



SOP Title	Procedure for Investigating Concerns Involving Animal Care and Use (Animal Research Non-Compliance)				
Date Last Revised		Date Created	02/01/2022	Revision #	
SOP Number	16	Required by:	<input type="checkbox"/> OHRP <input type="checkbox"/> Funding Agency <input checked="" type="checkbox"/> OLAW		
Applicability	<input type="checkbox"/> RGC Internal	<input type="checkbox"/> Researcher	<input checked="" type="checkbox"/> Institutional		
Subgroup	<input type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input checked="" type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

1.0 PURPOSE

This SOP describes the process for the reporting, reviewing and investigating allegations of mistreatment of animals or non-compliance of IACUC (Institutional Animal Care and Use Committee) -approved activities. Incidents of potential animal research non-compliance may be discovered through self-report, report by a third party or during an IACUC post approval monitoring visit or semi-annual inspection.

2.0 GENERAL INFORMATION AND SCOPE

A. DEFINITIONS

Complainant: The person alleging animal research non-compliance.

Conflict of Interest: Individuals responsible for carrying out any part of the non-compliance procedures must not have any unresolved, personal, professional or financial conflicts of interest with the complainant, respondent or witnesses. Any conflict of interest must be disclosed.

Continuous non-compliance: Failure to correct deficiencies identified by the IACUC.

Serious non-compliance: Conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual animal harm or death. Shortcomings in programs of veterinary care, occupational health or training identified during semi-annual program review and not corrected within the institutionally determined time frame.

Non-compliance: The failure or refusal to comply with a federal or internal regulation/procedure or to deviate from protocol procedures approved by the IACUC.

Minor non-compliance: Typically arises in instances where a policy or regulation has been violated, but the risk of harm to researchers or animals is minimal and the IACUC authority or function has not been compromised. Minor non-compliance can often be corrected at the institutional level.

Respondent: The researcher of the project for which the allegation has been made against or other relevant individuals included in the initial report.

B. SCOPE

The complainant or the IACUC is required to provide enough evidence that a reasonable person would reach a particular conclusion, also known as the substantial evidence standard. Reasonable differences of opinion or misunderstanding by the IACUC of research practice in the respondent's field of study should not be the basis for an IACUC finding of non-compliance. The alleged non-compliance must represent a substantial deviation from accepted norms that meets one of the definitions for non-compliance listed in 2.0. Section A. Adverse events should be reported using the Mentor Protocol mechanism along with corrective actions taken. The Manager of Research Compliance will determine whether the reported adverse event constitutes non-compliance in consultation the IACUC Chair and/or Attending Veterinarian if needed.

C. CONFLICT OF INTEREST

No person should be involved in the initial inquiry or investigation if there is a potential conflict of interest. All individuals involved in the process must sign a conflict of interest statement.

D. ROLES

PRINCIPAL INVESTIGATOR (PI)

The PI is ultimately responsible for all work that is conducted in the research study and should make the approved protocols available to all research staff. If the respondent is not the PI, the PI will be included in all conversations and communications with the respondent.

MANAGER OF RESEARCH COMPLIANCE (MRC)

The MRC will serve as the coordinator throughout the initial inquiry and investigation. The coordinator will ensure proper documentation through the inquiry and investigation and ensure that timelines are met.

The MRC is also responsible for documenting the suspected non-compliance in writing as soon as possible to ensure a timely capture of information including:

- the time, date and location of the alleged incident;
- a complete description of the event(s) as provided by the complainant;
- any relevant background that concerns the incident;
- the complainant's name, position, and relationship to the institution;
- the time and date that the allegation was reported;
- contact information for any individuals who were involved.

The MRC may prepare drafts of any letters to respondents, PIs or regulatory agencies. The MRC will be responsible for the secure and confidential maintenance of all documents related to inquiries and investigations of non-compliance.

IACUC CHAIR AND ATTENDING VETERINARIAN (AV)

The IACUC Chair and, when appropriate, AV must determine the accuracy of the allegations at the initial inquiry through an evaluation of the initial evidence. The Institutional Office (IO) shall appoint a backup in situations where the Chair is unable to lead the inquiry and/or investigation or if the Chair

has a conflict of interest. The Chair and, when appropriate, AV are responsible for determining if the allegation is unsubstantiated, minor or serious/continuous during the investigation. Letters to respondents and PIs will be signed by the IACUC Chair. The Chair and/or AV are permitted to take immediate action to ensure animal welfare in instances where there is a significant risk of harm to the animals.

