**SLaM/IoPPN R&D Risk Assessment Guidance v16**

The remit of the SLaM/IoPPNrisk assessment committee is to formally assess the following types of studies that involve the Institute of Psychiatry, Psychology & Neuroscience and /or South London and Maudsley NHS Foundation Trust, where those studies are required to be reviewed by an NHS ethics committee or Health Research Authority (HRA).

* Clinical trials of investigational medicinal products (CTIMPs)
* All other research studies that involve administering a drug or substance
* Any other research studies that are deemed by the R&D office to require a formal risk assessment

For studies where IoPPN and/or SLaM will take the role of sponsor for your study, the risk assessment is part of the sponsorship review. It fulfils the expectations of the Health Research Authority for organizational sponsor oversight which includes the need for proportional risk assessment of research studies. As the risk assessment forms part of the sponsorship review, please read this guidance in conjunction with the SLaM/IoPPN sponsorship guidance. Please note that if you are an IoPPN researcher and your lead R&D office is King’s College Hospital or Guy’s and St Thomas’ NHS Foundation Trusts, with no involvement of SLaM, your protocol will not need to be reviewed by SLaM/IoPPNas KCH and GSTT have their own mechanisms for risk assessment (please see sponsorship guidance for details).

If your study is externally sponsored, please contact the R&D office to discuss before submitting your protocol.

Protocols are reviewed at a monthly RAC meeting. Please contact the R&D office for dates of forthcoming meetings.

The following will need to be in place before the RAC can review your protocol:

* Your CAG/Department is required to review and sign off your protocol prior to submission to the RAC. Each CAG/Department has its own arrangements for signing off protocols (see appendix for further details). Please forward confirmation of CAG approval with your protocol.
* Please ensure that your study is classified as either a clinical trial of an investigational medicinal product (CTIMP), clinical trial of a medical device, combined CTIMP/medical device study, other clinical trial, basic science study, or other study type. Please see R&D protocol guidance section on classifying studies.
* Please use an appropriate protocol template for your study type, this ensures that information needed for review is included. Please see the attached R&D protocol guidance and templates – there are protocol templates for CTIMPs, non-CTIMP clinical trials and basic science studies along with web links to templates for other study types.
* Where a drug is used the RAC asks that the protocol is assessed KHP CTO in the first instance to rule out that it is not a CTIMP. KHP CTO will assess and send the protocol to the MHRA if required. If this assessment has already occurred prior to the RAC meeting please include the correspondence with your protocol for risk assessment. If the protocol has not yet been assessed as either CTIMP or non-CTIMP by either the KHP CTO or the MHRA, please email the protocol to Helen Critchley, KHP CTO Quality Manager (helen.critchley@kcl.ac.uk) and include the response with your documents for risk assessment.
* Please include the source of study funding on the protocol, and whether anything is being provided (for example if a company is providing the study drug at no cost). For externally funded studies please include details of the funder(s). Where studies have not been awarded external funding please contact the R&D office for an R&D costings form and return this to us with your protocol.
* Where a protocol has not been scientifically reviewed by an external funder, the R&D office will organize an independent peer review. This will be done in parallel with risk assessment review. Please provide the R&D office with the names and contact details of three potential reviewers who have expertise in the area but are independent of the study. We will organise the peer review and forward the comments to you.

Please also note the following points which should be included in your protocol where applicable:

* Where participants will be recruited from (for example whether from the NHS, advertisement, existing registries).
* Where the consent and screening visit and subsequent study visits (post consent) will take place.
* Whether consent is taken by a medic, if not how the consent process will be properly delegated.
* Where the drug/placebo is sourced, and which pharmacy is storing and dispensing.
* An outline of risks and burdens and a description of side effects of the study drug, including contraindications.
* Safety reporting as per HRA guidelines (<http://www.hra.nhs.uk/resources/during-and-after-your-study/progress-and-safety-reporting/> . Any safety reporting to the HRA must also be copied to the sponsor via the SLaM/IoPPN R&D office.
* Randomisation details – process of randomization and blinding, procedures and conditions for unblinding. (please see the *Emergency out of hours code break Flow Diagram* document)
* Include details of storage and analysis of all tissue samples (including urine, saliva, hair samples) - where they are stored and analysed and for how long, whether they are stored under an organizational Human Tissue Authority licence, who will have access to the samples in the future (including any other organisations/commercial companies).
* Details of data management – how data will be managed appropriate to the study type, including data handling and coding for computer analysis, monitoring and verification and assuring the quality of the data. Include a description of the statistical methods to be used for the data analysis, reasons for selection of the sample size and power of the study.
* Details of the Data and Ethics Monitoring Committee (DMEC) and Trial Steering Committee (TSC) arrangements, or the reasons if these are not being set up. DMECs and TSCs apply to clinical trials only. For all other study types such as basic science please include an explanation of appropriate oversight arrangements.
* It would also be helpful if you could include details of quality assurance of the conduct of the study using Good Clinical Practice standards and SPIRIT statement. Although these standards relate primarily to clinical trials, where appropriate they should be used as a reference for basic science and other study types. Details of GCP and SPIRIT are on the R&D office protocol guidance.

If you have any questions about these points or would like to discuss your protocol before submitting it for risk assessment, please contact the R&D office, otherwise please forward the protocol and confirmation sign off from the appropriate CAG/department as well as any other relevant documents such as R&D costings form and MHRA correspondence to slam-ioppn.research@kcl.ac.uk

**Appendix: CAG Protocol Processes**

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| SLaM CAG | Contact |
| Child and Adolescent Mental Health Services(CAMHS) | Email details of the project to : Sophia Morelli Sophia.Morelli@slam.nhs.uk  |
| Addictions | Email details of the project to Emily FinchEmily.Finch@slam.nhs.uk |
| Mental Health of Older Adults and Dementia(MHOAD) | Complete the MHOA & Dementia CAG Research Application form and email with the protocol to Laura Broadley (Laura.Broadley@slam.nhs.uk) who will organise the review at the CAG research meeting which is held every 2 months. The research application form for this CAG can be obtained from the Laura Broadley directly. |
| Behavioural and Developmental Psychiatry (BDP) | Email details of the project to Grainne McAlonan grainne.mcalonan@kcl.ac.uk  |
| **Adult Mental Health Services** |
| **CAG** | **Borough/Operational Directorate** | Single Panel Review for Adult Mental Health servicesThe process is still being finalised, the R&D office will advise. We always recommend feasibility discussions with the relevant clinical services. |
| * Psychosis
* Pathway Integration
* Psychological Medicine and Integrated Care
 | Southwark And AddictionsLewishamLambethCroydonPsychological Medicine (excluding Older Adults) |