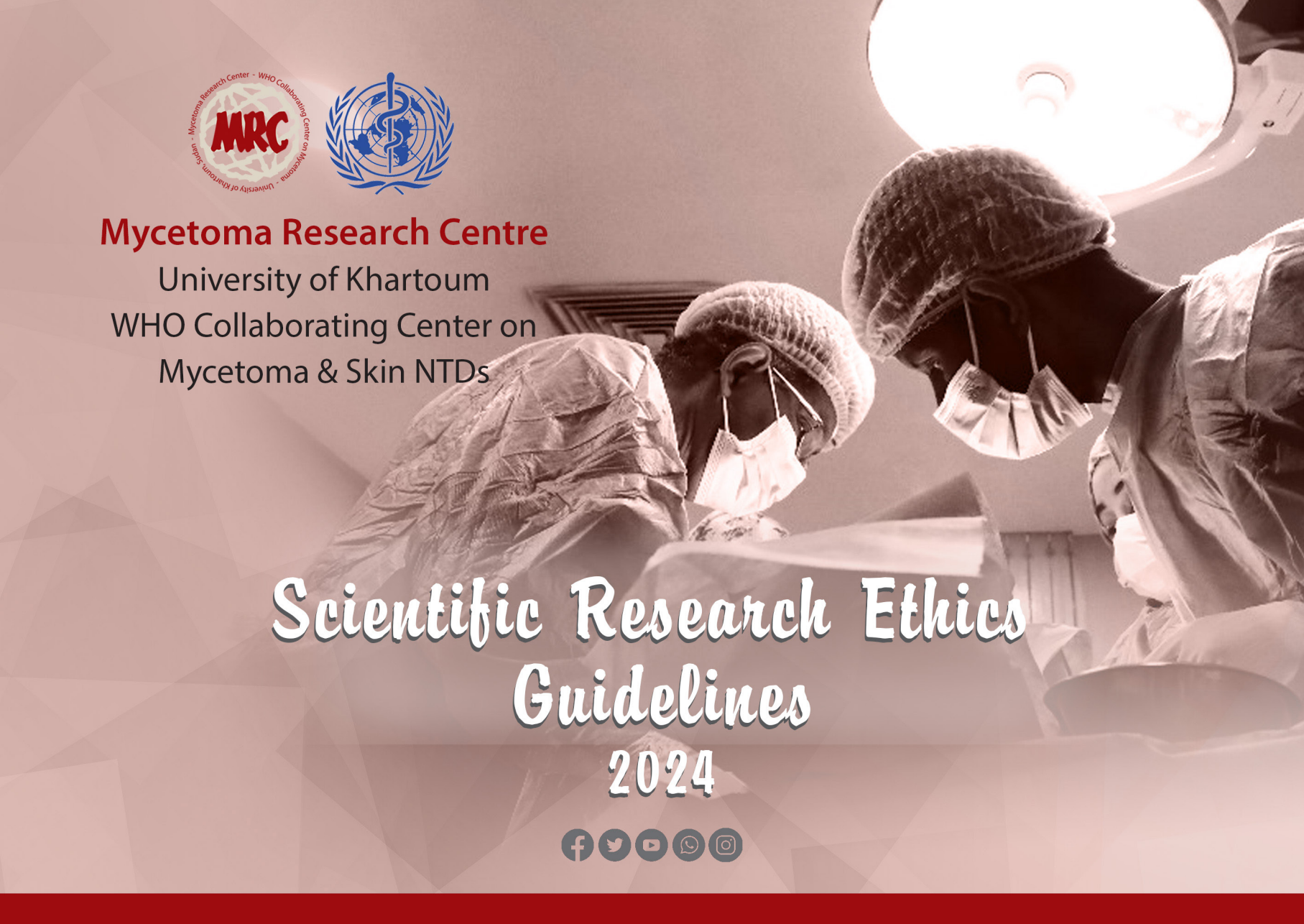

Mycetoma Research Centre

University of Khartoum

WHO Collaborating Center on

Mycetoma & Skin NTDs

Scientific Research Ethics Guidelines

2024

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Background

At the Mycetoma Research Centre, our dedication to advancing knowledge and tackling significant health challenges is deeply ingrained in conscientious and accountable research practices. Fundamental to our scientific pursuits is an unyielding commitment to the principles of research ethics. We understand that ethical behaviour extends beyond mere adherence to regulations; it forms an essential foundation for conducting research that benefits society. By firmly grounding our research in these principles, we aim to make substantive contributions to both the scientific community and broader society.

