

University



Research with NHS Trusts: Guidance Sheet for Students and their Supervisors

Much of the health research at Bournemouth University involves collaborating with the NHS and therefore requires Trust approval and in most cases, the approval of the Health Research Authority (HRA) and an NHS Research Ethics Committee (REC). Indeed, it is hoped that such research will make a difference to patients and the NHS. Although there is a Memorandum of Understanding in place between the local Trusts and the University and collaboration agreements drawn-up for individual research projects, this short complementary document suggests some recommendations when carrying out such University-NHS collaborations to assist both students and their supervisors in the smooth running of their research. These recommendations are summarised in Figure 1 whilst Table 1 provides some useful points of contact.

Approaching the Trust

It is first recommended to make contact with the Head of Research, Trust Research Governance¹, or research facilitators within the NHS Trust(s). This should be done as early as possible and before ethical approval is sought. Although the Trust(s) will require documents such as the full proposal/ protocol for the research, it may be helpful at this point to provide a short plain English summary of the intended research given the extremely busy nature of their roles. By providing this information they will be able to properly assess the feasibility of conducting the study at their site.

Working relationships with the NHS Trust(s) must be built so it is useful to plan a face-to-face meeting for the key people involved i.e. the student, supervisors, R&D staff (manager or facilitator) and BU Clinical Research Coordinator and/or Clinical Governance Advisor. As well as putting faces to names and building rapport, this is an opportunity to clarify expectations and responsibilities as well as legal obligations on both sides (along with anticipated timelines). This also means that assumptions and misunderstandings are minimised which can be common via e-mail correspondence. A meeting will also help identify the key players within the NHS Trust (other than direct supervisors) who will need to be on board for the project to be delivered successfully.

Logistics and processes

At such a meeting, each party will be able to obtain clarity of the often complex processes involved at each institution e.g. HRA, NHS ethics as well as institutional

¹ A list of contacts can be found on the R&D Forum <u>website</u>.

specific policies. The processes have been mapped out for funding applications (with web links), sharing some similarities with student research: https://research.bournemouth.ac.uk/wp-content/uploads/2013/12/Process-v-3.0-October-2018.pdf. For example, confirmation of Trust capacity and capability will be required to conduct the research within the Trust even if NHS ethics is not required e.g. in the case of research with NHS staff. Indeed, it is essential to establish as early as possible what approvals will be required for your research project, and guidance is found here: (https://www.hra.nhs.uk/approvals-amendments/whatapprovals-do-i-need/). There are likewise tools available on the Clinical Governance addition to the more streamlined Universitv ethics bloa. in process (http://blogs.bournemouth.ac.uk/research/researcher-toolbox/research-ethics/). Due to the amount of work and number of people involved facilitating the process, the NHS Trust(s) may nominate a main point of contact within the Trust to facilitate/ guide external researchers through the NHS processes. A Clinical Supervisor (Principal Investigator or local collaborator) may also be required for student research. Suzy Wignall is the contact for sponsorship, ethics and clinical governance advice and similarly Juan Campos-Perez from an NHS perspective, both are based at the Lansdowne campus (Table 1).

An honorary contract or research passport may be required in order to work as a 'guest' in the Trust(s) i.e. if researchers require patient contact or access to patient records. To apply for an honorary contract you will need to complete a research passport form which can be found via the National Institute for Health Research (NIHR) website, as well as a guidance <u>document</u> detailing what is required based on the 'employment' of the researcher. There may also be other mandatory research training requirements such as undergoing training or an update in Good Clinical Practice (<u>http://www.crn.nihr.ac.uk/learning-development/good-clinical-practice/</u>) as well as the University ethics training accessible from Brightspace.

Sponsorship should be discussed early in the process and on a case by case basis. Bournemouth University normally takes responsibility for the sponsorship of student and staff projects (<u>http://blogs.bournemouth.ac.uk/research/files/2012/09/Obtaining-Acceptance-of-Sponsorship-from-Bournemouth-University_SOPs.pdf</u>). However in cases where funding for the research is held by the Trust, or the student is a member of Trust staff, it may be more appropriate for the Trust to take on sponsorship. Please note that sponsorship refers to taking overall *responsibility* for the study not to be confused with *funding* the study.

Ongoing communication

There must be regular communication with the Trust(s) since one of their many responsibilities is to monitor their many projects. Indeed, the NHS will need to log such communications including essential documentation e.g. funding confirmation, sponsorship agreement, ethical and governance approvals, and annual reports.

Therefore, it is suggested that appropriate communication mechanisms are agreed upfront during the initial face-to-face meeting e.g. regular meetings in person to update on progress etc. Indeed, some projects may have Advisory Groups/Steering Committees which could incorporate this role. Relevant information to update the Trust(s) on may include timeframes for recruitment and the sharing of findings.

Feedback

Finally, the Trust(s) will require a final report or presentation summarising the overall findings and should be acknowledged where appropriate in any reports and resulting publications etc. Similarly, the research participants themselves should be provided with feedback on the study in an accessible format. It is advised that whenever possible, feedback to patients is provided via their GP/nurse/consultant as opposed to direct contact with participants. Anonymised research data may be kept on BORDaR, the Bournemouth Online Research Data Repository, which is publicly available. However, personal data collected for the purpose of the study (with consent) may be held for five years, from the end of study (PI signed final declaration). Retention periods may differ dependent on the nature of the study.

