AN ELECTRONIC BASED EXPERIMENTAL PROTOCOL HAS "ARRIVED"

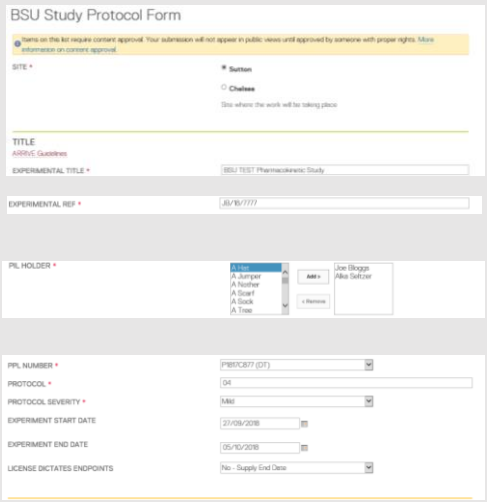
I. Wilson, J. Mary-John, K. Duncan, C. Preston, P. John-Baptiste, M. Allen, L. Dorsett and A. Thornhill
Institute of Cancer Research, 15 Cotswold Road, Belmont, Sutton SM2 5NG

Background and Objectives

Historically Study Protocols are paper based, at the ICR each research group generated their own protocol template making documents difficult to follow for persons conducting out of hours support as well as the Home Office Inspector.

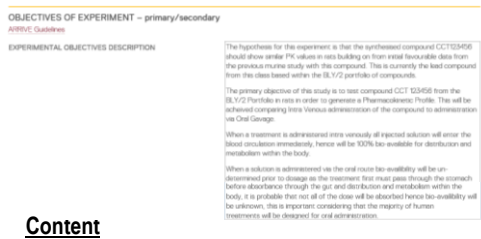
Other additional disadvantages experienced with the paper system such as potentially slow approval processes where study proposals are passed back and forth between submitter and approver, the lack of version control to approved documents or even the un-necessary flow of potentially "dirty" documents in to the animal facility.

In attempt to revolutionise and harmonise our Study Protocol designs we have developed an online protocol and submission process, This has streamlined the process and eradicates many of "copy and paste" errors associated with previous versions.



Creating a Document

Protocols are initiated via the internal intranet. It is possible for any member of staff to submit a protocol. Submitters are only permitted to view their own documents and each study must be assigned to one or more active PIL holders. This is made possible by the large volume of dropdown fields embedded within the document. To minimize data input errors Project and Personal Licences numbers along with PIL contact details have been uploaded to a separate database that links with the protocol and will fill in details automatically.



Content

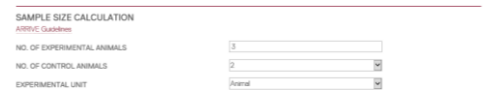
The submitter is encouraged to be as detailed as possible when explaining their proposal. The protocol should be detailed enough to permit repeatability of study conditions as well as ensuring other PIL holders involved with the study can follow.

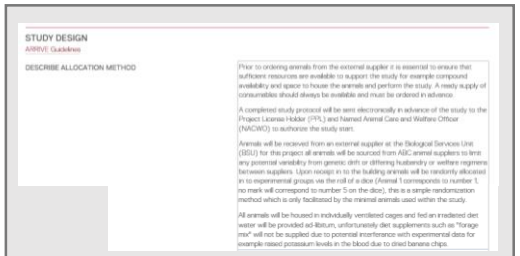
Particular attention is drawn to the objectives or hypotheses for the experiment to be clearly defined. A number of Pre-Populated drop down boxes are provided to ensure accuracy.

ARRIVE Guidelines

The ARRIVE - Animal Research: Reporting of *In Vivo* Experiments guidelines are intended to improve the reporting of research using animals – maximising information published and minimising unnecessary studies. The Electronic Protocol has been developed with full consideration to the ARRIVE guidelines, each title section has a direct link to the guidelines enabling the submitter to fully understand the requirements for each section. This places animal welfare at the core.

The protocol template has been designed to capture the spirit of the 3'rs through the questions it poses the submitter, aiding the publishing of work or repeating of experiments. The protocol is primarily a working document so a balance was found as to the areas of ARRIVE to include in the study design and areas to omit until the write up phase of the experiment.