INSTITUTIONAL OFFICIAL (IO)

The IO will submit written reports to regulatory and/or funding agencies, if applicable.

THE IACUC

If, following the investigation, the IACUC Chair and, when appropriate, AV determine that the allegation meets the definition of non-compliance and can be substantiated, the IACUC will be convened to review the information and determine if the non-compliance is serious and/or continuous.

The IACUC, IACUC Chair, and /or AV should make direct observations of the animals to determine risk of harm to animals and/or personnel as needed throughout the process.

3.0 PROCEDURES

Throughout the procedures, the MRC may offer options for anonymity, but should inform the complainant that complete or sustained anonymity may not be possible given due process considerations. The IACUC and IACUC Chair should take appropriate interim actions to protect the rights of both the complainant and respondent so that neither is prejudiced in future proceedings.

Any documents distributed to respondent and/or PIs throughout the process should include a reminder that there can be no actions that are, or could be perceived as, retaliatory against a person who has raised this allegation, is thought to have raised an allegation, those investigating the allegation, or witnesses.

During this process, rights of the respondent include:

- The right to be informed of the allegations of non-compliance.
- The right to receive and review all evidence put forward in support of the allegations, to challenge the evidence and to provide alternative interpretations of it, and to put forward evidence in defense against the allegations.
- The right to have the allegations of the complainant and the responses of the respondent heard and decided by [an] impartial and fair decision maker/s, and based solely on evidence included in the proceedings.
- The right to assistance from counsel or another adviser if necessary.
- The right to an appeal.

A. REPORTING NON-COMPLIANCE

Each laboratory shall conspicuously post phone numbers, email addresses and office locations for reporting of complaints and violations in all animal facilities. Such information must also be included on the NKU IACUC web site for easy public access. Contact information will be provided for the MRC

and IACUC chair.

Incidences of potential animal research non-compliance may be reported by a third party, a researcher self-report, or discovered and reported during an IACUC post approval monitoring visit or semi-annual inspection. Allegations or self-reports of non-compliance should be reported directly to the Office of Research, Grants and Contracts, MRC, Institutional Official (IO), IACUC Chair or anonymously through the Research Compliance hotline. Reports made to individuals not listed here should contact the MRC as soon as reasonably possible and be advised of procedures in Part 3B.

B. ALLEGATIONS AND INTAKE

Any person who receives an allegation or self-report of non-compliance related to IACUC-approved activities should quickly relay the allegation to the MRC. During intake of the allegation, the MRC should document the following information if possible:

- the time, date, and location of the alleged incident;
- a complete description of the event(s) as provided by the complainant;
- any relevant background that concerns the incident;
- the complainant's name, position, and relationship to the institution;
- the time and date that the allegation was reported;
- contact information for any individuals who were involved.

The MRC will serve as the coordinator throughout the initial inquiry and, if applicable, investigation. The MRC will ensure proper documentation and assist in ensuring that timelines are met. After receiving and documenting the report/allegation, the MRC will inform the IACUC Chair.

C. INITIAL INQUIRY

PURPOSE

The purpose of the initial inquiry is to determine if the allegation meets the definition of IACUC non-compliance or if additional information is needed.

TIMELINE

All reasonable efforts will be made to complete initial inquiries within twenty (20) business days of receipt of the allegation. The entire IACUC will be informed of all allegations of non-compliance at the next IACUC meeting or sooner if deemed necessary.

PROCEDURES

1. The IACUC Chair and, when appropriate, the AV will conduct an initial inquiry into allegations or reports of non-compliance to determine if the allegation meets the definition of IACUC non-compliance. If additional information is needed to make the determination, the Chair may contact the complainant. If additional information cannot be obtained (e.g. anonymous report), the Chair should notify the MRC for documentation purposes and no further action is required. If the allegation does not meet the definition of non-compliance, the IACUC Chair

should inform the MRC and respondent if previously notified. If the allegation does not meet the definition of non-compliance the inquiry ends.

