



Establishment of IACUCs, the Roles & Responsibilities of IACUC, Host Institutions, Investigators, Sponsors, and the Challenges and Opportunities

The 12th Annual National Research Ethics Conference (ANREC)
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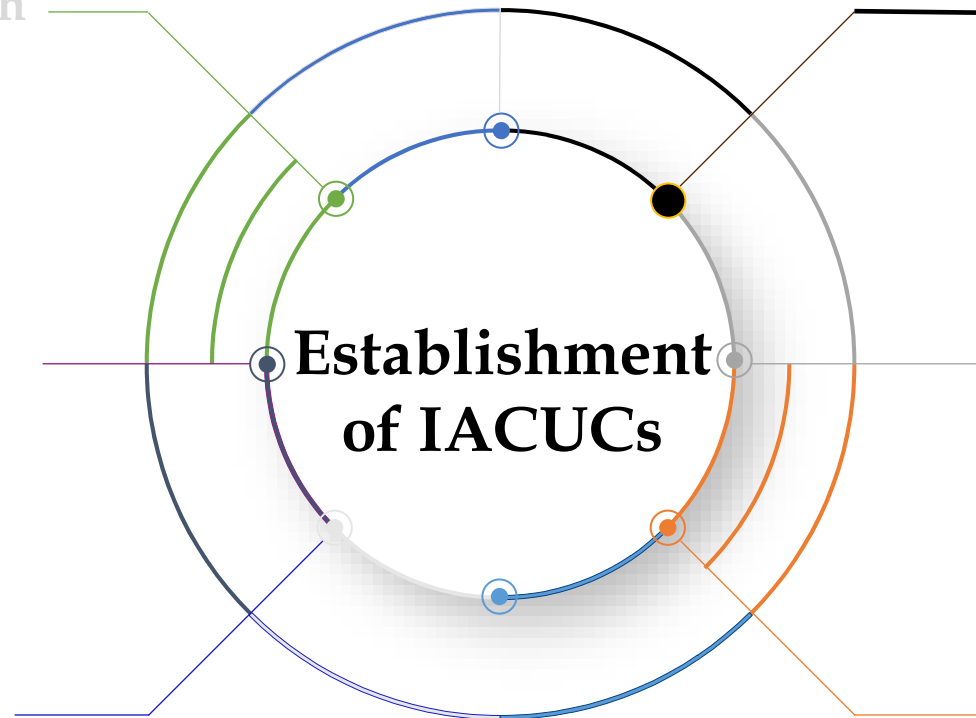


Introduction

In case an institution cannot set up an IACUC, it shall rely on an accredited IACUC of another institution to review their research protocols

IACUCs are accredited by the Accreditation Committee (AC) established by UNCST

The goal of each IACUC is to ensure the humane care and responsible use of animals in research and teaching in compliance with the National guidelines and regulations



Institutional Animal Care and Use Committees (IACUCs), also referred to as Animal Ethics Committees (AECs), are essential components of the Animal Care and Use Program (ACUP)

Should be established by institutions owning and caring for animals used for the purpose of research and teaching

They exist to conduct initial and continuing review of research protocols to ensure the ethical integrity, scientific justification, and welfare of animals used in research and teaching

