DEVELOPING YOUR OWN RESEARCH STUDY

A guide for research studies sponsored by South Tees Hospitals NHSFT and North Tees & Hartlepool NHSFT as part of the Tees Valley Research Alliance (TVRA)

Please note that this guide is intended to support (not replace) existing national guidance. Please contact R&D if you have any specific queries.

Where should I start?

If you would like to set-up your own research study then, irrespective of what stage you have reached and which other contacts are involved, please contact our R&D team to arrange an initial discussion.

Complete our simple online form
https://www.cognitoforms.com/TeesValleyResearchAlliance/NewResearchProjectNotification

Or

email **tvra.projects@nhs.net**

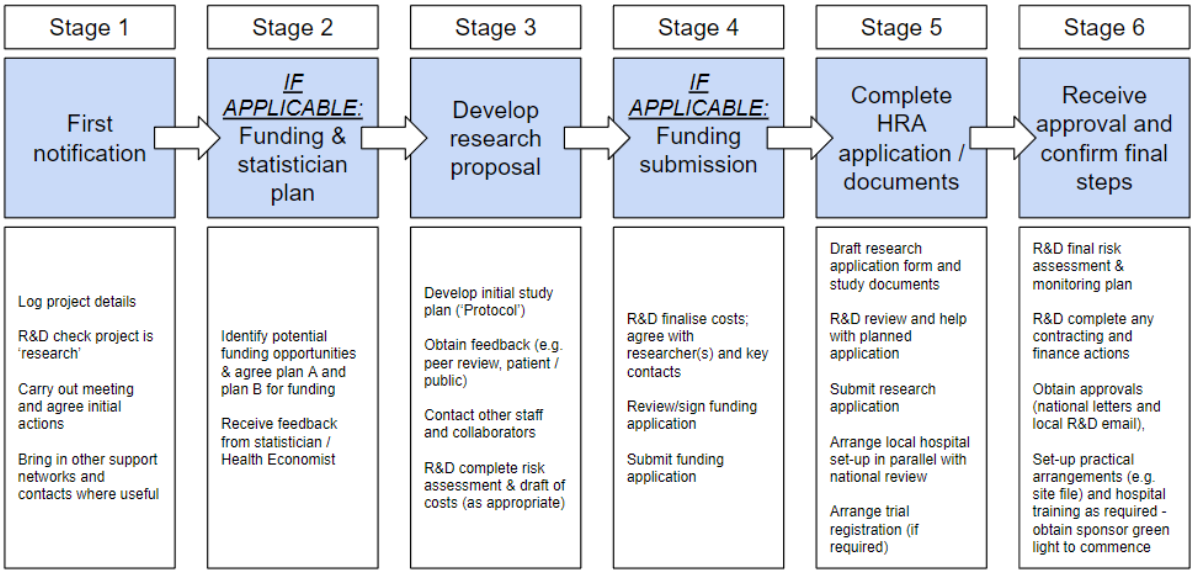
We work closely with our Academic Research Units within the TVRA, so if your research relates to cardiovascular care then we will confidentially share your email with the Academic Cardiovascular Unit (ACU). You can also directly contact the team at **stees.acu@nhs.net**. Further information on the support they can provide can be found here: **https://www.southtees.nhs.uk/about/strive/research-team/academic-cardiovascular-unit/**.

If your research relates to surgical care then we will confidentially share your email with the Academic Centre for Surgery (ACeS). You can directly contact the team at **aces@nhs.net**. Further information on the support they can provide can be found here: **https://www.southtees.nhs.uk/about/strive/research-team/aces/**

We will use our initial meeting with you to confirm the level of support you need, agree a joint action plan and book a follow-up meeting. The actions and timescale agreed will depend on the study specifics, however R&D will aim to meet up or engage with you once a month to maintain momentum and reach a resolution for your research project (funding +/- HRA application) as soon as possible

What will I need to do?

