

# Post Approval Monitoring :

## A tool to improve best practices for animal use in science



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*May 14th 2010, CCAC*

**CRCHUM**

Centre de recherche du Centre hospitalier de l'Université de Montréal

# Overview

1. CRCHUM;
2. PAM program:
  - A. Which protocols are monitored;
  - B. Who visits;
  - C. What happens with the results;
  - D. Categories of non-compliance.



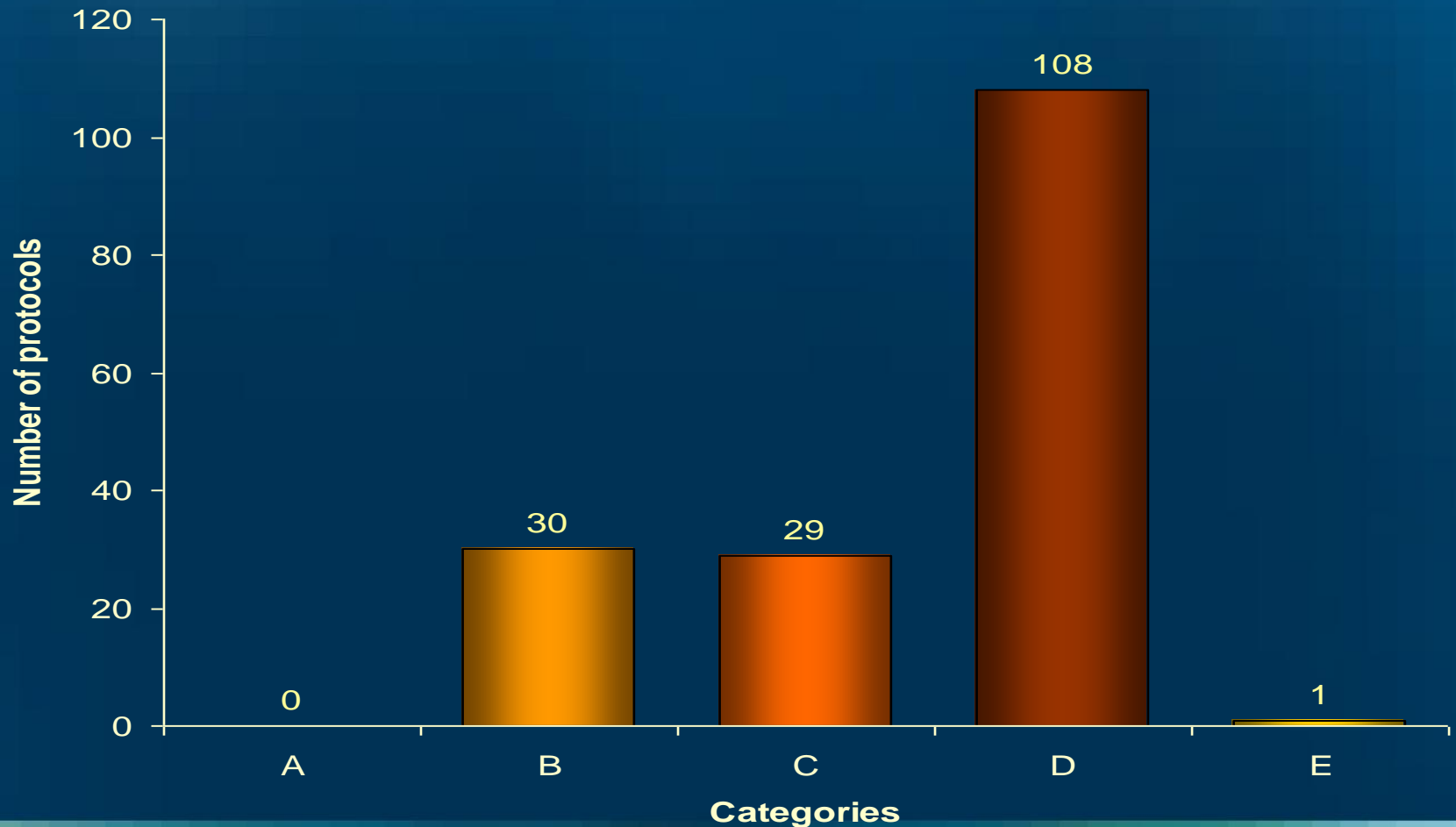
# Animal Care Committee CRCHUM



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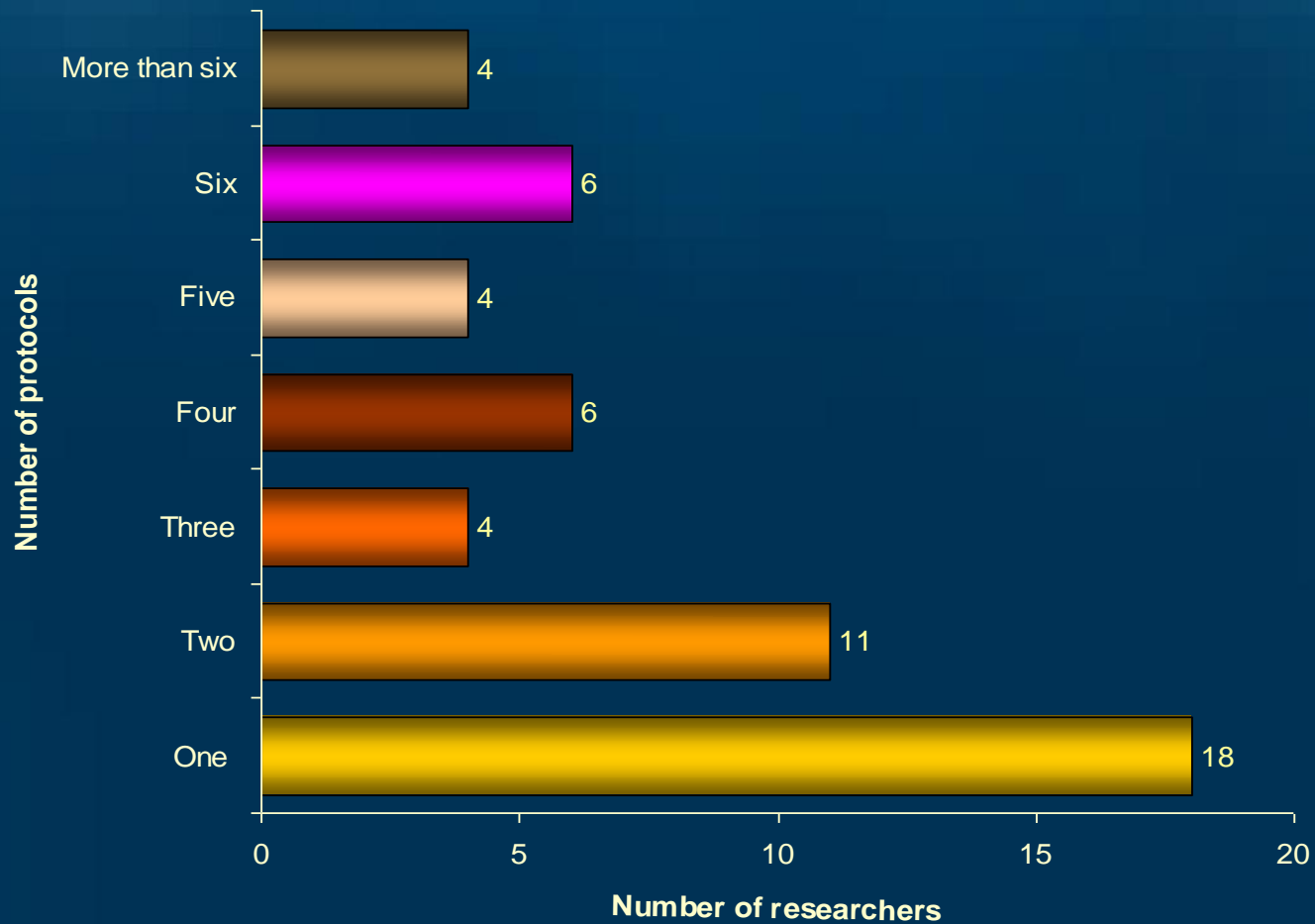
# Number of protocols per category of invasiveness (April 2010)



