Learning Scenario 3. Safety Assessment of novel therapeutic agents: The Functional Observational Battery (FOB) (skills training)

Functional observational battery (FOB) tests in laboratory animals are similar to clinical neurological examinations in humans in that they assess the presence and severity of behavioural and/or neurologic dysfunction. FOB tests are widely used in safety pharmacological studies because, if they are carried out by carefully trained observers, they can alert researchers to potential safety issues with novel pharmacological agents including sedative potential, motor impairments and abuse liability. If the FOB test highlights these effects, further, more specific safety pharmacological evaluations are carried out to confirm these findings.

In this scenario, working in groups, hands-on practical experience in gained of conducting an FOB on a rodent. In doing so, experience is obtained of animal handling, the assessment of rodent physiology and behaviour, and knowledge and understanding of how specific physiological or behavioural measures or indices can be modulated by different classes of pharmacological agents. A greater appreciation is earned of the impact of researcher expertise and skill on the reproducibility and reliability of data from animal studies.

Subject	**Safety Assessment of novel therapeutic agents: The Functional Observational Battery (FOB)**
Author/owner/ possible copyright issues	Dr Dave Lewis (School of Biomedical Sciences, University of Leeds, UK). Email: d.i.lewis@leeds.ac.uk
Topics	Safety Pharmacological assessments; animal physiology and behaviour; animal welfare; animal handling and restraint; experimental design; reproducibility and reliability of animal studies.
Eligible student level	Undergraduate: Pharmacology, Physiology and related disciplines. Experience of handling and restraint of the species (rat or mouse) used. Prior knowledge and understanding of the use of the Functional Observation Battery in the safety pharmacological assessment of putative new medicines.
Teaching time	3.5 hours
Examples of online teaching material	Contact Dr Dave Lewis (d.i.lewis@leeds.ac.uk)
Examples of offline teaching material	Adult rodent (rat or mouse); quiet room in animal facility or other suitable location/laboratory; Protocol sheet, 1 per student; Clipboard, 1 per student, helpful but not essential; Thermistor or other means of measuring rectal temperature (1 per 4 groups or per room); Lubricant for inserting thermistor/thermometer; Home cage (1 per animal); Open field area (1 per group, measurements approx. 50-60cm x 50-60cm x 20-30 cm (width x length x height); Stopwatch or clock; Coarse tweezers (1 per group); Penlight (1 per 4 groups or per room); A3 paper Ink & means of applying to animal's paws (container to dip paw in?) (1 per 4 groups or per room); 30cm ruler; Wire grid (to estimate grip strength) mounted on a wood frame (20 × 45 cm; grid units 2 mm) or grip strength meter; Bar fixed on two vertical supports for traction measurement (27 cm length, 40 cm height, 0.4 cm diameter (1 per 4 groups or per room); Pharmacological agent or saline; appropriate PPE.
Helpful resources	Published articles that have used this battery.
Licenses, certification	

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or accreditation	Non-commercial-ShareAlike 4.0 International License.
Integration in curriculum	May be used to provide experiential (Hands-on) learning of safety pharmacology, animal handing, welfare, physiology and behaviour in undergraduate and Taught Masters programmes in Pharmacology, Physiology and related disciplines.
Examination	Scientific abstract; reflective account.
Aims and learning objectives / outcomes	By the end of this session, participants should have: • A greater knowledge and understanding of rodent physiology and behaviour. • A greater knowledge and understanding of the use of the Functional Observational Battery to assess the impact of pharmacological agents on rodent physiology and behaviour. • Gained hands-on practical experience animal handling and of conducting functional observations in rodents. • Gained experience of experimental design, team-working, leadership, problem solving; communication skills; reporting of scientific studies, and an increased ethical awareness. • A greater appreciation of the care and skill required when undertaking physiological and behavioural studies in laboratory animals; and the impact of researcher skill and expertise on the reproducibility and reliability of data from animal studies.
Activities/ programme	
Assignment	Group activity, 4-5 students per group.
Student and teacher feedback	
Helpful Resources	