Setting up new studies where NBT are sponsor

Task	Why Task Should Happen	When Task Should Happen	Who Should Complete Task	How Task is Completed
TASK 1: Apply for confirmation that NBT can sponsor the study	All research needs a sponsor who takes on the legal responsibility for the study.	Before any applications are made to regulatory bodies including REC, HRA, and MHRA. The earlier you engage with the R&I department, the better. Ideally when you are starting to plan your project. An application for sponsorship must be submitted even if R&I are funding the project or have been listed as sponsor in research grant applications.	Chief investigators, trial managers or others working on developing research protocols.	Read SOP RI/QMS/SOP/007 and complete the accompanying sponsorship request form. If you have a draft protocol/consent form/information sheet, please provide these at the point you submit the sponsorship request form. Please refer to the NBT HRA checklist (available on the NBT website) when preparing these documents (see Task 3, below). Be prepared that you may to need to amend your documentation as part of the sponsorship review process.
TASK 2: Sponsorship risk assessment	A risk assessment needs to take place prior to R&I agreeing that will NBT sponsor any research.	After an application for sponsorship is received by R&I.	R&I	Read SOP RI/QMS/SOP/007 for detail regarding the risk assessment process that will take place.
TASK 3:	These are core documents that	This can start before	Chief investigators,	Work through the NBT HRA checklist,

Develop your protocol and other supporting documentation	will need to be submitted in support of your application to regulatory bodies including REC, HRA and MHRA. These documents need to meet certain criteria prior to submission, as outlined in the NBT HRA checklist.	approaching NBT to discuss potential sponsorship (but be prepared that you are likely to need to amend your documentation as part of the sponsorship review process).	trial managers or others working on developing research protocols	ensuring that you address each item in the checklist. Tick off each item as you complete it, and return the completed checklist and accompanying documentation to R&I. Sponsorship cannot be confirmed (i.e. no IRAS signatures can be issued by R&I) until this checklist is completed and returned with the final study documentation.
TASK 4: Complete the Statement of Activities and Schedule of Events	All studies require these documents to be submitted to the HRA (one of each, per site 'type' including Participant Identification Centres - PICs) unless the study is a single-site study that involves NBT only (in which case, no statement of activities or schedule of events is required).	These need to be completed prior to submission as part of the HRA application, and must be checked by R&I prior to submission.	Chief investigators, trial managers or others working on developing research protocols	Templates and guidelines are available via the HRA website. It is important that you complete these documents carefully and that the schedule of events for each site 'type' accurately reflects the full activity that will take place at that site. Guidance on the attribution of costs required for completion of the schedule of events is available via the government services website.
TASK 5: Obtain draft contract from R&I	Some studies (not all) may require a contract between NBT as sponsor, and each participating site. R&I will confirm when this is required. If a contract is required, this must be submitted to HRA as part of the full application pack.	This needs to be checked prior to submission as part of the HRA application.	Chief investigators, trial managers or others working on developing research protocols	Check the requirement for a contract with R&I by emailing researchsponsor@nbt.nhs.uk. R&I will provide the contract, if one is required.
TASK 6:	Studies that meet certain	This application can be	Chief investigators,	Complete and submit a Portfolio Application

