Suzy Wignall, Clinical Governance Advisor – RDS: swignall@bournemouth.ac.uk or researchethics@bournemouth.ac.uk

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New clinical researcher checklist

First steps:

Task	Support/resources	Resolution/notes	Date complete
Is my study research (in an NHS setting)?	Defining Research table Decision tool to calculate the decision.	*If not, then BU ethics checklist required only, in addition to the appropriate permissions and letters of access etc. to undertake this activity.* *Get in touch with Research Ethics or Bournemouth University Clinical Research Unit (BUCRU) for assistance with gaining these.*	
Sponsorship	Follow the sponsorship SOP, ensuring that you have a suitable Chief Investigator (CI)*. Follow the guidance set out also, in the UK Policy Framework for Health and Social Care Research.		
Familiarise yourself with the Clinical Governance workflows and SOPs	Find the workflows here and SOPs here.		
Data Management Plan (DMP)	Complete your Data Management Plan here.	For assistance email bordar@bournemouth.ac.uk	

*The CI should be available throughout your study, if not or in the event that the CI leaves BU, then a suitable replacement should be available at the earliest opportunity.

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Practicalities and documentation:

Task	Support/resources	Resolution/notes	Date complete
What external approvals are required? *Health Research Authority (HRA) approval is required for **all** research taking place that involves the NHS.*	Is NHS ethical approval required? Is MHRA clinical trial authorisation required?		
'Medical devices' – the MHRA now class certain types of software as medical devices.	Take a look at page 6 of the flowchart, and email Research Ethics or BUCRU as early as possible to discuss the implications.		
Storing and/or processing 'relevant material'?	Get in touch with Research Ethics as soon as feasible to discuss the implications/requirements.		
Ensure that your study is on Edge, the clinical research management system.	Gain access by contacting the Clinical Governance Advisor for access to, and training of, the Edge system.		
To apply for your approvals, register on the IRAS system.	Register via https://www.myresearchproject.org.uk/ and email Research Ethics or BUCRU, for support with the system. Check the blog for any training opportunities. Complete the Edge workflow.		
Determine which study documents you will need to submit for approval.	Consult the suggested study files index and HRA guidance on participant documents, and the study protocol. It's advisable to create a study flowchart to submit alongside your study documents, so that the external bodies can easily see what the project involves.		
Ascertain whether your study requires safety reporting or data collection tools	Designing these early can help to inform your IRAS application responses, and protocol writing.	.	
Ensure that appropriate archiving facilities are available.	Consult the archiving workflow and SOP, and requirements dependent on your study data storage method (i.e. electronic, paper, or both).		
Select/contact your research sites.	Get in touch with your sites' R&D departments to ascertain their interest	.	

	in the study. Support from BUCRU is available. They have links with NHS sites. The sites can then be added to 'Part C' of your IRAS form. *You may already have a site that has agreed to participate (in the case of a matched studentship for example).*		
If you are visiting the NHS site(s), make sure you have been given a letter or access or honorary contract.	Consult the clinical governance workflow (and SOP).		
Make sure you have current and up to date GCP certification.	Complete the training and other useful modules, via the NIHR Learn website. Details on how to book can be obtained by emailing the Clinical Governance Advisor.		
Make sure you submit a BU ethics checklist in **all** cases, and before you start your project.	Submit via https://ethics.bournemouth.ac.uk/ and select the appropriate external approvals required, when prompted. Very little information will be required as a consequence, due to the NHS review process you will go through.		
We strongly encourage you to seek external funding where possible. With this in place, the study may be eligible for the NIHR portfolio. Please see list of funders which are NIHR partners.	See further details here and here. The application to the portfolio is made via IRAS.	.	
Once your IRAS form is complete and documents finalised*, they should be reviewed by the Clinical Governance Advisor who will inform the Head of RDS that the project can be authorised, once requested.	Send the form via the IRAS system by using the 'transfer' tab. Send the study documents via email for proofreading and comment.		
The IRAS form is signed off by the CI and Head of RDS.	Within IRAS, signatures are obtained by 'requesting' within the system via the 'authorisations' tab. Complete the Edge workflow.		