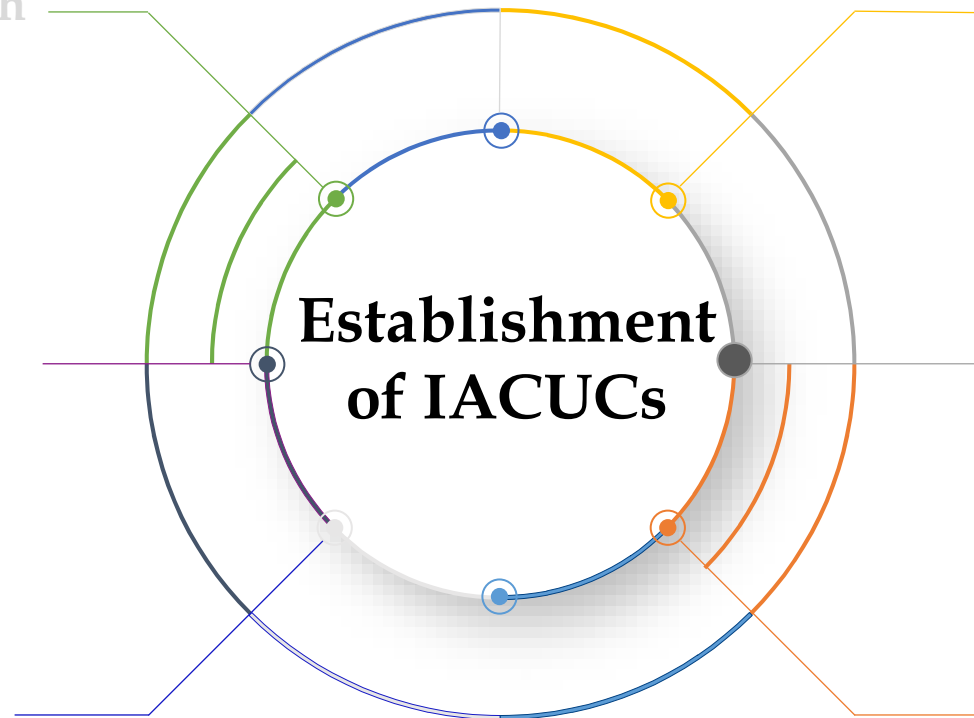


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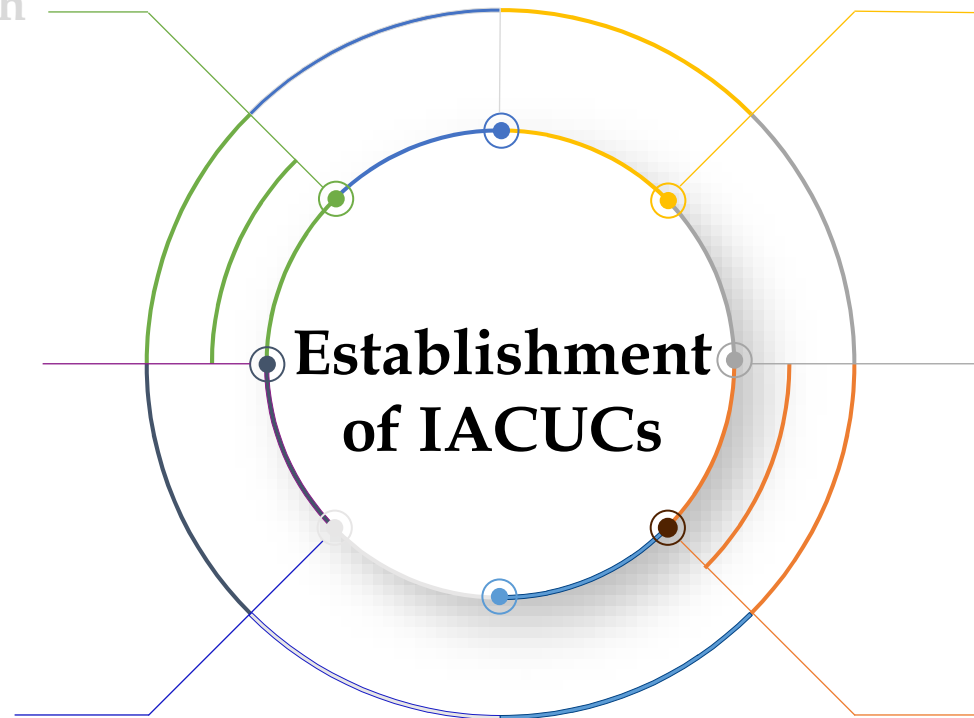


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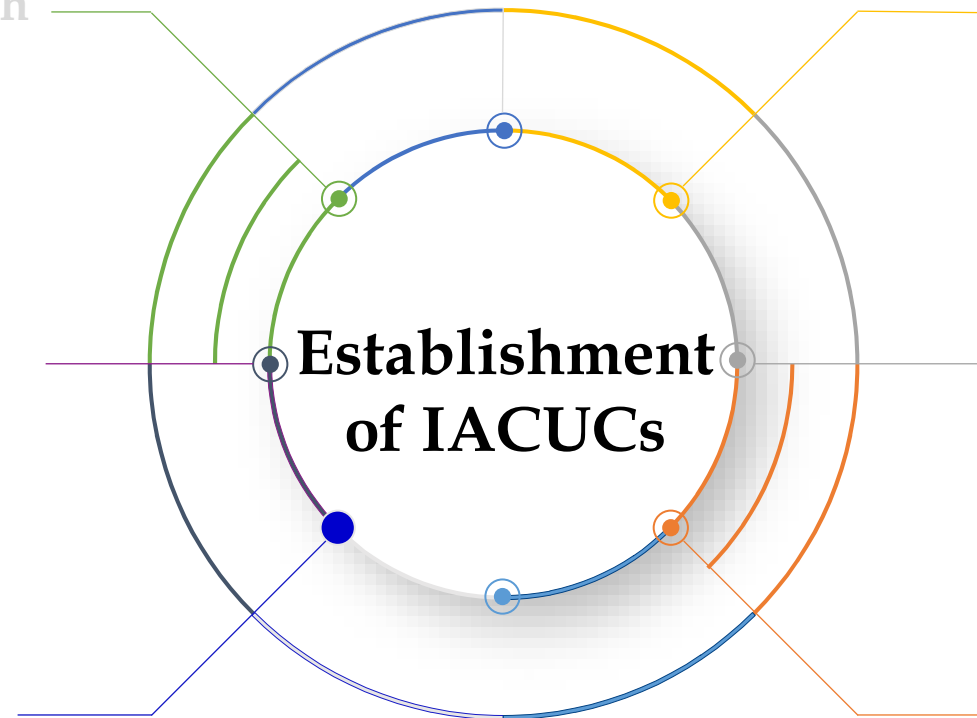