In summary, it is good practice to make contact with the Trusts as early as possible, establish good working relationships and regular communication channels in order for research to run as smoothly as possible. It is also a good idea to keep the Clinical Governance Advisor/Clinical Research Coordinator up to date with developments or any issues with your project. This is particularly essential for studies sponsored by the University, as in these cases the University has overall responsibility for the study.

Figure 1: Recommendations for researchers working with NHS Trusts

Approaching the Trust	 Have I contacted the Trust R&D Department and sent a study summary? Have I discussed my study with Trust R&D staff and BU's Clinical Governance Advisor/Clinical Research Coordinator? Have we agreed expectations, responsibilities, and obligations (with timelines) on both sides?
Logistics and processes	 Do I have an understanding of the HRA and NHS ethics processes and local Trust policies? Have the Trust(s) granted me access to NHS facilities? Have I read the sponsor's research SOPs and policies? Has a Pl/local collaborator been identified within the Trust? Do I need to attend training in Good Clinical Practice as well as complete the University's ethics module on Brightspace? Is a Sponsorship agreement in place? Is my study eligible for NIHR portfolio adoption?
Ongoing comms	 Have I agreed communication mechanisms? Have I provided the Trust with all study-related documents (ideally after approval by an NHS ethics panel if required)? Am I regularly updating the Trust(s) with information of relevance e.g. amendments or recruitment issues? Am I updating recruitment progress on Edge?
Feedback	 Have all the study-related documents and data been archived as per the sponsor's SOP? Have I sent a final report to the Trust(s) and acknowledged them where appropriate in any reports and publications? Have I summarised the findings for research participants?

Organisation	Contact details
	Louise Bryant Health and Social Sciences Postgraduate Research Administrator Tel: 01202 962119 e-mail: fhssresearch@bournemouth.ac.uk
Bournemouth University	Suzy Wignall (for sponsorship, ethics and clinical governance) Clinical Governance Advisor Tel: 01202 961073
	e-mail: <u>researchethics@bournemouth.ac.uk</u> Juan Campos-Perez (for NHS sign-posting and general advice) Clinical Research Co-ordinator Tel: 01202 961181 e-mail: jcamposperez@bournemouth.ac.uk
Poole Hospital NHS Foundation Trust	Margaret Younger (headed up by Sarah Chessell) Research & Innovation Manager Tel: 01202 442982 e-mail: margaret.younger@poole.nhs.uk
Royal Bournemouth and Christchurch NHS Foundation Trust	Laura Purandare (headed up by Caroline Jamieson-Leadbitter) Research Quality & Improvement Manager Tel: 01202 962376 e-mail: laura.purandare@rbch.nhs.uk
Dorset County Hospital NHS Foundation Trust	Dr Zoe Sheppard Head of Research Tel: 01305 255298 e-mail: zoe.sheppard@dchft.nhs.uk
Dorset HealthCare University NHS Foundation Trust	Dr Ciarán Newell Facilitator in Research and Development Tel: 01202 492147 e-mail: c.newell@nhs.net

Table 1: Useful contact details for researchers working with NHS Trusts

	Elaine Baddeley (headed up by Alice Mortlock)
Portsmouth Hospitals NHS Trust	Research Facilitator
	Tel: 02392 286236
	e-mail: research.office@porthosp.nhs.uk
	Tracey Tidbury (headed up by Alexandra Punter)
Isle of Wight NHS Trust	Research Facilitator
	Tel: 01983 552354
	e-mail: <u>tracey.tidbury@iow.nhs.uk</u>
	Headed up by Christine McGrath
University Hospital Southampton NHS Foundation Trust	
	Division A : surgery; cancer; critical care and theatres (managed
	by Hope Howard). Facilitator: Kristine Criste; email:
	Kristine.criste@uhs.nhs.uk T: 023 8120 8689
	Division B : Emergency medicine; medicine for older people;
	ophthalmology; pathology and specialist medicine: (managed by
	Shauna Marshall). Facilitator: Emma Perry; email:
	emma.perry@uhs.nhs.uk; T: 023 8120 5424
	Division C : Women and newborn; child health and support
	services: (managed by Natasha Chigbo). Facilitator: Chloe Sayce;
	email: <u>chloe.sayce@uhs.nhs.uk</u> T: 023 8120 4245
	Division D : Cardiovascular and thoracic; neurosciences;
	radiology, trauma and orthopaedics: (managed by Emily Watkins).
	Facilitator: Claire Ayling; email: <u>Claire.ayling@uhs.nhs.uk</u> T: 023
	8120 8678
	General R&D enquiries:
	Tel: 023 8120 5314
	e-mail: <u>ResearchManagement@uhs.nhs.uk</u>

	Louise Bell (headed up by Steph Scott)
Salisbury NHS Foundation Trust	Research Support Manager
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	Nicky Marks(headed up by Joanna Allison)
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