- a. Minor non-compliance issues that are unrelated to significant risk to animal welfare, if possible, should be handled by protocol amendments, retraining or other appropriate mitigation steps. A brief examination may identify easily rectifiable problems or find the absence of non-compliance.
2. Within five (5) business days of the IACUC Chair's receipt of the allegation, the respondent, and PI if appropriate, will be notified by the Chair that an allegation of non-compliance has been lodged against them and that an initial inquiry is being conducted to determine if the allegation merits a full investigation. At this time the respondent will be informed of the nature of the complaint and the Chair will request a written response from the respondent. The PI response will be returned to the IACUC Chair within ten (10) business days after notification by the chair.
3. After reviewing the written response from the respondent, the Chair or the Chair and the AV will determine if a formal investigation is warranted within five (5) business days after receiving the PI's response.
4. If the allegation meets the definition of non-compliance and cannot be easily rectified, an investigation will be initiated.
 - a. If initiated, the IACUC chair will notify the respondent, and PI if appropriate, that a decision was made to conduct an investigation. The Institutional Official (IO), respondent's Dean, and the Department Chair (or equivalent), and complainant (if possible) will also be informed within ten (10) business days of determining that an investigation is warranted.
5. If a formal investigation is not warranted, the respondent and the IACUC Chair will create a plan to rectify the issue if appropriate. The IACUC Chair will notify the IACUC at the next meeting or via email, notify the MRC and complainant (if possible).

D. INVESTIGATION

PURPOSE

The purpose of the investigation is to determine if the allegation is:

- substantiated
- minor
- serious non-compliance
- continuous non-compliance.

TIMELINE

All reasonable efforts will be made to complete the investigation within forty (40) business days of determining that one is warranted. The entire IACUC will be informed of all allegations of non-compliance at the next scheduled IACUC meeting or sooner if necessary.

PROCEDURES

1. The IACUC Chair and, when appropriate, the AV will investigate allegations or reports of non-compliance following the initial inquiry. The IACUC Chair may appoint a subcommittee if necessary. These additional members may consist of IACUC members with expertise

appropriate for review of the alleged non-compliance including, veterinarians; Research, Grants and Contracts staff or others with expertise relevant to the situation. Individuals investigating the allegation will meet as necessary to ensure a timely review of it.

2. Individuals conducting the investigation:
 - a. May interview or request written responses from witnesses of alleged non-compliance and/or the researcher/PI whose animal use and care has been alleged to be in non-compliance.
 - b. May audit research records or medical records.
 - c. Will consider materials and recommendations from the initial inquiry, the respondent's reply, and other information relevant to the investigation (e.g., interviews, audit reports, literature researches, etc.).
 - d. Will create a summary report that includes the allegation, information considered during the investigation, conclusions and recommendations. This report will be presented to the IACUC at the next convened meeting.
3. The investigation should be completed within forty (40) business days of determining that an investigation is warranted. All evidence that is gathered should be provided to the respondent (draft report) with the opportunity to review and comment on or to provide additional documentation.
4. Upon receipt of the draft report, the respondent will be requested to submit a written reply to facilitate the investigation. This reply should be returned to the IACUC Chair within ten (10) business days of receiving the draft report.

E. DETERMINATION AT INVESTIGATION STAGE

After receiving the written response from the respondent, the IACUC Chair or the IACUC Chair and AV will make one of three determinations:

1. Unsubstantiated – There is no evidence to support the concern or complaint of animal welfare breaches or serious risk thereof. When further investigation or convened IACUC review is not warranted (e.g. dismissal of the allegation or referred to other University process) the incident will be considered resolved. The MRC, respondent/PI, IO, Dean, Department Chair and complainant (if possible) will be notified in writing. The IACUC will be informed of all allegations and outcomes of the inquiry at the next convened meeting and a record of the investigation will be filed with Research, Grants and Contracts (RGC).
2. Minor non-compliance – The complaint is valid; however, no additional action is needed after correction and mitigation steps have been implemented (see Section F).
3. If the allegation is substantiated and not minor, the IACUC will be convened (see section G).

As situations vary considerably, determinations are made on a case-by-case basis based on the totality of the circumstances, including self-reporting, voluntary corrective actions and any other relevant considerations. State of mind – knowing, reckless and intentional – is an important part of consideration in determining whether the non-compliance or protocol violations constitute misconduct and appropriate sanctions.