We have separated the research project development and set-up process into 6 stages as shown in the flowchart below. Please do not be alarmed by the number of tasks listed. Some of these actions are routinely completed by R&D or other support contacts and some tasks may not be applicable for your research.



R&D support

As a quick summary, we can support you to:

- Develop your idea into a research protocol
- Engage as necessary with other NHS Trust contacts, external collaborators and support networks
- Identify required resources and funding options; submit a funding bid if necessary
- Clarify and set-up research 'sponsor' arrangements
- Draft an application to the HRA and secure approvals
- Draft key research documents (e.g. participant information sheet, consent form)
- Engage with the NHS sites where the research is due to take place to support study set up at those sites

To provide effective support and maintain momentum our usual practice is to finish each meeting with you by booking a follow-up meeting. However outside of meetings you can also always contact the R&D support team at tvra.projects@nhs.net whenever you have a query or require support.

FAQs
DEVELOPING YOUR RESEARCH

R&D are happy to guide you through each stage of developing a research study through our meetings and correspondence with you. However we have also created a series of 'FAQs' below, providing key information and document templates for individual aspects of the process, in case this is useful.

1. How do I develop my research idea?

These are some of the key support services who we closely work with.

Research Design Service - North East and North Cumbria (RDS NENC)	With offices in Newcastle, South Tees and North Cumbria, RDS NENC is ideally placed to help your research team plan an effective study. They are able to advise on all aspects of preparing applications for funding in applied health and social care research as well as providing specialist expertise in Patient and Public Engagement (PPIE) and Equality, Diversity and Inclusion (EDI)	https://rds-nenc.nihr.ac.uk/how-we-can-help/
MedConnect North	Supports both companies and NHS-based researchers with potential medical device/medtech research and innovations with project development, set-up and management. Provides guidance and assistance throughout the Medical Technology Research and Innovation Pathway.	https://medconnectnorth.com/
Academic Centre for Surgery (ACeS)	Provides support and guidance on applying for funding, study design and development, regulatory obligations and patient involvement for surgical research	https://www.southtees.nhs.uk/about/strive/research-team/aces/
Academic Cardiovascular Unit (ACU)	Provides support and guidance on applying for funding, study design and development, regulatory obligations and patient involvement for cardiovascular research	https://www.southtees.nhs.uk/about/strive/research-team/academic-cardiovascular-unit/
Library service	Provides support with accessing and reviewing literature, including training on how to conduct a literature review. Also provides support and advice on publication and dissemination activities.	Access via intranet at either North Tees & Hartlepool NHS FT or South Tees Hospitals NHS FT
Health Research Authority	The Health Research Authority provide different templates for developing a research Protocol:	https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/

In addition there may be some informal support that could be useful, such as CI mentors which the R&D team could help you investigate or introduce you to.

2. How do I access statistician support?

The Research Design Service and MedConnect North services can arrange for initial review and feedback by a Statistician, Methodologist and/or Health Economist. The R&D team also has links to contacts at different Universities.

Please note that more extensive support - e.g. writing a statistical analysis plan, carrying out data analysis - will usually come at a cost (which may lead to a funding application being required for your study).

3. What is the significance of peer review? How do I arrange this?

Arranging independent, expert peer review can help improve the quality and robustness of your study. As well as being good practice, you may need to provide evidence of two independent peer reviews in order to secure NIHR Portfolio adoption for your study (see the 'What is the NIHR Portfolio?' FAQ for information on why this is important). TVRA R&D, working with other support contacts, can help identify peer reviewers if this is beneficial.

A peer review template is in development and will be made available as soon as complete

4. What is the significance of patient and public involvement ('PPI')? How do I arrange this?

PPI can help inform study design and management decisions, for instance checking that your planned project and its outcomes appropriately reflect patient concerns and that study documents are well designed from a user perspective.

As well as being good practice, some funding bodies require evidence of PPI as a prerequisite before considering a funding application.

