Ms. KOO (LIFS) was preparing a special diet for a pilot study on storage and mobilization of fat in a transgenic mouse model, in a barrier facility in APCF.

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Pilot Study and Experimental Design

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Pilot Study

Pilot study is a small-scale preliminary experiment aiming at collecting information, such as statistical variability, technical feasibility, cost and adverse events, for preparing a main experiment in which a greater investment is to be involved.

In the *Guide for the Care and Use of Laboratory Animals: 8th Edition (2011), NRC*: "If little is known about a specific procedure, limited pilot studies, designed to assess both the procedure's effects on the animals and the skills of the research team and conducted under IACUC oversight, are appropriate."(p26). "When novel studies are proposed or information for an alternative endpoint is lacking, the use of pilot studies is an effective method for identifying and defining humane endpoints and reaching consensus among the PI, IACUC, and veterinarian. A system for communication with the IACUC should be in place both during and after such studies."(p.28).

In many animal studies, pilot studies are used to obtain experimental data variation for sample size calculations to perfect the main study. It helps to reduce the unnecessary excess use of animals (i.e. reduction of the *Principles of the Three Rs*).

National Center for the Replacement, Refinement & Reduction of Animal in Research provides a brief introduction in conducting a pilot study. In which, logical issues revealed by the study are well listed. An experiment designer can learn more by following the literatures listed in the webpage, which include a technical guide to pilot study design, general experimental design and statistical tools.

In addition, Dr. David Redden at Center for Clinical and Translational Science, UAB contributed a lecture video on designing a pilot study in their YouTube channel.

Experimental Design

For designing the main animal experiment, Dell *et al.*, (2002), in *Sample Size Determination*, provided methodology in estimating the sample size from pilot study or previous experience.

Another educational article titled *Practical Aspects of Experimental Design in Animal Research* by Johnson and Besselsen (2002) further discussed practical considerations in animal experimental design including:

- defining the necessary control groups,
- randomly assigning animals to control/treatment groups,
- determining the number of animals needed per group,
- evaluating the logistics of the actual performance of the animal experiments,
- identifying the most appropriate statistical analyses and
- potential collaborators experienced in the area of study

Note: all references are hyperlinked to the highlighted text.