Apply to have the study included on the NIHR CRN portfolio	eligibility criteria are eligible to be included on the NIHR portfolio and receive NIHR CRN support.	submitted at any point during the set-up of the project, although it is advised to do this early in the process. R&I can advise whether your study is likely to be eligible for adoption onto the NIHR Portfolio.	trial managers or others working on developing research protocols	Form (PAF) in IRAS.
TASK 7: Invite sites to take part	This enables sites to start assessing whether they are likely to have the capacity and capability to support the study.	Sites should be invited at any time before or after the site has been listed in Part C of the IRAS form and that IRAS form submitted to the HRA. The best time to do this is once you have your final protocol ready to submit to HRA after R&I have agreed that they will sponsor. This also applies to NBT, where NBT are a site. Sites should confirm within a relatively short timeframe whether they are likely to be able to be able to deliver the project. If you do not hear from sites with the outcome of this assessment within a few weeks, you should chase them. Please ensure that the	Chief investigators, trial managers or others working on developing research protocols	Provide sites with the protocol in a version to be submitted for regulatory review (i.e. the final version that you will be submitting to HRA). This must be sent by email to the R&D department at each participating site including NBT, using the contact details available via the R&D Forum Website. If you are applying to have the study included in the NIHR CRN portfolio, you must also copy each corresponding LCRN into this correspondence. Contact details for corresponding LCRNs are provided against each site via the R&D forum website.

		outcome of this assessment by each site is communicated with R&I via researchsponsor@nbt.nhs.uk		
TASK 8: Request sponsor sign-off of regulatory applications	The sponsor must sign all regulatory applications to indicate their intention to sponsor the research.	R&I should not be asked to sign off any regulatory applications until the full risk assessment is complete and all study documentation (e.g. protocol, information sheet, consent form, HRA checklist, Statement of Activities, Schedule of Events) is completed to R&I's satisfaction. R&I will confirm when you have reached this stage.	Chief investigators, trial managers or others working on developing research protocols	Authorisation requests should be submitted via IRAS. The authorisation requests should be sent to researchsponsor@nbt.nhs.uk
TASK 9: Sponsor sign-off of regulatory applications	The sponsor must sign all regulatory applications to indicate their intention to sponsor the research.	R&I will not sign off any regulatory applications until the full risk assessment is complete and all study documentation (e.g. protocol, information sheet, consent form, HRA checklist, Statement of Activities, Schedule of Events) is completed to R&I's satisfaction.	R&I	A delegated individual from R&I will sign the application via IRAS.

TASK 10: Submit your application to the relevant regulatory bodies for approval	All research must have the relevant regulatory approvals before it commences.	This cannot happen until sponsor signature has been obtained via IRAS.	Chief investigators, trial managers or others working on developing research protocols	Guidance on how to apply for HRA (incorporating ethics, where REC approval is needed) is available via: http://www.hra.nhs.uk/research-community/applying-for-approvals/hra-approval/ Applications to the MHRA need to be submitted separately. Further details are available via: https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk NBT will upload to the application to the CESP system on behalf of the researcher once the application is ready
TASK 11: Obtain regulatory approvals	All research must have the relevant regulatory approvals before it commences.	This will not be issued by the regulatory bodies until all of their conditions/requirements have been met, thus the researcher must liaise with these regulatory bodies (i.e. REC, HRA, MHRA). Please ensure that any changes you make to study documentation during this stage are notified to R&I via researchsponsor@nbt.nhs.uk so that R&I have the correct copies on file.	Chief investigators, trial managers or others working on developing research protocols	The study cannot start without HRA approval, and HRA approval will not be issued until any other relevant regulatory approvals are in place, including REC and MHRA.

TASK 12:** Commence arrangements for sites to deliver the research	All sites involved in the research, including NBT, must confirm in writing that they have made appropriate arrangements and therefore have the capability and capacity to deliver the research at their site, before any activity can commence at that site. There is a different process to follow if you are including sites in Scotland, Wales, or Northern Ireland. **	Sites can be asked to undertake their assessment of capacity and capability at any time once the IRAS form has been submitted to the HRA and the HRA initial assessment letter has been released.	Chief investigators, trial managers or others working on developing research protocols	You should send the following local document package simultaneously to the R&D department at each site (including NBT, if NBT are a site) and the LCRN (where applicable) once you have received the HRA Initial Assessment letter (or HRA Approval Letter where no Initial Assessment letter is issued). This should be sent using contact details available via the R&D Forum Website. • Copy of IRAS Form as submitted for HRA Approval • Protocol • Any amendments • Participant information and consent documents • Statement of Activity relevant to that participating NHS organisation * • Relevant template contract (if needed) • Schedule of Events * • Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study • Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions – you must send sites one of these documents as a minimum. If the final HRA approval letter is not available at the point you send the documentation through to sites, you must send it as soon as it becomes available.