There are different types of PPI activity you can carry out for instance focus groups, interviews and surveys. PPI activity does not require formal approval from national regulators or the TVRA but must be conducted in accordance with national legislation (e.g. data protection) and NHS Trust policies.

The NIHR RDS service provides specialist advice and support for conducting meaningful and appropriate PPI. They can provide access to "consumer panels" for your research project to discuss the study in more detail from a patient perspective and can also provide specialist advice to ensure your project maximises opportunities to ensure equity, diversity and inclusion (EDI).

There is some online guidance on PPI available from the HRA https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/. The TVRA can also provide templates from previous PPI activity on request (although please note these should only be used as starting points, the PPI should be tailored to your study)

5. What is the significance of a research 'sponsor'? How do I arrange this?

Each research study requires an organisation to agree to take on the role of 'sponsor'. The sponsor organisation "takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project." (https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#sponsor)

In practical terms the sponsor needs to ensure the following (either by completing the task itself or delegating the task):

- There is a completed risk assessment and monitoring plan
- The research application has been reviewed and approved by the sponsor
- Monitoring visits/assessments are carried out in accordance with the monitoring plan
- Research finances are appropriately costed and finance contracts (e.g. with funders, other collaborators) are effectively managed

The TVRA has a two-stage process ('in-principle' approval & final approval) for confirming agreement for one of its NHS Trusts to act as sponsor. This process is fully outlined in the Trust's 'sponsorship decision' SOP (available on the R&D intranet pages or on request from R&D). Every study is assessed on a case-by-case basis in accordance with the SOP.

6. Can I work with external contacts in developing my research study?

Yes, you can. Many of our projects have involved external collaborators from the NHS, academic sector, commercial sector, public sector and third sector and in fact the most successful research projects and funding applications are those that work with multiple partners and collaborators demonstrating a breadth of expertise and input.

If there is potential Intellectual Property and/or funding distribution involved in these collaborations then you should arrange a contract at the earliest stage possible. Our R&D team has different collaboration agreements and data sharing templates available and will advise on the most appropriate one for your study. In addition we can link you to the Trust's NHS innovation department or the Academic Health Science Network for further guidance where this is beneficial.

7. When do I need funding for my study? How do I apply for funding?

Obtaining funding is recommended for all research as there are always costs associated with running a research study. However, we understand that sometimes researchers may look to submit a research application without a formal funding bid if a study is deemed to be lower risk (e.g. questionnaire or data analysis only) and has already secured staff support and access to essential resources. The potential requirement for a funding application and different options (e.g. formal grant applications, approaches to companies) will be discussed during your initial meeting with R&D.

8. If I successfully secure funding then how do I access this?

The R&D team will create a unique finance account (aka 'cost centre') for your research study for storing income and making payments. The cost centre code will be shared with you during the final stages of setting up your study (stage 6 of the above flowchart).

When you apply for funding our R&D team will liaise with you to create a budget for how the funds will be allocated to support your research study (and capacity building for future research but ONLY IF this is permitted within the terms of the funding award).

When your study is open the R&D Grants Officer will endeavour to meet with or engage with you once per quarter to provide updates on income and expenditure, help with any queries and check if the budget is still accurate or needs to be re-profiled.

Payments for internal staff time will be transferred across on a regular basis to the relevant NHS Trust department. However, if there is a need to directly pay an individual (not just reimburse their department) then please inform R&D as we will need to liaise with their line manager / Clinical Director to inform them of the funding and duration so that they can make appropriate arrangements in job plans to accommodate this activity. We will ensure the funding is then transferred to your directorate to cover this activity.

Regarding payments for external staff and subcontracted services we would usually arrange a collaboration agreement which will include an invoicing schedule and instructions.

When arranging payments/orders for non-staff costs please follow the normal NHS Trust processes but ensure to reference the study-specific cost centre code. This should then ensure that our R&D team is notified and that the expenditure is directly charged to the study cost centre.

