

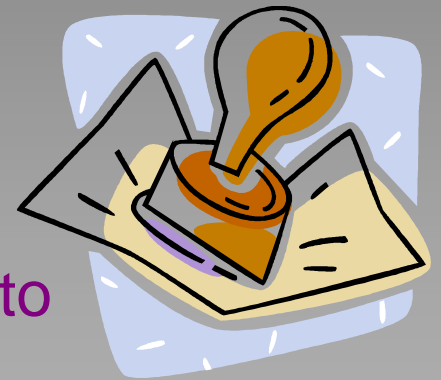
Post-approval monitoring: guiding principles and procedures in place

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What is post-approval monitoring?

- To provide insurance that the procedures performed on animals are compliant with those approved by the ethical committee
- Insurance is requested by the funding agencies supporting research, the University and the community at large
- This is no rubber stamping, but a way to educate and sensitize research personnel to the importance of animal care and ethical principles.

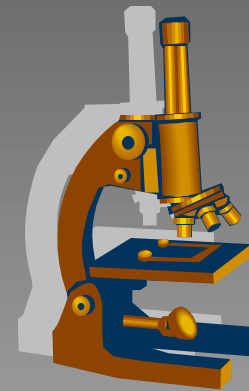


The Bases of Post-approval monitoring

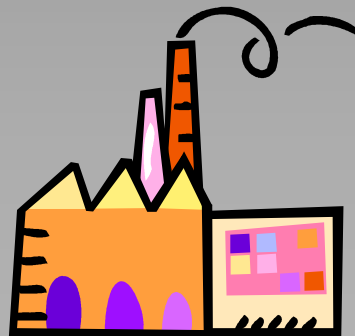
- The animal protocol



- Observation of procedures



- Adequacy of facilities to conduct the procedures



Potential post-approval problems (1)

- Personnel, procedures or drugs not listed in animal care protocol
 - classes of drugs vs. specific drugs
 - “umbrella” type of protocols
- Personnel without required training (undergraduate students, summer students in particular)
- Procedure not performed as described in protocol or in breaking compliance with ethical review
 - Importance of cage level monitoring
 - Access to protocols in animal facility is primordial
- Post-operative procedures not respected

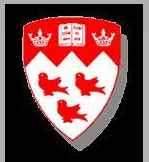
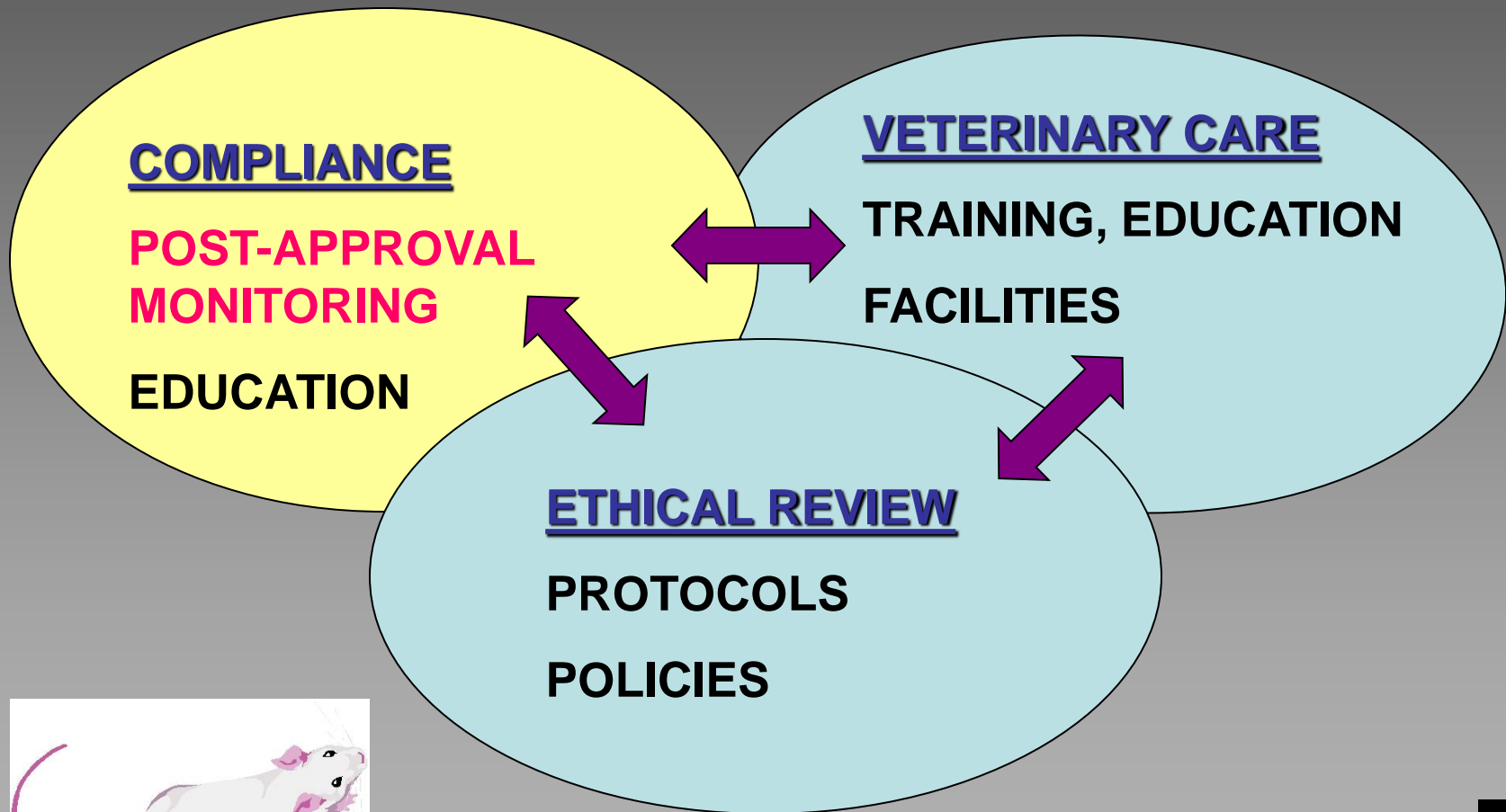


Potential post-approval problems (2)

- Drugs used for a different purpose than stated in the protocol. Used past expiration date, improperly stored
 - In particular controlled substances and analgesics
 - Changes in practices due to Health Canada restrictions
- Animal abuse and/or neglect
- Inadequate protection of research personnel
 - Species-specific training required
 - Efficient link to OHP
- Deviance in adequacy of facilities and equipment from approved protocol



Present McGill structure... and evolving



How to implement a reasonable post-approval monitoring in a large decentralized institution?

Compliance Branch

- Risk assessment: linked to specific protocols or procedures, species, facilities, functioning of local animal care and user committees. Know the local culture.
- Random audit generation based on risk factors and established list of non-conformity.
- Establish priorities and frequency of audit.
- Set up appropriate lines of communication



Communication is key

- Procedure level: animal health technicians and research personnel (students, technicians, investigators). **Access to protocols**
- Veterinary involvement: procedures assessment, **education and training of research personnel**, feedback to animal users and investigator.
Regular visits
- **Compliance office: risk assessment, link to protocol review and feedback to investigator and clinical veterinary services. Regular or random visits**



View post-approval monitoring as a way to educate and improve overall care

- Drug monitoring
- Analgesia procedures
- Rationalization of procedures
- Help IS available
- Training
- Facility approval



**Overall benefits
to research**