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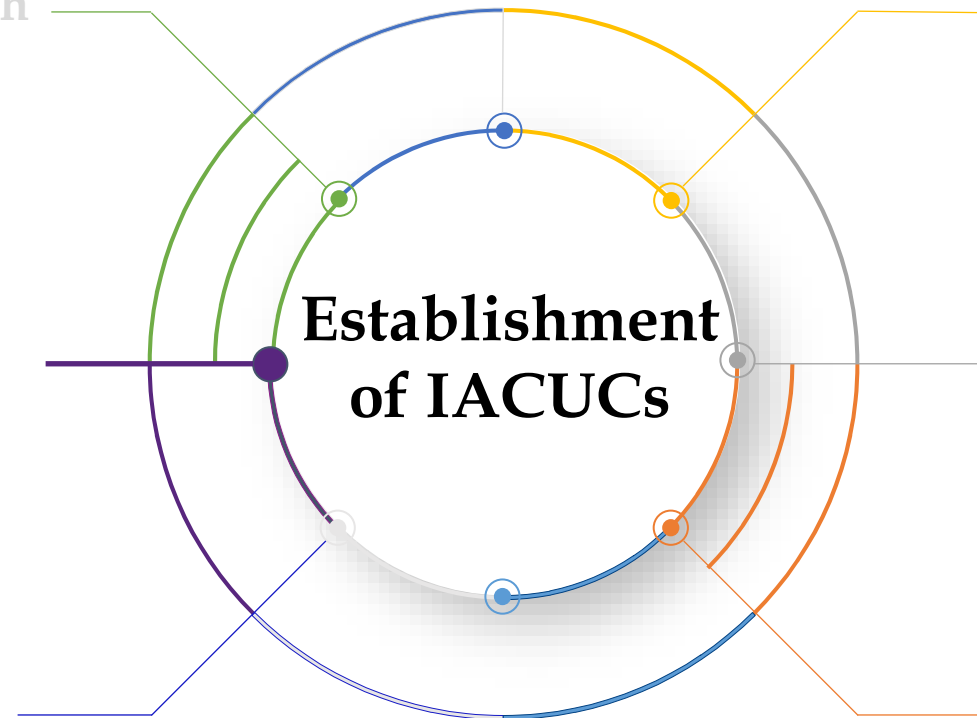


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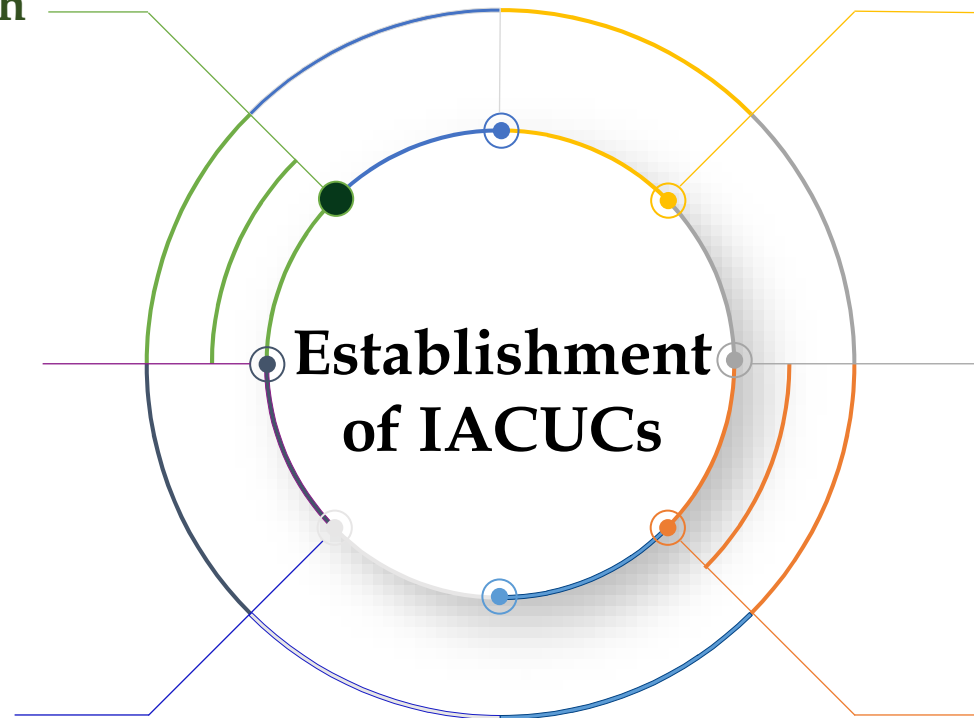


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Establishment of IACUCs

An institution that wishes to establish an IACUC applies for accreditation from UNCST and complies with the requirements in these guidelines