9. What is the NIHR Portfolio?

"All high-quality research studies, eligible for NIHR CRN support in England, are included on the NIHR CRN Portfolio."
(https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/crn-portfolio.htm)

In practical terms there are two benefits from NIHR Portfolio adoption:

- Your study can access support from funded R&D staff (e.g. research nurses, clinical trial assistants) at each research site location in the NHS
- The recruitment of participants to your study contributes to NHS Trust annual research recruitment goals

A study can secure NIHR Portfolio adoption if:

- It is funded by an NIHR grant
- It is funded by an NIHR partner organisation* (see https://www.nihr.ac.uk/partners-and-industry/charities/plan-and-deliver-research/nihr-non-commercial-partners.htm#:~:text=What%20is%20an%20NIHR%20non,social%20care%20or%20public%20health)
- It is funded by a company (on the basis that the study has received a funding award letter and at least 2 independent peer reviews).

R&D can guide and support you through the NIHR Portfolio requirements and different funding options.

10. How do I draft and submit a research application? What approvals do I need?

Your research application can be drafted and submitted using the 'Integrated Research Application System' ('IRAS') at https://www.myresearchproject.org.uk/Signin.aspx. The R&D team can provide a tutorial if you have not used the system before.

If you are applying for grant or commercial funding then it may be possible to delegate the research application process to another contact, which we can discuss during our meetings with you.

Alternatively if you are taking the lead on drafting the research application then our normal process is we ask you to complete the initial form as best you can. We then meet up to review/revise the answers

together and to help you with any questions of which you were unsure. R&D can also advise and support you with finalising the application, obtaining authorisations and submitting this for review.

In most cases you will need to complete an 'IRAS form' and submit this along with copies of the study documents.

11. What documents do I need for my research study?

The key document is the **Study Protocol** which outlines all essential aspects of the study e.g. study rationale and design (including number of participants/records needed), objectives and outcome measures, study delivery plan (procedures to be performed, visits/assessments taking place, etc), data analysis plan and dissemination plan. The HRA provides examples of most protocol templates here https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/

Our team can provide a simplified Protocol template designed for lower-risk projects

Other documents may be needed - for instance if you were approaching patients for their consent to take part then you would normally have a 'participant information sheet' and 'consent form'. Guidance and templates are available from the NHS HRA at http://www.hra-decisiontools.org.uk/consent/

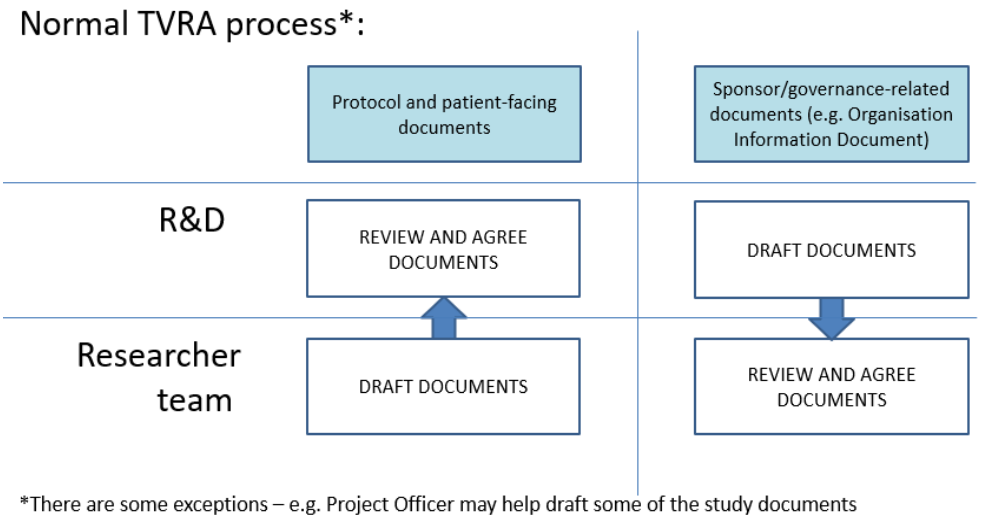
A full list of potential study documents can be found on the 'IRAS' research application website if you create a project, select 'IRAS form' on the left hand side and then click on the 'checklist' tab - you should see something like this:

Document Type	File	Subtitle	Enclosed	Document Date	Document Version	Reason not supplied	
Project Information: (All documents must be dated and/or have version numbers)							
Research protocol or project proposal			Mandatory				
Letter from statistician			No				
Summary CV for Chief Investigator (CI)			Mandatory				
Participant information sheet (PIS)			No				
Participant consent form			No				
Letters of invitation to participant			No				
GP/consultant information sheets or letters			No				
Sample diary			No				

Please note the checklist shows all potential documents and therefore many of these may not be applicable for your study.

R&D can help you in various ways:

- We can explain what documents are and are not needed for your study if you are unsure
- We can provide templates for some standard documents - e.g. patient invite letter and GP letter
- We will draft certain 'sponsor' documents for your study (e.g. Organisation Information Document (OID) and Schedule of Events(SoE)/SoECAT) - the standard process for creating and reviewing documents is explained in the below table:



12. How should I collect data for my study?

It is important that the data collected for your research study is accurate, consistent and usable/relevant. You therefore need to carefully consider what data items and systems you will be accessing, how this information will be recorded for your study and what checks will be carried out throughout the study to provide assurance in regard to data quality and to ensure that any queries are resolved as promptly as possible.

Standard practice is to create a 'Case Report Form' ('CRF'), in other words a bespoke data collection form designed for your study. You may have CRFs that need to be filled in at different time points (e.g. 'Baseline', '1 month after treatment starts', etc) and/or that cover different types of information.

Your CRF may be paper-based or use an electronic database. The TVRA has access to the 'RedCap' database system and an in-house team member who can provide support in creating an electronic CRF in this system. However the TVRA's RedCap system can only be used if your study meets certain eligibility criteria as outlined in our RedCap SOP on our intranet pages and there is funding available from your study for this support.

Whichever system you proceed with it is important to ensure that data is stored securely and that the access to this data and the personal data items collected are appropriately limited to meet data protection requirements. Also you should prepare the study appropriately in advance to help minimise potential data collections issue later - for instance creating parameters for how data items can be recorded (e.g. to avoid incorrect unit of measurement being used), and setting-up regular data quality reports to sites about missing or unclear data (where appropriate).

In addition to CRFs, you may be using existing 'validated' questionnaires or assessment/reporting tools in order to collect data. In this situation it is important to consider which validated tool is the best fit for your study and whether there is a requirement to include an acknowledgement and/or pay a licence fee cost.

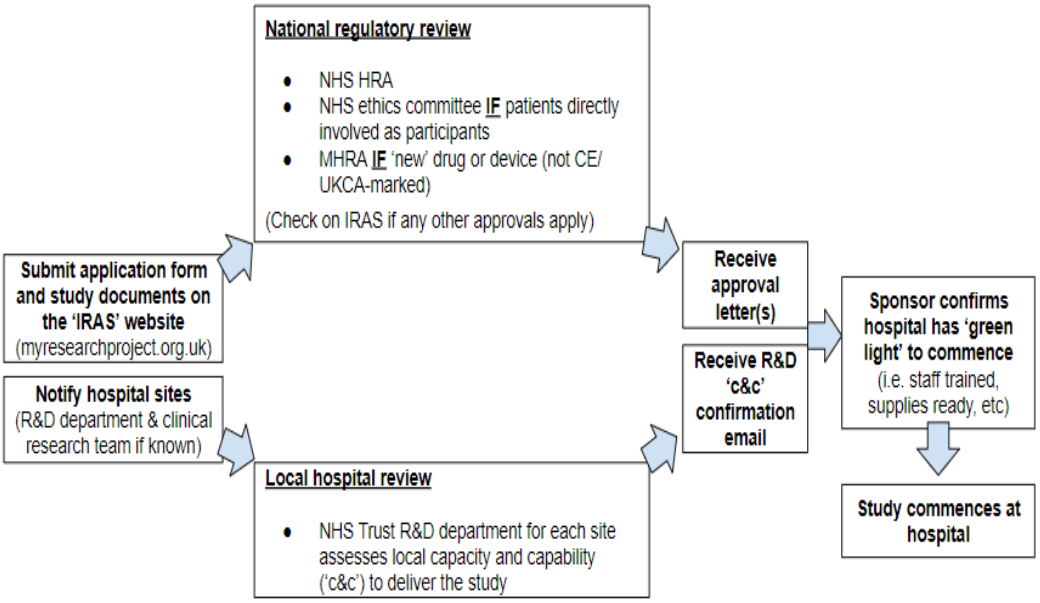
13. When do I need to formally register my research study?