The anticipated outcome of adhering to these guidelines is the fostering of a culture of ethical research within the Mycetoma Research Centre. This will result in enhanced research practices, positively impacting the caliber of our publications and solidifying our institution's position as a leader in scientific rigor and ethical standards. As researchers embrace these principles, they actively contribute to nurturing an environment characterised by integrity, transparency, and accountability, thereby reinforcing our commitment to advancing knowledge for the betterment of society. The implementation of these policies and procedures is expected to cultivate a culture of ethical research at the Mycetoma Research Centre, leading to improved research practices and positively influencing the quality of our publications. This, in turn, establishes our institution as a frontrunner in both scientific precision and ethical excellence.

The Guidelines Justifications

The guidelines are meticulously crafted to address the following justifications.

Credibility and Reliability

- Ensuring the credibility and reliability of research outcomes is paramount for upholding the scientific rigour of the Mycetoma Research Centre's work.

Responsible Research Practices:

- Researchers are expected to adhere to principles of honesty, integrity, transparency, and accountability at all stages of the research process. This includes the design, implementation, analysis, and dissemination of research findings.
- Clear documentation of research methodologies, data collection processes, and analytical techniques must be maintained to facilitate transparency and reproducibility.

Participant Rights and Well-being:

- Researchers must prioritise the protection of the rights and well-being of research participants.
- Informed consent procedures must be meticulously followed, ensuring participants are fully informed about the research purpose, procedures, and potential risks.
- Ethical considerations should guide the recruitment, treatment, and follow-up of research participants, with due respect for their autonomy and dignity.

Public Trust:

- Upholding public trust is fundamental to the Mycetoma Research Centre's mission.
- Researchers must ensure that their conduct aligns with ethical standards, maintaining transparency in all communication and collaboration with the public, stakeholders, and collaborators.
- Any potential conflicts of interest must be disclosed promptly to maintain the trust of all stakeholders.

The Mycetoma Research Center Research Ethics Policies and Procedures

The Mycetoma Research Centre is steadfast in its commitment to conducting research with the utmost integrity, responsibility, and ethical consideration. These research ethics policies and procedures are designed to provide a comprehensive framework that ensures all research activities align with the highest standards of scientific integrity and ethical conduct.

Responsible Research Practices Policies

Researchers at the Mycetoma Research Centre are expected to adhere unwaveringly to the principles of honesty, integrity, transparency, and accountability throughout the research process. These principles serve as the foundation for ethical decision-making in various research contexts.

The documentation of research methodologies, data collection processes, and analytical techniques is essential, promoting transparency and reproducibility in our scientific endeavours.

Procedures for Responsible Research Practices Policies

These procedures aim to ensure that researchers at the Mycetoma Research Centre consistently uphold responsible research practices, fostering a culture of ethical conduct and contributing to the credibility and impact of our scientific endeavours. These include:

- Create a good research proposal by clearly defining the research objectives, hypotheses, and methodologies during the planning phase.
- Conduct a thorough literature review to inform study design and ensure alignment with existing knowledge.
- Submit the research proposal to the scientific committee for approval.

Biological Material and Data Collection and Transfer Procedures

Biological Material Collection

Ethical Approval and Informed Consent

Obtain ethical approval from the Institutional Review Board (IRB) or relevant ethical committee before initiating any biological material collection.

Ensure that participants provide informed written consent before the collection of any biological samples.

Standardised Collection Procedures

Develop and implement standardised protocols for the collection of biological materials, specifying techniques, equipment, and storage conditions.

Provide thorough training to personnel involved in sample collection to maintain consistency and minimise variability.

Participant Privacy and Confidentiality

Safeguard participant privacy during the collection process, ensuring that sensitive information is kept confidential.

Implement coding systems to anonymise samples while maintaining a secure link between the sample and participant data.

Quality Control Measures

Implement quality control measures to ensure the integrity of collected biological materials.

Regularly monitor and assess the condition and viability of collected samples.

Chain of Custody Documentation

Establish a comprehensive chain of custody documentation system to track the handling and transfer of biological samples from collection to storage.

Ensure that all personnel involved in the process are trained to maintain the chain of custody.

Biological Material Storage

Secure Storage Facilities

Store biological materials in designated and secure facilities, equipped with appropriate temperature controls and monitoring systems.

Implement access controls and security measures to prevent unauthorised access to stored materials.

Inventory Management

Maintain an accurate and up-to-date inventory of all stored biological materials.

Implement a labelling system to clearly identify samples and link them to relevant participant and research data.

Periodic Audits and Monitoring

Conduct periodic audits of biological material storage facilities to ensure compliance with storage protocols and regulations.

Monitor storage conditions regularly and address any deviations promptly.