1

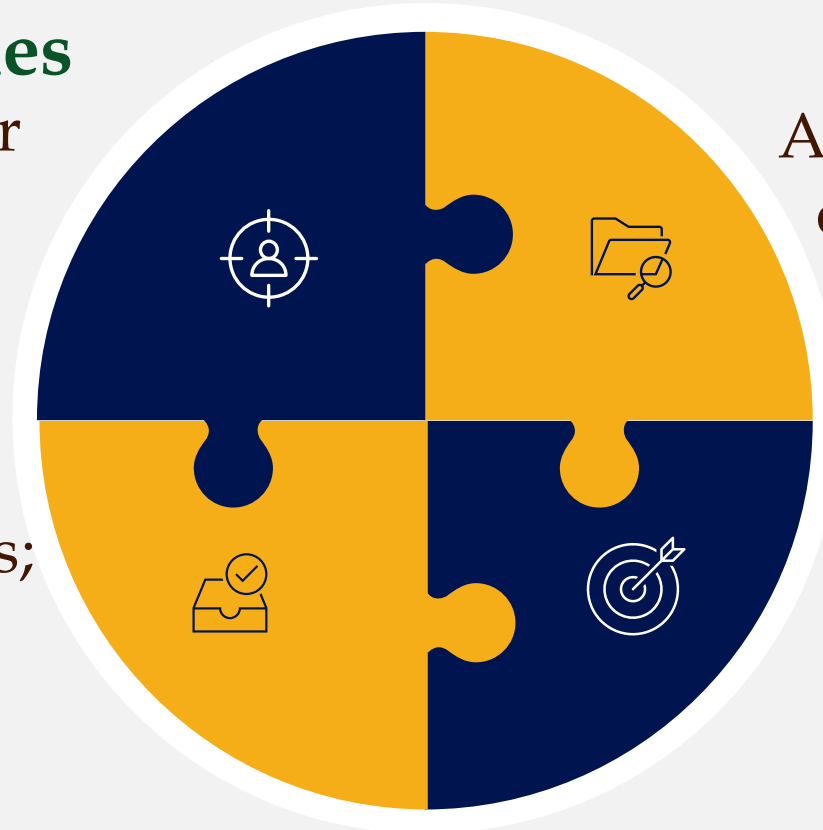
A statement of principles

A statement of principles for protecting the welfare and humane care of the animals in research and teaching

List of members

A list of appointed members; identified by name, qualifications, profession, specialty, institution, etc

4



2

Availability of staff

Assurance of availability of staff, office, meeting space, resources to support the IACUC's operations

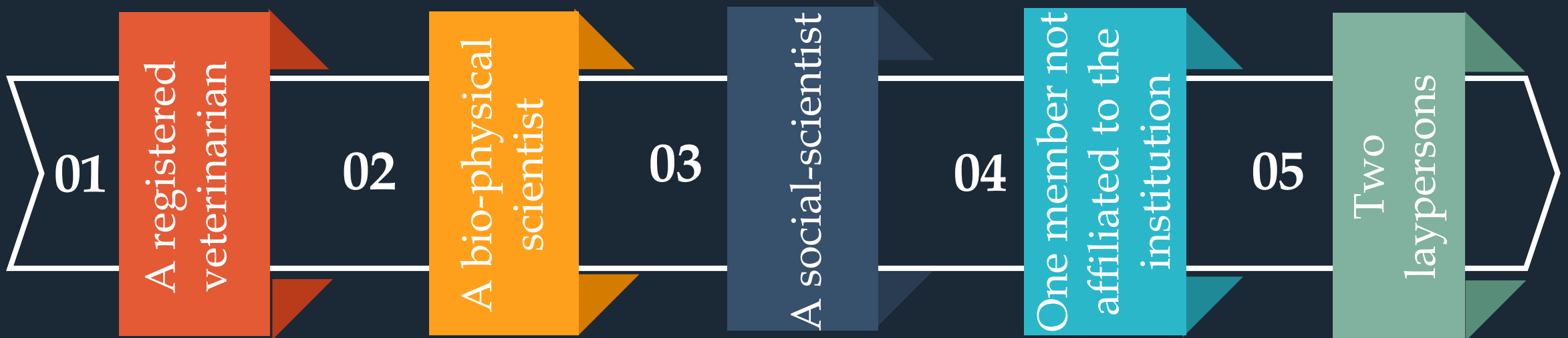
SOPs

Written standard operating procedures for the IACUC

3

Composition of IACUCs

- Each IACUC shall comprise ≥ 6 members, with varying backgrounds to ensure balanced & adequate review of research activities conducted by the institution
- The members shall be sufficiently qualified through experience, expertise and diversity; gender, equity, cultural backgrounds and sensitivity to social issues
- Each IACUC shall include at least;



Best practices of IACUCs

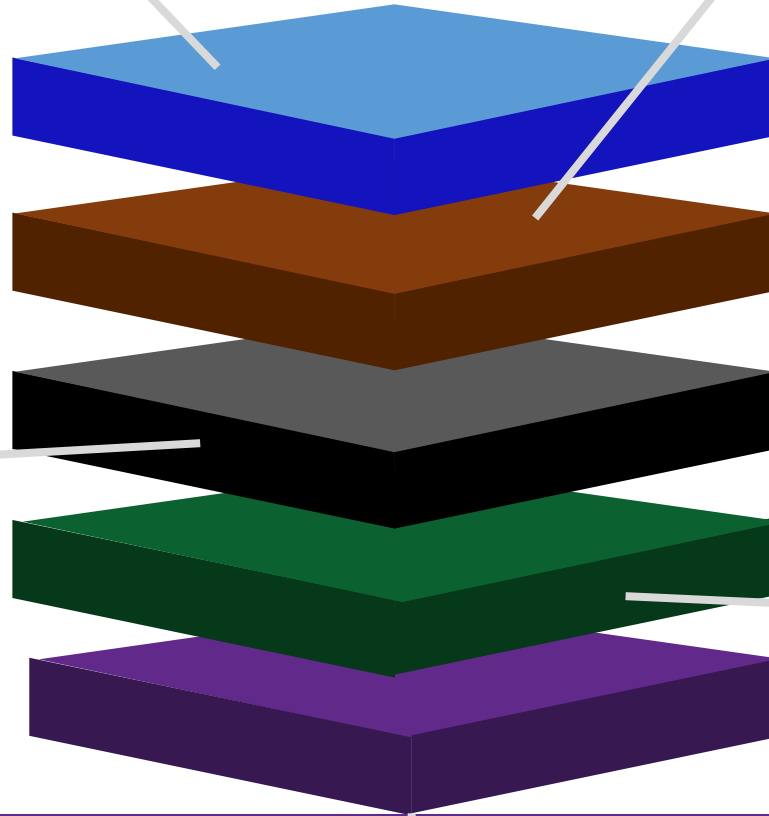
No IACUC member shall participate in the IACUC's initial or continuing review of any study in which such a member has a conflict of interest