The national approval body (Health Research Authority (HRA)) may require you to formally 'register' your research study details within a certain timescale as a condition of approval (e.g. 'within 6 weeks of the first recruit'). It is important to note that:

- Registration is usually only mandatory for studies deemed to be a 'clinical trial' (e.g. so if you were setting up a questionnaire-only study then registration would not be mandatory)
- If your study is adopted to the NIHR Portfolio then the national portfolio team can potentially arrange free ISRCTN registration on your behalf (you should receive instructions for this)
- If your study definitely does require manual registration then our R&D team can arrange this on your behalf using 'clinicaltrials.gov' which does not charge any fees

14. How soon can I start my research study? What do I need in place?

The below figure summarises the approvals you need:



National approvals

Most research studies require review by the NHS Health Research Authority (HRA) and an NHS Research Ethics Committee (which work closely together and review the same documentation). These bodies will issue a formal 'favourable opinion' or 'approval' letter - sometimes these letters list conditions which must be complied with/completed in order for the approval to be valid. Their approvals apply to all NHS sites nationwide, irrespective of where the reviewer/research ethics committee is located.

Local 'approval' ('confirmation of capacity and capability')

For each NHS Trust where you will carry out your research study you require the local R&D department's approval. However this approval is focussed on local resources and staff availability (i.e. it should not duplicate the national ethics/governance review) and is typically issued as a confirmation email as opposed to a letter.

To expedite the local approval process we recommend contacting the local R&D department with the research application form and study documents in parallel with your national research submission as opposed to waiting for national approval(s) first. Also you should provide clear details to the R&D contact - e.g. whether you have already engaged with local clinicians, the ideal timescale for opening the

study, etc. (For studies taking place within the TVRA we will routinely pass on the study details and documents to our local study set-up team)

Sponsor 'green light' approval
Once you have these approvals it is important to ensure that all practical and governance arrangements are in place for the study (e.g. there is a 'site file' with completed delegation log, there is a template for recording any 'adverse events' or 'protocol deviations', R&D have finalised the monitoring plan) and that there is evidence that the site staff are fully trained and ready to proceed. These arrangements are listed in the 'Site Initiation Visit checklist' - we will be publishing this to the intranet in due course.

If you were running a study involving external NHS research sites then you would typically perform a 'Site Initiation Visit' ('SIV') to provide training on the study requirements, obtain evidence of the site's readiness to begin and resolve any final queries. You would complete the SIV checklist to provide evidence that the SIV has been successfully conducted. This can be conducted remotely via MSTeams in some cases – the R&D team will advise if this is possible for your study.

Alternatively if you are running a single-site study only, or if your study is generally considered lower-risk, then it may be possible to instead complete the 'Site confirmation checklist (when no SIV)' template. Please speak to our R&D team.

Once we have received the relevant checklist and have assurance that essential requirements are in place at an NHS site then as sponsor we will issue a 'green light' email to give our final go-ahead to open the study at that location.

