The benefit of study plans to facility management

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Why?

Study plans were part of a contingency plan during the COVID-19 pandemic. They provided a way to ensure that all Named Persons had knowledge of the work being carried out. This was especially important with fewer people on the campus.

The introduction of this contingency plan meant that researchers across all sites at King's College London (KCL) were required to complete and submit a study plan before carrying out work across the animal facilities.

This requirement was introduced quickly to permit research to resume and allow them to access the animal facilities within the limits of the COVID-19 restrictions.

An additional welcomed outcome of the study plan process was the ability to identify experiments that would have been non-compliant with the Home Office regulations and the process also highlighted protocols which required refinement. This resulted in positive outcomes that included reduced adverse effects to laboratory animals.

Aims

The aims of a study plan are to:

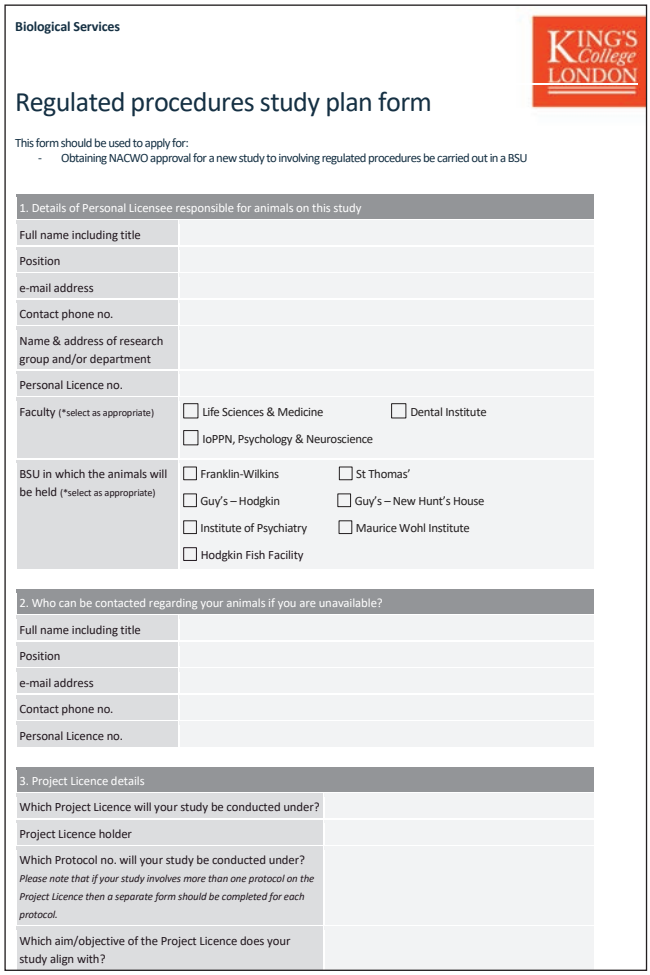
- Promote collaboration between project licence holder (PPL), personal licence holder (PIL) and Named Persons regarding the regulated procedures animals will undergo during an experiment.
- To enable an experiment to be assessed to ensure Home Office compliance (e.g. PIL and PPL authorities and training records) preventing unnecessary non-compliance and potential Animal Welfare issues.

Study plans

When study plans were first introduced they were submitted as a word document (Figure 1).

However to integrate study plans and animal management better, the process is now managed by the web based laboratory animal management system we use.

Using the software reduced the administrative burden involved with completing study plans as they can be duplicated/copied easily and with alerts automatically being sent to the people responsible for approval. This has created a centralised transparent and easy to audit record for interested parties.



Biological Services

KING'S College LONDON

Regulated procedures study plan form

This form should be used to apply for:
- Obtaining NACWO approval for a new study to involving regulated procedures be carried out in a BSU

1. Details of Personal Licensee responsible for animals on this study	
Full name including title	
Position	
e-mail address	
Contact phone no.	
Name & address of research group and/or department	
Personal Licence no.	
Faculty (*select as appropriate)	☐ Life Sciences & Medicine ☐ Dental Institute ☐ IoPPN, Psychology & Neuroscience
BSU in which the animals will be held (*select as appropriate)	☐ Franklin-Wilkins ☐ St Thomas' ☐ Guy's – Hodgkin ☐ Guy's – New Hunt's House ☐ Institute of Psychiatry ☐ Maurice Wohl Institute ☐ Hodgkin Fish Facility

2. Who can be contacted regarding your animals if you are unavailable?	
Full name including title	
Position	
e-mail address	
Contact phone no.	
Personal Licence no.	

3. Project Licence details	
Which Project Licence will your study be conducted under?	
Project Licence holder	
Which Protocol no. will your study be conducted under? *Please note that if your study involves more than one protocol on the Project Licence then a separate form should be completed for each protocol.*	
Which aim/objective of the Project Licence does your study align with?	

Figure 1. Snapshot of study plan.

Study plan steps

1. Study plans are prepared by the researchers and submitted on the animal management system.

2. PPL holder receives notification to check and approve the study plan and ensure the study is compliant with the PPL authorities.

3. The Named Animal Care and Welfare Officer (NACWO) receives notification the PPL holder has approved it and will check and authorise it as the facility sign off. The NACWO will ensure the study plan is compliant with the project licence and that endpoints and actions to be taken are clearly stated and Animal Welfare costs have been minimised.

As the study plan process evolved it has become much more than a tool to approve and manage researchers plans of work. The information from study plans help to review the training and competency records of researchers. This also helps with health and safety by checking occupational health status and reporting of any substances which would be hazardous to health.

Conclusion

The introduction of the study plans has been a great positive for research at KCL by ensuring compliance and helping to promote the principles of the 3Rs.

They have helped prevent non-compliance and given the animal facility staff easy access to the study plans and a better understanding of the experiments being performed on the animals.

3Rs

Replacement: avoiding or replacing the use of animals in areas where they would otherwise have been used.

Refinement: minimising the number of animals used which is consistent with scientific aims.

Refinement: minimising the pain, suffering, distress or lasting harm that research animals may experience. There have been many different refinements made to the study plans due to the approval process. Examples are:

- Refinement of sepsis scoring system and endpoints for a severe protocol.
- Experiment involving myocardial infarction that was going to be performed as a recovery model and as a severe protocol. This led to it being carried out as a non recovery procedure instead.
- The change of the duration of the time course for mice on a severe protocol, reducing the time the mice would have potentially been suffering due to the administration of the drug.
- Non regulated instead of regulated experiments being carried out.