				Sites have a target of 70 days to recruit their first participant from the date they receive a full, valid submission that consists of all of the documentation listed above.
TASK 13: Negotiate/agree with sites the content of the statement of activities and/ clinical trial agreement*	All sites will need to agree with the NBT the content of the statement of activities and schedule of events (and contract, where relevant).	Sites will have been provided with the draft statement of activities/schedule of events/contract as part of Task 12, and will negotiate/agree this with NBT as part of their site assessment. If sites request changes to any of these documents, please ensure this is discussed with R&I.	Chief investigators, trial managers or others working on developing research protocols This must be done in collaboration with R&I.	R&I should be consulted regarding any changes to the statement of activities, schedule of events, or contract.
TASK 14: Obtain confirmation from sites that they have the capacity and capability to deliver the research ***	All sites involved in the research, including NBT, must confirm in writing that they have made appropriate arrangements and therefore have the capability and capacity to deliver the research at their site, before any activity can commence at that site. ** There may be instances where this step is not required in which case you are advised to liaise with R&I for further guidance.	Sites will issue this when they are satisfied that all the necessary arrangements are in place to enable the site to deliver the study. Sites will not be able to issue this until full HRA approval is obtained.	Chief investigators, trial managers or others working on developing research protocols	Sites will provide written confirmation. Please ensure this is forwarded to researchsponsor@nbt.nhs.uk. The study must not start at the site until that site has issued conformation of capacity and capability to undertake the study. If the study is interventional, Tasks 15 & 16 must also be complete before the study can start at the site.

TASK 15 (Interventional Studies Only): Collate information for green light approval	If the study is interventional, R&I will issue a green light approval for each recruiting site (except NBT). Activity at that site cannot commence until this green light approval has been issued. At NBT, the study can start once confirmation is issued by R&I. R&I will confirm if your study requires this task to be completed.	R&I will issue this when a core set of documentation is available for the site. This documentation can be provided to R&I at any point during the set-up of a site and it is advised this is provided early to prevent delays with green lighting once	Chief investigators, trial managers or others working on developing research protocols	You should provide the following documentation to R&I for each site: • Signed and dated CV/GCP for PI at site • The appropriate R&D contact details • R&I confirmation of capability and capacity from the site • Final agreed statement of activities and schedule of events agreed by the site. • Final contract (where relevant) that has been signed by the site.
TASK 16 (Interventional Studies Only): Issue green light approval	If the study is interventional, R&I will issue a green light approval for each recruiting site (except NBT). Activity at that site cannot commence until this green light approval has been issued. R&I will confirm if your study requires this task to be completed.	R&I will issue this when a core set of documentation is available for the site.	R&I	R&I will provide written green light approval for the site. The study must not start at a site until green light approval has been issued for that site.
*Not needed if the study is a single site study taking place at NBT only ** Researchers wishing to conduct research in the NHS in Scotland or Wales				

(or Health and Social Care (HSC) in Northern Ireland) need to obtain NHS or HSC management permission for each NHS/HSC research site. The documentation that you need to submit is different for these sites (e.g. it includes Site Specific Information Forms – SSIs – instead of the Statement of Activities and Schedule of Events. Further information about applying to open sites outside England is available via the HRA website. *** In some instances where there are minimal arrangements to be put in place, there will be no requirement for sites to confirm capacity or capability. The HRA will inform NHS participating organisations for studies where this applies. The HRA will provide them with the Initial Assessment letter or HRA Approval letter, statement of activities and schedule of events. Provided HRA Approval is granted, if the sites do not raise an objection within 35 days (or as stated in the letter) the study may commence.				