F. MINOR NON-COMPLIANCE

1. The IACUC Chair and respondent and/or PI will create a plan to rectify the issue which includes a written response regarding how the incident occurred, how it was corrected and how it will be prevented in the future.
2. Corrective action(s) will be based on the nature of the non-compliance, the extent to which animals were placed at risk, occurrence of previous non-compliance, etc. The range of possible corrective actions that the Chair, AV, others involved in the investigation or IACUC may consider includes but is not limited to:
 - Modification(s) of the animal use protocol through amendments initiated by the PI.
 - Monitoring of animal use activity (including audits or assessments of technical abilities).
 - Education or training for the PI and/or research staff.
 - Confirmation of receipt of required materials (e.g., drugs or equipment).
 - Additional reporting (e.g., more frequent review).
 - Limitations on research activities or use of IACUC-monitored research facilities.
3. At any point, the minor non-compliance may be reclassified as significant if necessary. If reclassified, it may trigger actions associated with significant non-compliance.
4. The MRC, respondent/PI, IO, Dean, Department Chair and complainant (if possible) will be notified.

G. CONVENED IACUC REVIEW

PROCEDURES OF SIGNIFICANT NON-COMPLIANCE

1. The allegation of non-compliance will be presented to the committee at a convened IACUC meeting. The meeting must contain a quorum of members (one more than half of the IACUC member count). The IACUC meeting must be held within thirty (30) business days of determining significant non-compliance.
2. Information from the initial inquiry, summary report from the investigation, the respondent and/or PI's response (if any) and any other relevant materials (e.g., research protocol, medical or facility records, occurrence of previous non-compliance, etc.) will be distributed to all members in advance of the meeting.
3. During the meeting, the IACUC will:
 - a. Review any past history of serious non-compliance by the respondent and/or PI if applicable.
 - b. Discuss mitigating factors. For example, the IACUC should consider evidence of self-identification and self-correction of non-compliance by a PI and/or researcher as evidence of the respondent's intentions.
 - c. Discuss and deliberate the issue.
4. Following discussion/deliberation, the IACUC will determine:
 - a. if the non-compliance is:
 - i. Serious and/or
 - ii. Continuous;
 - b. a corrective action plan and/or

- c. if sanctions are needed.
 - i. If protocol suspension is recommended, a vote must be conducted.

PROTOCOL SUSPENSION DUE TO SIGNIFICANT NON-COMPLIANCE

1. If an occurrence of non-compliance has a significant and immediate negative impact on animal welfare, the IACUC Chair and/or AV has the authority to immediately stop all procedures necessary to protect the health and welfare of the animals.
2. If the IACUC votes for protocol suspension, all procedures and ordering privileges encompassed by that protocol must cease during the period of suspension.
3. If a protocol is suspended, the IACUC Chair will send a letter to the respondent and/or the PI, his/her department Chair and their Dean as soon as possible. The respondent must respond in writing to the corrective action plan laid out by the IACUC (see section 3.0 G.4) .
4. The respondent and/or PI may be asked to meet with the IACUC, the IACUC Chair and, if appropriate, the Institutional Official as a condition of reinstatement.

A majority vote of the IACUC with a quorum present, in consultation with the IO, may lift a suspension only after it has been determined that the protocol's activities can be accomplished in full compliance with the relevant rules and regulations and that adequate measures have been taken to prevent recurrence of the non-compliant activity.

H. FINAL DECISION AND NOTIFICATION

1. All reasonable efforts will be made to notify the respondent and/or PI in writing within five (5) business days of the decision of the IACUC. Notification will also be sent to the respondent/PI, IO, Dean, Department Chair, MRC and complainant (if possible) within five (5) business days of the decision of the IACUC.
2. If the respondent/PI does not request an appeal, the IACUC Chair creates the final report and distributes to the respondent/PI within ten (10) business days of the final decision made by the IACUC and requests a written response from the respondent/PI due within ten (10) business days of the final decision.
3. The IACUC and/or Chair review the respondent/PI's response to the corrective action and approve or disapprove.
4. The IACUC Chair follows up on corrective action as needed or reinstates the protocol if suspended by the IACUC (quorum vote required).

I. APPEAL

1. The respondent and/or PI will have ten (10) business days to appeal the IACUC decision in writing.
2. The appeal will be brought forth to the IACUC in a convened meeting within ten (10) business days of receiving the appeal. The respondent and/or PI may be invited to attend or request to speak.
3. The IACUC will make the final decision regarding the appeal.
4. The respondent and/or PI will be notified within five (5) business days of the final decision of the appeal.
5. If the appeal is upheld, the IACUC will determine if the issue is minor and create a plan to

rectify during the appeal meeting (see Section F).

