Process for gaining approval to run an NIHR portfolio adopted study at

Whittington Health NHS Trust

Engage with the research delivery team to discuss the potential new study through Research Portfolio Manager: Kathryn.simpson3@nhs.net

020 7288 3064

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Site selected for new study requiring Capacity & Capability (C&C) review

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- Noclor will lead on set-up for mental health and primary care studies

- CRN NT will set-up all other portfolio adopted studies; this will be processed by the division the study falls in to

Sponsors study team to submit full document pack to CRN North Thames, Noclor, the PI and Research Portfolio Manager: sss.crnnorththames@nihr.ac.uk contact.noclor@nhs.net Kathryn.simpson3@nhs.net

cc the relevant CRN divisional inbox

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CRN NT/Noclor will complete the relevant checks and request site information from the local research team to inform the assessment of C&C

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Once complete, CRN NT/Noclor will request approval from the relevant ICSU Clinical Director and once approved by CD (& if needed, contract signed) C&C is issued

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Once the Sponsor has received the confirmation of C&C email from CRN/Noclor and all required documents they will issue a greenlight email – the study can then officially begin

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Contact Noclor to be added to the study on EDGE (+ any additional team members that will be uploading recruitment data)

Whilst this is happening;

- Speak with clinical departments (this will be ongoing from prior to the official C&C assessment beginning)
- Set-up a site file (if one isn't provided by the Sponsor)
- Set date for Site Initiation Visit (SIV)
- Prepare documentation/tools for running the study (Useful templates saved in I:\Research Studies\Research Staff\Study Documents Template for anything not provided eg. stickers for notes, visit records)

Note: Recruitment data for all portfolio adopted studies must be uploaded on to www.edge.nhs.uk by a nominated person at the site.

Contact the research team if you require assistance with EDGE.