by the RPM. This network was advantageous in gaining an understanding of the process, while building an awareness of the challenges that may be faced and how they could be addressed. The RPM formed the network by liaising with faculty level personnel, the University's Joint Research Office and Medical School, which had relevant expertise. The network was beneficial across the whole lifecycle of the approval process and would remain so while the project was live. It was valuable to use the network's expertise when gaining feedback on the application before the final submission, as the network provided a viewpoint on the content from a range of relevant perspectives.

Recommendation three: seek expertise

Having a strategic network played a crucial role in the support and understanding of the approval process. However, forming such a

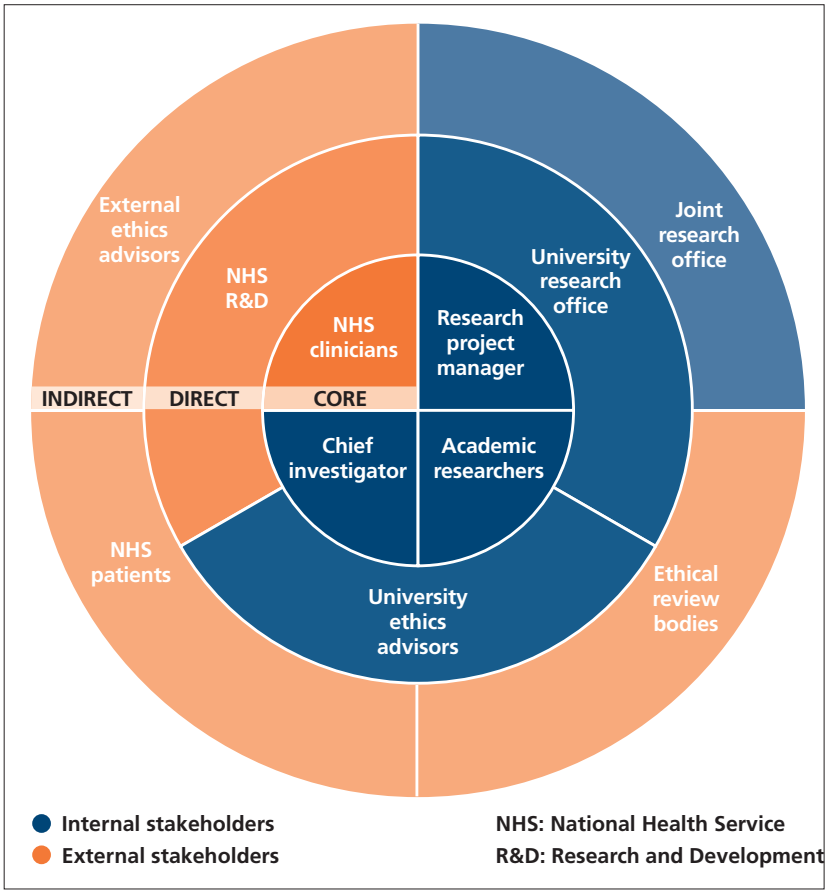

Figure 3. Stakeholder engagement

network was challenging, especially as the research team was new to the process. Therefore, it would be encouraging to see universities empowering internal ethics champions in order to understand the nuances of the HRA process. This could be achieved through a HRA initiative that provides training to a select group of champions. The approach has the potential to reduce the number of queries that are directed to the HRA, as they will be addressed at a local level within the internal university structure.

Theme four: stakeholder engagement

In order to engage stakeholders throughout this process, the research team interacted directly, on a face-to-face basis, wherever possible, as recommended by Greenhalgh et al (2017). Due to the multidisciplinary nature of the research team, coupled with the NHS clinicians, face-to-face interactions were critical in the establishment of a strong relationship from the onset. This approach provided an opportunity to openly discuss the research from a variety of perspectives, given each team members' roles and expertise.

A number of visual stakeholder maps were created by the RPM to enable the whole team to gain a thorough understanding of each stakeholder interaction and involvement in the project (*Figure 3*). This highlighted the relationships and connections that were going to be key in submitting a timely and strong application.

Recommendation four: working cultures

This paper presents an early-stage stakeholder engagement model, with foundations of trust formed through methods such as face-to-face working sessions. Over time, the engagement had the potential to grow into a network that was embedded in the NHS environment, enabling the research team to collaborate with larger participant numbers and clinicians within the field. It was beneficial to gain an awareness of different stakeholder working cultures for example, risk aversion, quick results, transparent information sharing, etc. The awareness formed over time and derived from the initial team interactions, paying particular attention to verbal and non-verbal communication. This enabled the RPM and chief investigator to appreciate different working styles and priorities, to create a working pace that was appropriate and effective for all parties.

