MAKING AMENDMENTS TO NBT SPONSORED STUDIES THAT ALREADY HAVE HRA APPROVAL				
Task	Why Task Should Happen	When Task Should Happen	Who Should Complete Task	How Task is Completed
TASK 1: Obtain confirmation that NBT are satisfied with the amendment	R&I must undertake a risk assessment to assess the implications of the amendment as they take legal responsibility for the project. This applies for ALL amendments, whether minor or substantial.	As soon as you start to think about making an amendment to the project.	Chief investigators, trial managers or others preparing amendments to projects	Send details of your planned amendment to researchsponsor@nbt.nhs.uk
TASK 2: Risk assess the amendment	R&I must undertake a risk assessment to assess the implications of the amendment as they take legal responsibility for the project.	Once R&I have been notified of a planned amendment.	R&I	R&I will review the amendment and any/all implications of that amendment. R&I will communicate the outcome of this assessment with the research team.
TASK 3: Classify the amendment as either minor or substantial	It is the sponsor's responsibility to determine if an amendment is minor or substantial.	Once R&I have been notified of a planned amendment, at the same time the risk assessment takes place.	R&I	R&I will classify the amendment as either minor or substantial using standard definitions, and will communicate the outcome with the research team.

TASK 4: Prepare amendment for submission	All amendments (whether minor or substantial) must be submitted to HRA for approval. Substantial amendments will also require review by REC.	Once R&I have agreed the amendment can be made and have classified it as minor or substantial.	Chief investigators, trial managers or others preparing amendments to projects	Substantial amendments require a substantial amendment application form, created in IRAS. Minor amendments require a minor amendment form to be completed.
TASK 5 (*MHRA studies only):* Prepare amendment submission	Some amendments require notification to MHRA only, others to REC/HRA only, and others to both MHRA and REC/HRA.	Once R&I have been notified of a planned amendment, at the same time the risk assessment takes place.	Chief investigators, trial managers or others preparing amendments to projects This must be done in collaboration with R&I.	R&I will liaise with researchers to determine if the MHRA needs to be notified of the amendment. If this is deemed to be the case, applications to the MHRA need to be submitted separately. Further details are available via: www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues
TASK 6: Request R&I signatures on amendment submissions	The sponsor must sign regulatory applications to indicate their intention to sponsor the research.	Once amendments are ready to submit to the relevant regulatory bodies.	Chief investigators, trial managers or others preparing amendments to projects	Authorisation requests for substantial amendments should be submitted via IRAS. The authorisation requests should be sent to researchsponsor@nbt.nhs.uk R&I do not need to sign notices of minor amendment forms as long as the tasks above are complete and R&I have confirmed that the amendment can be submitted and that it is classified as minor.

TASK 7: R&I sign off of amendments	The sponsor must sign 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 relating to that amendment is completed to R&I's satisfaction.	R&I	A delegated individual from R&I will sign the application via IRAS.
TASK 8: Submission of amendments	All amendments (whether minor or substantial) must be submitted to HRA for approval. Substantial amendments will also require review by REC (and in some cases, notification to the MHRA is needed).	Once the amendment is prepared and ready for submission to the relevant regulatory bodies, and signed off by R&I.	Chief investigators, trial managers or others preparing amendments to projects	**SUBSTANTIAL AMENDMENTS**: If the REC that reviewed the project initially is in England, substantial amendments need to be sent to that REC (who will then communicate the amendment with HRA). If the REC that reviewed the project initially is in Scotland, Wales, or Northern Ireland, substantial amendments need to be sent to that REC and copied to hra.amendments@nhs.net. Substantial amendments to projects that did not initially require REC review (e.g. staff projects) need to be submitted to hra.amendments@nhs.net.only. MINOR AMENDMENTS: Minor amendments should be submitted to hra.amendments@nhs.net.

				MHRA: For studies where MHRA need notification of the amendment, NBT will upload to the application to the CESP system on behalf of the researcher once the application is ready.
TASK 9: Notify sites of HRA categorisation *	The HRA will categorize all amendments as either Category A (requiring consideration by all participating organisations), B (requiring consideration by some participating organisations), or C (not requiring consideration by participating organisations). Once the amendment has been categorised by the HRA, the HRA notifies the applicant who is then responsible for notifying sites of the amendment. This includes notifying NBT. If the study involves sites in Scotland, Wales or Northern Ireland then a different process applies for those sites *	Once the amendment has been categorised by HRA	Chief investigators, trial managers or others preparing amendments to projects	CATEGORY A: Send the categorisation email from HRA (together with the amended documentation) to the R&D department and local research teams at your participating NHS organisations in England. The organisation will then make the necessary arrangements to implement the amendment. CATEGORY B: Send the categorisation email from HRA (together with the amended documentation) to the R&D department and local research teams at the relevant participating NHS organisations (I.e. those affected by the amendment). These organisations will then make the necessary arrangements to implement the amendment. CATEGORY C: Participating organisations do not need to put any arrangements in place for the amendment. However the local research team still need to be aware of the amendment so the applicant should send the categorisation email from HRA (together with the amended documentation) to the R&D department and local research teams at the participating NHS organisations.

				Contact details for each R&D department are available via the R&D Forum Website. You may be provided with a template email to use for notifying sites when you receive the categorisation email from the HRA. In all cases, retain a copy of the email that you send to sites as evidence that sites have been notified of the amendment.
TASK 10: Implementing the amendment at sites	The amendment categorisation (as either category A, B or C) determines whether the participating organisation has an opportunity (within 35 days of receipt by the organisation) to raise an objection to implementation of an amendment due to local considerations (category A or B), or whether the sponsor may implement the amendment within their own timescales once any relevant regulatory approvals are in place (category C).	Once the amendment has been categorised by HRA	Chief investigators, trial managers or others preparing amendments to projects	CATEGORY A: If you have not received objection from a site within 35 days of submitting the application pack to them (as per Task 9, above), you may then implement that amendment at that site either immediately (if you have received HRA approval for the amendment) or as soon as HRA approval has been received (if not yet received once the 35 days has passed). Therefore it is possible that you may be implementing an amendment at a site even though no written confirmation/acknowledgement has been received from that site (as long as they have had a minimum of 35 days to review that amendment). However, HRA approval must be in place before the amendment is implemented and you must ensure a copy of the HRA approval is provided to each site by sending it to the relevant R&D departments using contact details available via the R&D Forum Website.

				CATEGORY B: For sites affected by the amendment, the same process applies as for Category A amendments. You do not need to wait for any correspondence from sites at which the Category B amendment is not relevant but you still need to send them the documentation as per Task 9 above. CATEGORY C: You can implement the amendment at all sites as soon as HRA approval is received. You do not need to wait 35 days.

***** Details of where to send documentation for sites outside of England is available via the HRA website.