An IACUC may, at its discretion, invite individuals with competence in special areas to assist in the review of protocols

Each member should take at least one course in Research Ethics training within 3 months and undergo continued ethics training at least once every three years

A member shall serve for a term of three (3) years renewable upon satisfactory performance

A person shall not serve as a member in more than two IACUCs concurrently



Roles and responsibilities of IACUCs

IACUCs act as independent reviewers and are responsible for the oversight of the entire institutional animal care and use programme, and while performing their duties, members must ensure;

Maintenance of ethical standards of practice in research

Protection of research animals and researchers from harm or exploitation

The welfare and humane care of research animals

Assure the public of the protection of the welfare of research animals

Functions of IACUCs



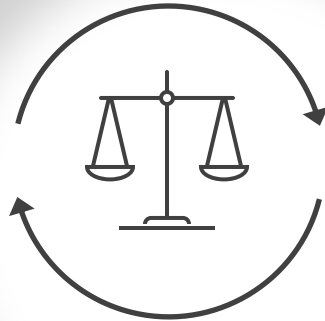
Evaluate and approve protocols and their amended versions



Monitor the care and use of animals in approved research protocols to confirm compliance



Inspect any facilities or areas where animals are kept or used



Investigate suspected or reported non-compliance or misconduct and refer to the regulatory bodies



Suspend or withdraw approval for approved research studies in cases of non-compliance

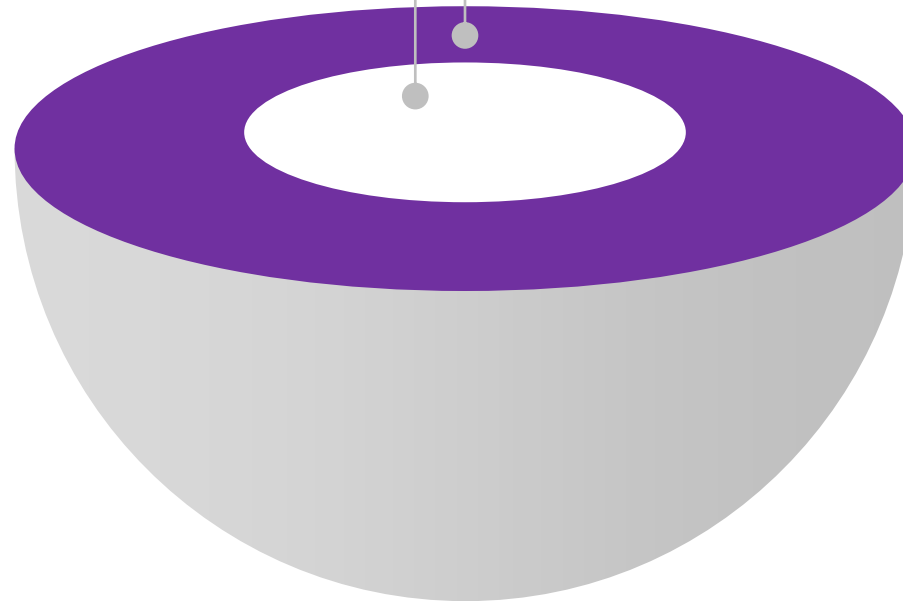
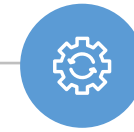


Ensure that sick research animals receive appropriate treatment/are terminated



Powers of IACUCs

IACUC shall have authority to halt, suspend or terminate approved research that is not being conducted in accordance with the approved protocol



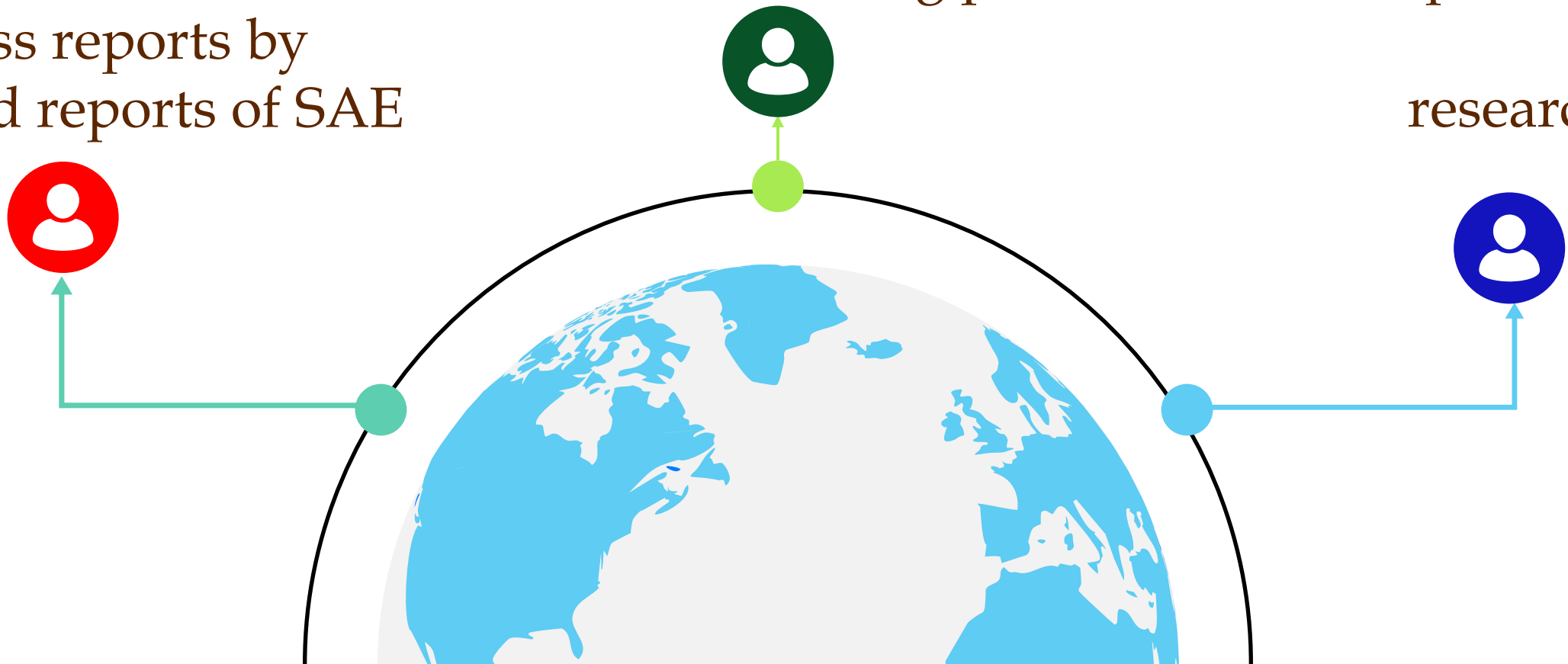
Suspension or termination of approval provide written statement of the reasons for the action, report the same to the PI, proper institution official, UNCST and other relevant authority