6. If the appeal is denied, the IACUC Chair creates the final report and distributes to the respondent/PI within ten (10) business days of the appeal decision made by the IACUC and requests a written response from the respondent/PI due within ten (10) business days of the final decision.
7. The IACUC and/or Chair review the respondent/PI's response to the corrective action and approve or disapprove.
8. The Chair follows up on corrective action as needed or reinstates the protocol if suspended by the IACUC (quorum vote required).
9. When approval of animal use activities is suspended, the reason(s) will be communicated to the respondent and/or PIs and their department heads, along with any corrective actions required to ensure future compliance with the regulations. Other University committees, such as Institutional Biosafety or Radiation Safety Committees, responsible for oversight of the PI's research will also be notified, if applicable.

J. REPORTS

1. Final decisions on non-compliance will be provided in a written report to the respondent. Any inconclusive or questionable aspects of the investigation should not be included in these reports.
 - a. The report should include a summary of the concern or allegation, the condition of animals and their environment, results of interviews and results of a review of animal records and documents, together with any additional supporting documents; such as correspondence, reports and research records.
2. Federal Reporting of Non-Compliance - Incidents of significant non-compliance that are deemed serious or continuing, or represent a serious deviation from the provisions of the Guide, including suspensions, will require reporting to the OLAW (Office of Laboratory Animal Welfare) through the Institutional Official and may be reported to the federal funding agency supporting the activity.
3. If not previously reported to regulatory agencies, any suspension or termination of IACUC approval or non-compliance that is determined to be serious or continuing will be reported by RGC followed by a written report from the IO if required.

K. RECORDS RETENTION

- Records of non-compliance claims that substantiate serious or continuing non-compliance with the Public Health Service (PHS) policy or the Guide should be kept in full and should be secured and identified with a code or other method of masking identities in all records, minutes and reports in the Office of Research, Grants and Contacts.
- Inquiry, Fact Finding Records – Typically not available under open records acts. These records should be kept for a minimum of 3 years or for the duration of a protocol plus 3 years.
- Unsubstantiated claims or those that describe neither serious nor continuing threats to the welfare of animals should be expunged.

- If a report has been made to OLAW and later found to be unsubstantiated, a formal retraction by the IO should be followed by expunging the records of the institution and IACUC.

4.0 REFERENCES

Article
OLAW

5.0 FORMS OR ATTACHMENTS

Conflict of Interest
Timeline Tracking

6.0 DEFINITIONS

Examples of significant non-compliance include, but are not limited to:

- Acquiring animals for research or performing unapproved procedures without the IACUC approval.
- Performing a procedure in such a manner that animals endure pain or suffering that is not addressed by the approved protocol.
- Willful acts of abuse.
- Performing a procedure with improper technique or safeguards which puts either the staff or animals at risk.
- Failure to adhere to proper aseptic technique for survival surgery.
- Repeated or willful incidents of minor non-compliance.
- Failure to provide adequate anesthesia or analgesia according to protocol.
- Housing conditions outside of Office of Laboratory Animal Welfare (OLAW) standards or approved protocol description.
- Food or water levels in home cages outside of OLAW standards or approved protocol description.
- Overcrowding as defined by NKU IACUC Policy IR #1 or beyond approved protocol description.
- Failure to separate aggressive animals as required.

Examples of minor non-compliance include, but are not limited to:

- Not informing the IACUC of the addition of personnel.
- Not maintaining surgical and post-operative care records per IACUC policy and/or protocol requirements.
- Failure to respond to a corrective health concern and address the problem or failure to monitor the animals adequately following invasive procedures.
- Use of an unapproved procedure area resulting in failure of the IACUC to inspect this area as required by law or policy.
- Personnel not completing training within the required time frame or maintaining updated occupational health forms.
- Personnel accessing facilities without authorization.
- Inadequate controlled substance logs or controlled substance storage.
- Unapproved transfer of animals from one protocol to another.

- Housing animals in an approved satellite site beyond the time limit approved in the protocol.
- Minor protocol deviation which does not significantly compromise animal welfare.

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	02/15/2022	<input type="checkbox"/>
IACUC Chair	<input checked="" type="checkbox"/>	02/15/2022	<input type="checkbox"/>
NKU, General Counsel	<input checked="" type="checkbox"/>	09/14/2021	<input type="checkbox"/>
Institutional Official	<input checked="" type="checkbox"/>	03/22/2022	<input type="checkbox"/>