Please ensure that you do not proceed with your study at an NHS site until you have received the relevant approvals listed above and our final 'green light' email as sponsor.

15. What do I need to do once my study is underway?

Aside from the key elements of delivering the study (e.g. identifying potential recruits, taking consent, carrying out research procedures and data collection) there are essential governance and administrative tasks which need to be completed by either yourself or an appropriate delegate. Please see summary below:

TASK	FREQUENCY	DETAILS
Maintain up-to-date site file, delegation log and training log	Immediately	Clinical research team members (e.g. research nurse) can potentially help with this.
Report any adverse events and reactions and any protocol deviations	Immediately	The R&D intranet has a template reporting form and an SOP about reporting standards (which may already be outlined in your Protocol). It is important to review these incidents promptly to assess seriousness and expectedness and to respond accordingly.
Report research study recruits on local database system ('LPMS')	Ideally daily (but at least within 1 week)	Clinical research team members (e.g. research nurse, administrator) can potentially help with this. It is essential to report recruits or you may

		miss out on official acknowledgement & funding.
Review and confirm accuracy of research study recruits on national database system ('CPMS')	Monthly	An R&D team member or research team member (e.g. research nurse, administrator) can potentially help with this. It is essential to 'confirm' recruits or you may miss out on official acknowledgement & funding.
Carry out study oversight meetings (e.g. trial management group or 'TMG')	Recommend every 1-2 months (unless greater urgency is required)	An R&D team member or research team member (e.g. administrator) can potentially help with booking meetings and circulating invites.
Carry out data quality checks	Recommend every 1-2 months (unless greater urgency is required)	In-house R&D Governance and Monitoring Officer can potentially help (pending capacity).
Respond to R&D quarterly email/meeting to check progress and status of study, and check if you require any support	Quarterly update check	R&D team member will either send an email query to you or meet with you (depending on what approach is agreed as most beneficial) - this is just a regular status check and to offer R&D support for any queries or requests in case it is beneficial
FOR GRANT-FUNDED STUDIES: Review budget and expenditure with R&D	Quarterly update check (and annual finance returns)	R&D Grants Support Officer will contact you to arrange a meeting and provide budget updates - please contact us if you have been contacted about a financial return or report that is due
Submit regulatory updates reports (e.g. 'annual progress report', 'DSUR' for medical device studies, etc)	Normally once a year	
(WITH SPONSOR SUPPORT AND ONLY IF APPLICABLE) Update trial registration record	Normally once a year	
AD HOC TASKS (NOT ROUTINE, ONLY IF REQUIRED): Submit amendment Add new sites Contract amendment	As and when required (after checking feasibility and process with sponsor & within lead research team)	

16. How do I properly close down my study when complete ?

Once your research study has recruited the participants needed, and finished all 'follow-up' activities (i.e. all procedures/visits and data collection) then it is ready for the R&D close-down process.

R&D will routinely track the status and end date of your study, but please contact our R&D team with an update on when these activities are complete as this is helpful confirmation for our records and enables us to provide more efficient support.

Our R&D team will be liaising with you as necessary so that we can complete the following activities:

- Complete close-down visit
- Coordinate the completion of the 'close-down checklist' available from the R&D office (will be uploaded to the intranet in due course)
- Issue sites the go-ahead for archiving
- Check that R&D database systems (LPMS and CPMS) are accurate
- Update trial registration websites
- Support dissemination publication/event (if necessary)
- Share and promote dissemination publication/event
- Inform TVRA R&D archivist when archiving can commence
- Check all funder monies claimed
- Arrange final payments to sites and collaborators
- Complete final finance return/report
- Check that final ethics report is submitted

As part of the 'close-down checklist' we will ask you to check that each site has answered any outstanding research data queries. This confirmation will assist you in terms of completing data analysis and knowing when the study database can be 'data locked'.

Please do not hesitate to contact us if you need any support with any study completion and close-down activities.