Types of records to be kept by IACUC

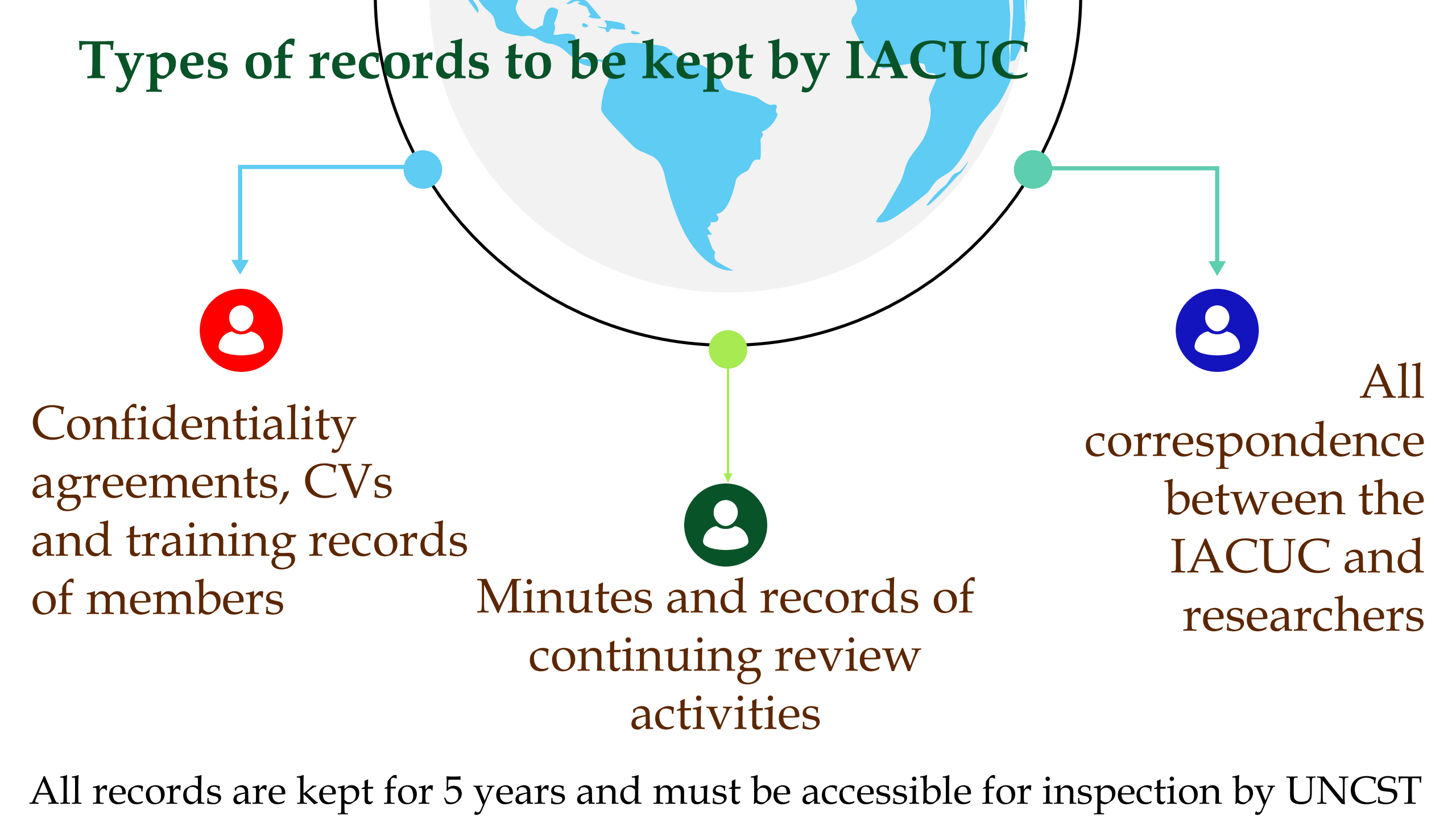
All protocols reviewed and accompanying documents, approved consent documents, progress reports by PIs, and reports of SAE