*Remember to also provide the HRA Organisation Information Document and Schedule of Events, available from the HRA website.

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Study set-up:

Task	Support/resources	Resolution/notes	Date complete
Ensure record complete on ClinicalTrials.gov or the ISRCTN registry.	Request access to ClinicalTrials.gov via researchethics@bournemouth.ac.uk Once the project has been registered and made public, add the identifier in Edge.		
Informed consent training – if obtaining consent from research participants.	Contact Research Ethics for training opportunities.		
Once the study has been granted all the necessary approvals, contact your sites' R&D department.	*See SOP.* In order for sites to assess their 'capacity and capability' to undertake the study, you will need to send them the document pack referred to here. Seek support from Research Ethics or BUCRU if any issues or queries arise during this process Complete the Edge workflow.	.	
Prepare your study file – the file may be kept on the Edge system.	Consult the Trial Master File index and get in touch with the Clinical Governance Advisor for assistance with using Edge for this purpose.		

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Running the study:

Task	Support/resources	Resolution/notes	Date complete
Sponsor 'green light'.	Sites will request that the Sponsor sends them a 'green light' email before they start recruiting – this should be requested from the Clinical Governance Advisor. Add the Edge attribute when this is requested.		
Recording recruitment – dependent on your role and relationship with the NHS site, you may need to record the recruitment to the study.	Contact the Clinical Governance Advisor to discuss how to proceed and for support in discussing with your research site(s).		
Delegation of duties log	If you are acting as the 'site Principal Investigator (PI)' then you will need to ensure that the delegation log is complete and all appropriate staff signed off. See SOP. If you have a PI at each site, this is their responsibility to arrange.		
During the course of your study, you may need to submit amendments (to change the design, study documents etc.) If you experience any issues during the course of your related to the NHS such as recruitment, capacity etc. then BUCRU is on hand to negotiate a solution	Email Research Ethics for guidance, and consult the RDS workflow and HRA information. Amendments are classed as either substantial, or non-substantial. The classification of the amendment will inform the approvals required.. Complete the Edge workflow and amend any project details (e.g. study end date if amendment submitted for extension).		
Progress reporting – NHS Research Ethics Committee **(REC) approved studies**.	Yearly progress reports are required for as long as the study is running, and should be sent to the REC that approved the study or HRA if a non-REC study. Add the Edge attribute.		

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Study closure (i.e. end of recruitment/follow-up):

Task	Support/resources	Resolution/notes	Date complete
Closing down the study – notifying external bodies	The CI or the Researcher should notify the appropriate bodies (Sponsor, Funder, NHS REC, Trust R&D, HRA and MHRA [if required]) of the end of the study, within 90 days of the end date.		
Closing down the study – notifying the research site(s)	The CI or the Researcher should notify their research sites of the end of the study, so that they make preparations to archive their Investigator Site File.		
Closing down the study – notifying BU staff	Notify the Clinical Governance Advisor of the end of the study, as a close-out visit at site may need to be conducted. Complete the Edge workflow and update project details.		
Archiving	Dependent on the nature of the study, the files and records will need to be archived for a certain period of time (most likely 5 years). Complete the Edge workflow.		

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Study publication/dissemination of results:

Task	Support/resources	Resolution/notes	Date complete
Upload results to ClinicalTrials.gov/ISRCTN Registry	Seek advice from the Clinical Governance Advisor for any issues encountered with ClinicalTrials.gov.		
Provide your sites and participants with study results, especially if they have expressed an interest in receiving this	Usually this is provided in the form of a newsletter which should thank the participant for their time in contributing to the project. The NIHR provide guidance here.		
Make sure that your final anonymised dataset is on BORDaR (Bournemouth Online Research Data Repository) If using an alternative repository, ensure that your metadata is uploaded to BORDaR.	Email bordar@bournemouth.ac.uk for assistance		