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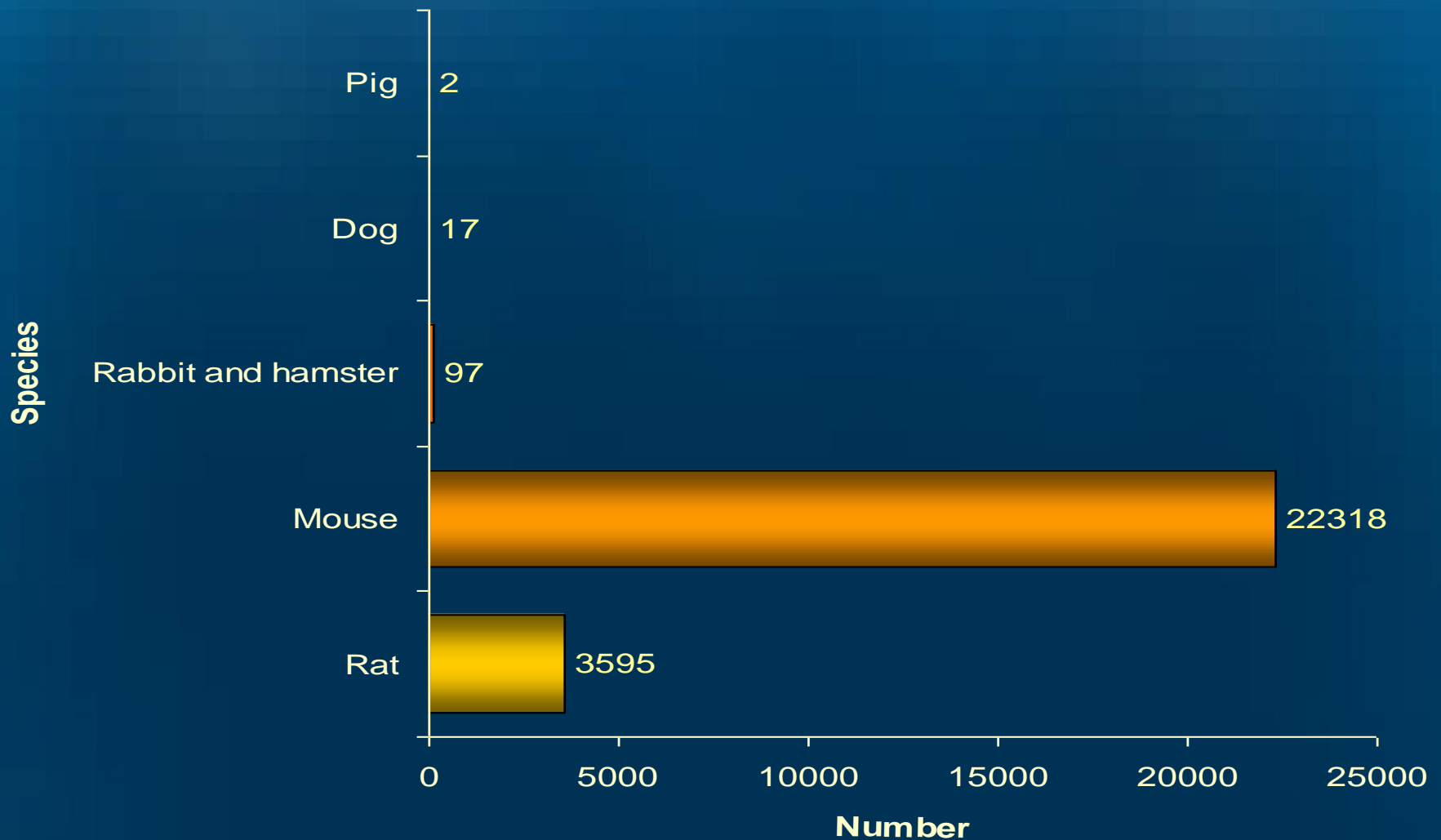
# Number of protocols per researcher (04/2010)



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# Animals used at CRCHUM in 2009



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# Objectives of PAM

- Monitoring one third of AUPs each year.
- Reducing concerns, problems or complaints received from members of the research center community.
- Establishing a confident relationship between animals users and ACC.

# WHY?



- ACC is responsible for identifying and correcting gaps in relation to compliance with approved protocols and SOPs so that procedures with animals are done efficiently and in the best conditions possible.



# Which protocols are monitored?

- All E protocols are monitored;
- All protocols that raise concerns, problems or complaints are monitored;
- For all breeding protocols, checking the number of animals produced and reported by the animal care staff and / or users against the number approved in the protocol;
- All other protocols are monitored randomly (protocol number drawn and put back in pool) at the ACC monthly meeting; It should be noted that Category C and D protocols are more likely to be the subject of post-approval monitoring.

# Monitoring before and after implementation of post-approval monitoring program



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# Who?

- All members of the ACC can visit, including researchers using animals or not, community reps. and coordinators.
- At CRCHUM, the ACC assistant-coordinator is the PAM officer.
- Exceptions: Members of the animal facilities and the veterinarian can't do PAM visits.
- A minimum of two people are required for a visit. In addition, one of them must be a researcher.
- Exception : Terminal procedures ex.: tissue harvesting (in this case, PAM officer is enough).

# Items to be evaluated during a visit

- Training of users, the safe and proper handling of animals and products used (drugs, radiation, biohazard);
- Procedures as described in AUP, or in a SOP;
- Aseptic surgery;
- Proper use of analgesia and anesthesia;
- The number of animals used;
- The endpoints and the method of euthanasia;
- Issues raised by team members.



# What happens with the results?

- For each visit, a report is issued to the committee (post-approval monitoring form);
- The user(s) and researcher are acknowledged by email for the visit;
- A copy of the report with the recommendations, if any, is sent to user(s) and the researcher before ACC meeting.

# Categories of non-compliance

## Problems most frequently observed

- Minor:
  - Animal users have no idea of the endpoints indicated on the protocol;
  - Users have never read the protocol;
  - Changes in protocol w/o ACC approved amendment;
  - Name of mouse strains.

# Categories of non-compliance

- Major:
  - Incorrect analgesia or anesthesia;
  - Incorrect aseptic conditions during surgeries.

# Actions taken

- According to the problems noted, an amendment to the protocol may be required;
- If the number of animals produced in breeding is different from what has been referred to in the protocol, the principal researcher / applicant is contacted and a justification is requested;
- If necessary, there will be a requirement to attend laboratory animal training;
- Any deviations must be corrected; the corrective action for the major problems will be decided by the committee.



# How to obtain success in a PAM program

- The officer knows the users;
- Presence of a researcher;
- PAM officer may help to apply 3R principles;
- Visit must be performed in a positive way;
- In case of non-compliance, the PAM officer must quickly find ways in collaboration with the users for them to comply.

# New CRCHUM

- Expected opening: 2013



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