Declaration of conflicts of interests where applicable, actions taken by the IACUC and decision making process

Copies of final research reports from the researchers



Types of records to be kept by IACUC



Confidentiality agreements, CVs and training records of members



Minutes and records of continuing review activities



All correspondence between the IACUC and researchers

All records are kept for 5 years and must be accessible for inspection by UNCST



Basic Ethical Considerations for Approval of Research Protocols

● Methods

The methods used are scientifically valid and practically feasible

1

The 3Rs ●

Appropriate justification for the use of animals and appropriate application of the 3Rs (replacement, reduction, & refinement)

4

The protocol has a clear scientific question & objective, acceptable scientific principles, and statistical power

2

The protocol has scientific or educational merit, and has potential benefit for humans, animals or the environment

3

Merit of the study ●

● Questions & Objectives



Basic Ethical Considerations for Approval of Research Protocols

The protocol demonstrates value by adding new knowledge or improving human/animal health, welfare, production

01



The protocol involves the minimum number of animals required to obtain valid data, minimal AEs on the wellbeing of the animals

02



Risks to research animals are minimized by using procedures that are consistent with sound research design

03



The educational outcomes achieved in science, are as specified in the relevant curriculum

04



Responsibilities of Investigators (25 in number)



Responsibilities of Investigators (25 in number)



06 Veterinary Oversight and Health Monitoring



07 Safety, Adverse Events, and Stakeholder Engagement



08 Quality Assurance and Data Integrity



09 Reporting, Feedback, and Communication



10 Ethical Accountability and Presence



Responsibilities of Sponsors

Approve the final study report whether the study has been completed or not

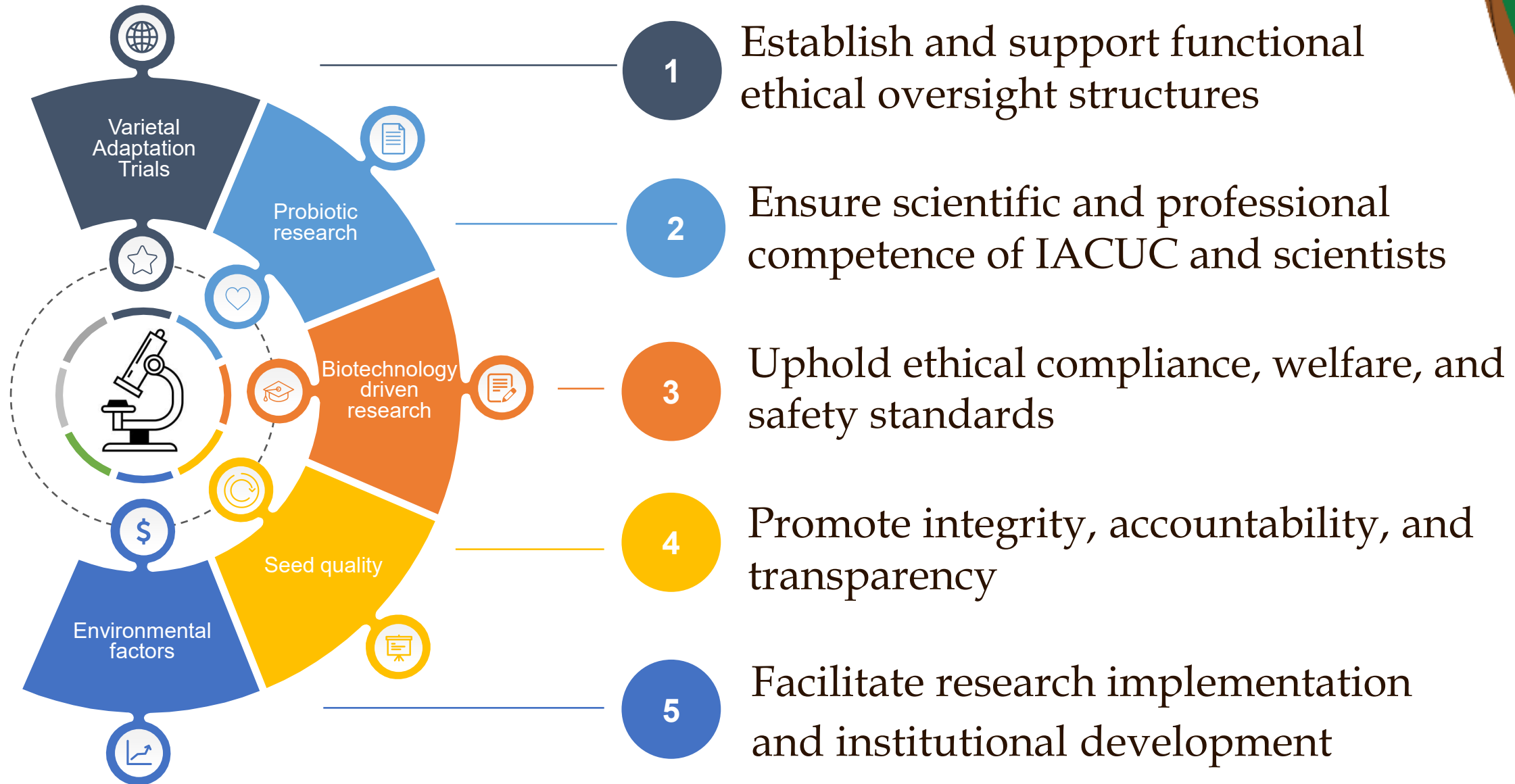
Be responsible for compensation or indemnity in the event of study related injuries, disability or

