HRA Approval **Managing Amendments**

Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Workflow for Participating Sites using EDGE as LPMS

Sponsor/CI submits amendment to one of the following

HRA.Approval@nhs.net	**– for sites listed on original application to bring under HRA Approval & for studies currently undergoing REC review that have not been submitted for R&D review**
REC email	**– for substantial amendments requiring REC review - including adding new sites for CTIMPs, (as you currently send to REC). Picked up internally.**
HRA.amendments@nhs.net	**- for all other amendments, including adding new sites for non-CTIMPs and substantial amendments not requiring REC review**

Step	Name	STEP START	Actions	STEP ENDS	Recording at site	Sites	Timepoints HRA	Timepoints REC
1	**Amendment Classification and submission**	Review of amendment by Sponsor	Sponsor determines whether amendment is **substantial or non-substantial** (see below) If substantial use SA form from IRAS If non-substantial use NSA form (word doc from HRA website) CI/Sponsor determines whether amendment **requires REC review or not**	Sponsor submits amendment by email - see submission options above Note - all amendments to be submitted to either HRA or REC (including non-substantial amendments)	N/A	N/A	N/A	N/A
2	**HRA Categorisation**	Receipt of amendment by HRA	HRA assessment team **categorise amendment** Category will be either A, B or C (see below)	HRA emails applicant with categorisation	N/A	N/A	5 days	
4	**Notification to Sites**	Sponsor emails amendment to all participating sites (**all categories)** Sponsor ensures amendment is sent/copied to site R&D generic email address (and to LCRN if portfolio study) Must includes **HRA categorisation email** (and HRA assessment letter if available)	Site checks amendment for capacity and capability (**categories A & B only**) R&D ensure PI/research team/support depts are aware of new amendment and have new documents For category C amendments no further action is required from R&D.	R&D save all amendment documents on EDGE (or local drive)			25 days to REC opinion 14 days for phase 1 studies	
	HRA / REC Actions	HRA assessment undertaken in parallel with REC review	HRA assess for compliance with HRA approval NHS REC review (if applicable)	**Outcome of HRA assessment** (including REC and MHRA response where applicable) sent to applicant by email	N/A	**35 days** (site window to confirm continued capacity and capability or object) Category A & B only	HRA currently have **no timescales** to complete assessment of amendment	
5	**Site Response & Implementation**	Applicant sends outcome of HRA amendment assessment along with any revised associated documents to sites Including REC opinion letter (if applicable)	Sites prepare for implementation of amendment Research team (e.g. clinical trials assistant/data manager) localises all relevant new documents Sponsor to confirm planned implementation date (if not straight away)	If site able to accommodate amendment - R&D team notifies Sponsor by email of continued capacity and capability if site unable to accommodate amendment - R&D team notifies Sponsor by email If 35 day window is reached and no response has been sent to Sponsor then implement amendment	Research team/PI updates ISF with new versions of relevant documents From implementation date site starts using new versions of study documents			

Definition of a Substantial Amendment

A **substantial amendment** is defined as an amendment to the terms of the application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree:

The safety or physical or mental integrity of the subjects of the study;
The scientific value of the study;
The conduct or management of the study; or
The quality or safety of any investigational medicinal product used in the trial.

Non-Substantial Amendment Form
http://www.hra.nhs.uk/resources/during-and-after-your-study/nhshsc-rd-notification-non-substantialminor-amendment-form/

HRA categories

A ***Category A – Amendment to a research study that ALL participating NHS organisations are expected to consider***
This category includes any amendment to a research study that has implications for, or affects, ALL participating NHS organisations hosting the research study.
The applicant should send the categorisation email from HRA together with the amended documentation, to the research management support offices and local research teams at your participating NHS organisations in England.
The organisation will then make the necessary arrangements to implement the amendment.

B ***Category B – Amendment to a research study that only those participating NHS organisations affected by the amendment are expected to consider***
This category includes any amendment to a research study that has implications for, or affects, SPECIFIC participating NHS organisations hosting the research study.
The applicant should send the categorisation email from HRA together with the amended documentation, to the research management support offices and local research teams at the relevant participating NHS organisations in England.
These organisations will then make the necessary arrangements to implement the amendment.

C ***Category C – Amendment to a research study that participating NHS organisations are not expected to consider***
This category includes any amendment to a research study that has no implications that require management or oversight by the participating NHS organisations hosting the research study.
The 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 to the research management support offices and local research teams at the participating NHS organisations in England.