Discussion

The presented work is in the context of gaining ethical approval that is mandatory for university laboratories to collaborate with the NHS. The research team experienced the new HRA approval mechanism for the first time, which was launched in May 2016. Prior to the HRA's launch, ethical approval was gained from the specific NHS research host organisation through the Research and Development system (previously termed: R&D Approval). This process ensured that the local NHS organisation had a duty of care to the patients or staff that

would be recruited to the study (Whitburn et al, 2016). Research and Development Approval was gained from the National Institute for Health Research Coordinated System for gaining NHS Permission. In addition to the various approval routes, the review procedure was noted as adopting highly stringent criterion (Jansari et al, 2015), leading to a system that did not allow appropriate levels of review, given the research complexity. Consequently, the approach was subjected to scrutiny, mainly due to regulatory complexities (Al-Shahi Salman et al, 2014) and lack of clarity on aspects such as patient information governance (Grace, 2014).

The reputation that the previous approval process established led to a number of changes, namely streamlining the practicalities for applicants and providing a more transparent approach to information sharing. For example, the HRA has updated their website (HRA, 2017a) and launched new eLearning modules, along with regular information that is disseminated via their Twitter account (HRA Latest, 2017) and LinkedIn page. Given the evolution of social media usage within the healthcare domain, a number of studies have evaluated how effective this relatively new communication platform is within the healthcare and academic fields. For example, there has been an observed increase in healthcare professionals using social media for both professional and personal circumstances (Panahi et al, 2014), and the platform has been documented as a powerful tool that provides an opportunity for collaboration between users (Moorhead et al, 2013). Conversely, studies have found that healthcare professionals adopt limited use of the medium for professional purposes, and when they do, they prefer to engage within closed communities (Rolls et al, 2016). With regards to academics, given the context of applying for NHS ethical approval, this audience may be deterred from the openness that is associated with interacting on social media, as it globally exposes individual project activity. Furthermore, the time required to become accustomed to social media platforms in order for the platform to be an effective communication option, may be a barrier within the science, engineering, technology and mathematics academic community (Donelan, 2016). The HRA's use of Twitter is in its infancy; however, it is encouraging to observe a mixed approach to information sharing, as this may increase the knowledge of the approval process among the multidisciplinary audience.

The authors acknowledge that experiencing the process for the first time was overwhelming, from building an awareness of how the application system works, to ensuring that the correct terminology and language was used. Therefore, allocating a proportion of the project to focus on gaining an understanding of the nuances associated with the application process was critical. However, the time commitment may discourage academic teams from seeking approval, or adapting the project proposal to suit a more plausible method (Al-Shahi Salman et al, 2014). This potentially dissuades academics who seek to conduct research with the NHS, which may affect healthcare technological development, effecting academic advancement, clinical care and patients' quality of life.

Given the topics discussed, the aim of forming a collaboration with the NHS was a prudent direction to take for the biomedical engineering team. This was especially the case as NHS patient participation was deemed essential to the project, in addition to the valuable relationships that could have potentially emerged from collaborating with clinicians. The latter is pertinent to highlight, as it emphasises the utilisation of a co-design approach that is centred on a collaborative process in which all stakeholders have an input (Donetto et al, 2015). The value of the collaboration was evident when building an understanding, from clinicians, of terminology, language and overall tone that needed to be applied to the written content of the application.

Biomedical engineering teams that are conducting research within a healthcare technology context have an opportunity to expand their internal network to incorporate

> "NHS patient participation was deemed essential to the project"

the knowledge, skills and expertise of external collaborators, such as NHS clinicians.

Furthermore, expanding an internal network within the team's institution, for example liaising with internal ethics advisors, is key to enabling a more streamlined and considered approach to the approval procedure. This scenario has the potential to benefit the broader field of engineering, by leading a step change in how multidisciplinary academic teams adopt an open approach to research, which in turn will enable collaborations to thrive in both academic and clinical environments.

Conclusion

To create a NHS ethical approval process that holistically addresses challenges from both the user (e.g. academic) and the approver (e.g. REC) perspective, organisations such as the HRA need to lead a co-design approach with a variety of stakeholders. In turn, this will establish a transparent process that enables a procedure to be conducted in a time-efficient manner, which reflects the research complexity and risk, while safeguarding research participants.

Given the complexities that have been documented within this article, the importance of collaborating with the NHS remains central to the laboratory's long-term vision and strategy going forward. BJHCM

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