Provide information about the investigational product/device the dossier, labels, and information on safety

Cause the timely reporting and management of adverse

The sponsor shall indemnify the scientist against claims that arise during or from the study

Responsibilities of Institutions (30)

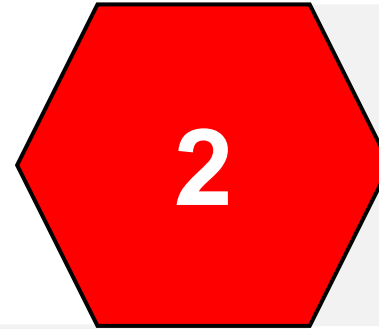
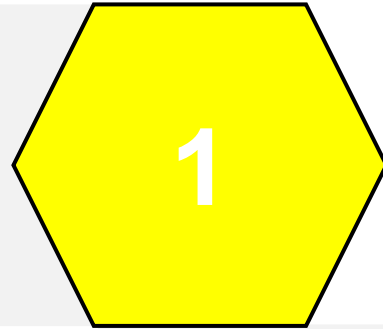


Challenges faced by IACUCs



Ethics review is a burden

The requirement for extra effort to make scientists fully appreciate the requirement for research ethics review and the rigor the process commonly takes



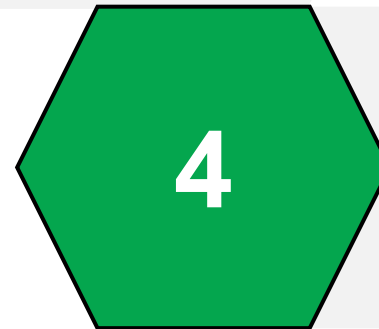
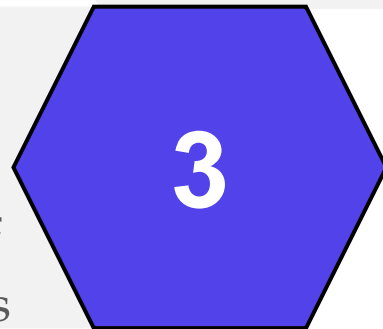
Species multiplicity

Because research involves different animal species, ethics review committees require diverse expertise for species-specific welfare and scientific considerations

The common challenges

Resource limitations

Resource limitations and inconsistent flow, and procurement delays that may affect timely, regular and consistent monitoring of the study sites of approved protocols



Delayed relay of information

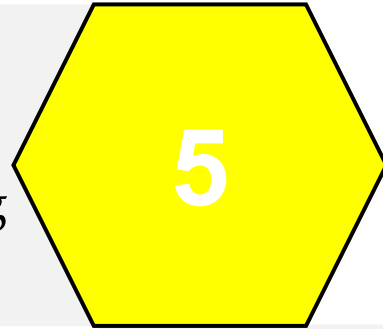
There is a delay by PIs in relaying information on project approval by UNCST, which usually affects the start of IACUC project monitoring

Challenges faced by IACUCs



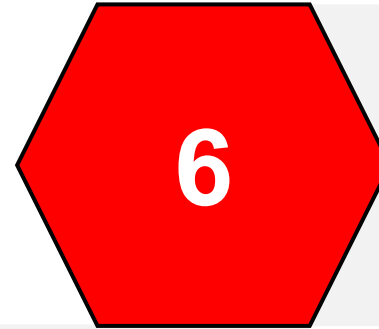
Need for committed lay persons

Scheduling meetings in order to ensure that a lay person(s) is/are present for effective decision making can occasionally a challenge



Appropriate capacity of members

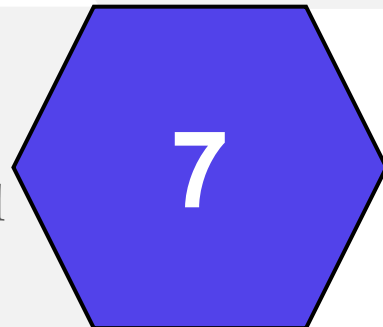
Building capacity of the all the members to ensure all members are up to the task



The common challenges

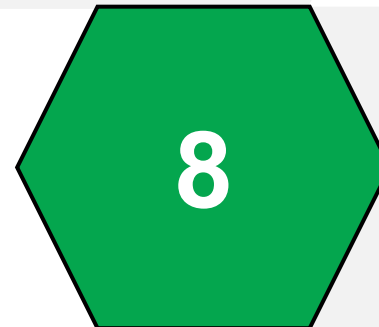
Conflict of interest

Management of Early-stage conflicts of interest and independence and unscrupulous demands for compensation by animal owners and site investigators



Delayed relay of information

Facilities and husbandry constraints/Field and wildlife research complexities



Challenges faced by IACUCs



Need for committed lay persons

Poor commitment to record keeping

Overlap and fragmentation in ethics governance

9

10

Documentation and reporting quality by researchers

The common challenges

Conflict of interest

Disappearing integrity

Cultural, social, and stakeholder factors

11

12

Management of unscrupulous demands for compensation by animal owners and site investigators



Opportunities in the establishment and use of IACUCs





**Thank you for your kind
attention**