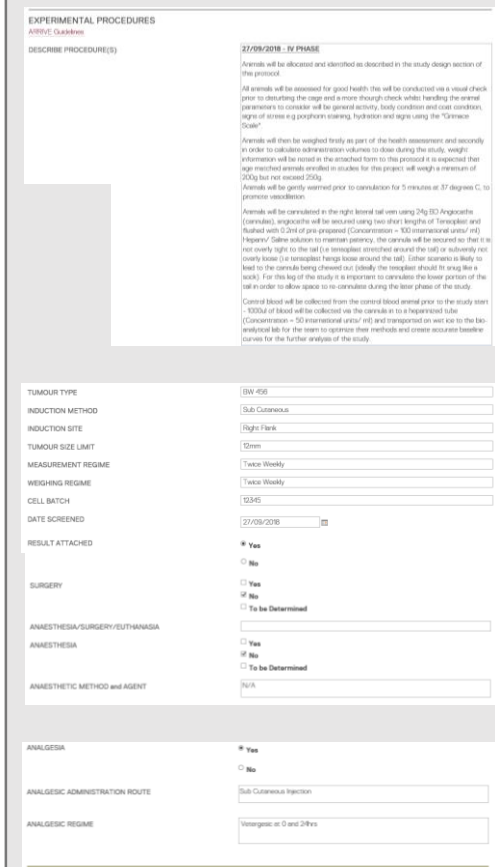


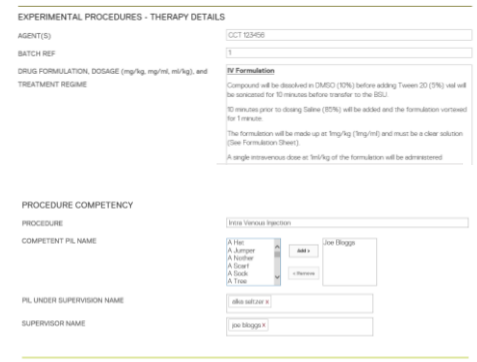


Electronic Submission and Version Control

Electronic submission and approval means that documents only require printing when approved, this eliminates the requirement to transfer paper items from outside of the facility reducing the risk of pathogen transferal and eradicates the risk of an unapproved version being used as the "official" version.

Version Control also means that changes are more easily tracked and that the approved version is easily identified.





Procedural Competency

Study Proposers are required to declare all regulated and Schedule 1 techniques to be performed within the study proposal in the procedural competency section of the submission. This will detail PIL holders whom are signed off within their Personal Training Record and those whom are working under supervision, In such cases a supervising PIL holder from the identified list must be indicated.

Auditing

Competency Declarations are spot audited to Personal Training Records by the Named Training and Competency Officer and inaccuracies are treated as a non-compliance.

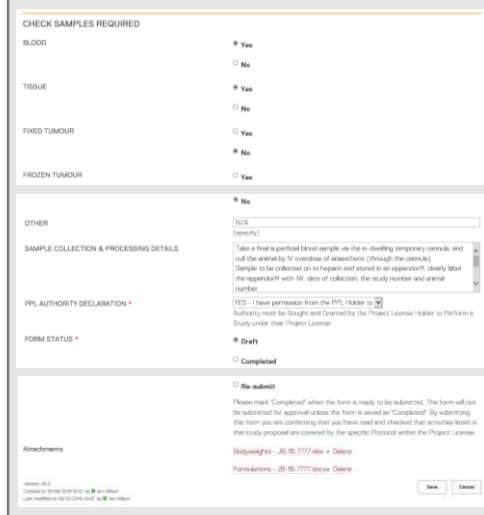
Submission Process

At each stage of the submission process both submitters and approvers will receive email notification of all status changes to the document.

An approver will check the study proposal and either approve it or reject it, when approved the document will be printed, signed and dated. Rejected submissions will be electronically re-directed to the submitter with an explanation for editing and resubmission.

Approvers will be NACWO's or NACWO Trained.

The primary advantage of electronic approvals is the ease and speed of ensuring the document reaches the correct person, this allows the reviewer to check the study proposal at a time that they can give it full attention.



Features and Benefits

- Faster approval process
- Drop-down boxes employed within the template to aid accuracy of information
- Author can save document as draft to re-edit prior to submitting
- Submitters must declare full Project License authority for their study
- Training and Competency auditing may commence prior to the study commencing.
- Version History allows both submitters and reviewers to track document changes and gives Quality Control as to the "Approved Version".