Biological Material Transfer Protocol

Key Points	Details
Purpose of Transfer	Define the purpose of the transfer, including research objectives and experiments.
Material Identification	Specify the biological material's species, strain, genetic modifications, and characteristics.
Regulatory Compliance	Comply with applicable regulations, permits, licenses, and ethical approvals.
Packaging and Labeling	Use appropriate packaging and labeling to ensure safety and integrity during transit.
Documentation	Prepare detailed documentation, including MTAs, certificates, and safety information.
Shipping and Handling	Select suitable shipping methods and provide handling instructions.
Recipient Responsibilities	Ensure the recipient is trained and capable of handling the material responsibly.
Communication	Establish clear communication channels between sender and recipient.
Follow-up	Monitor progress, provide support, and ensure proper disposal or return of materials.

Data Collection Procedures

Data Collection

Informed Consent for Data Collection

Obtain informed consent specifically for the collection, use, and storage of participant data.

Clearly communicate the purpose, scope, and potential risks associated with data collection to participants.

Secure Data Collection Methods

Implement secure and encrypted data collection methods to protect participant information.

Train data collectors on best practices for maintaining data integrity and confidentiality.

Data Quality Control

Implement data quality control measures to minimise errors and ensure the accuracy and completeness of collected data.

Regularly conduct internal audits to identify and rectify any discrepancies in the collected data.

Secure Data Transfer Protocols

Establish secure protocols for the transfer of research data, including encryption and secure file transfer methods.

Clearly define roles and responsibilities for personnel involved in the transfer process.

Data Transfer Documentation

Maintain detailed documentation of all data transfers, including a log of transferred materials, associated data, and recipient information.

Implement verification mechanisms to confirm the successful and secure transfer of data.

Compliance with Data Protection Regulations

Ensure compliance with data protection regulations and standards during the transfer of participant data.

Seek legal advice to address any international data transfer requirements or restrictions.

Record-keeping and Documentation

Comprehensive Documentation

Maintain comprehensive records for all aspects of biological material and data collection and transfer.

Document procedures, protocols, approvals, and any incidents or deviations from established protocols.

Retention of Records

Establish a systematic record retention policy, specifying the duration for which records must be retained after the conclusion of the research project.

Comply with regulatory requirements regarding the retention and disposal of biological materials and data.

Researchers Adherence to Ethical Principles

Researchers at the Mycetoma Research Centre are required to familiarise themselves with and adhere unwaveringly to the principles of honesty, integrity, transparency, and accountability throughout the entire research process. These principles are the bedrock of ethical decision-making and should guide researchers in all aspects of their work.

Ethical Decision-Making Training

All researchers must undergo specialised training in ethical decision-making, emphasising the application of principles like honesty, integrity, transparency, and accountability in diverse research contexts. This training is mandatory for all researchers before commencing any research activities.


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Documentation of Research Methodologies

Researchers are obligated to document all research methodologies employed in their studies thoroughly. This documentation includes detailed descriptions of experimental designs, sampling methods, and any deviations from the original plan. The purpose is to provide clarity on the research process, allowing for a comprehensive understanding and assessment of the study's validity.

Data Collection Processes Documentation

Comprehensive documentation of data collection processes is essential. Researchers must record the tools, instruments, or technologies used, as well as the procedures followed during data collection. This documentation ensures the transparency of the research process and allows for the replication of the study by other researchers.

Analytical Techniques Documentation

Researchers are required to document the analytical techniques employed in the study. This documentation should include details about statistical methods, software used, and any adjustments made during the analysis. Transparent documentation of analytical processes promotes reproducibility and facilitates the scientific community's scrutiny of results.

Regular Review and Verification

The Mycetoma Research Centre has established a systematic review process to ensure researchers' compliance with responsible research practices. Regular audits and verification procedures are conducted to assess the accuracy and completeness of documentation related to research methodologies, data collection, and analytical techniques.

Research Integrity Committee

A Research Integrity Committee was established to oversee and enforce responsible research practices. This committee is responsible for reviewing any concerns or allegations related to ethical breaches ensuring fair and impartial investigations.

Continuous Training and Professional Development

Researchers should engage in continuous training and professional development opportunities to stay abreast of evolving scientific and ethical considerations and standards. This ongoing education aims to reinforce the importance of responsible research practices and provide researchers with the tools to navigate ethical challenges effectively.

Sanctions for Non-Compliance

Non-compliance with responsible research practices may lead to sanctions, ranging from corrective actions and additional training to more severe consequences, depending on the severity and frequency of ethical breaches. The Research Integrity Committee will determine these sanctions.

Transparency and Reproducibility Advocacy

Researchers are encouraged to actively promote transparency and reproducibility in their work and within the scientific community. This advocacy extends to sharing research methodologies, data collection processes, and analytical techniques in a manner that facilitates collaboration, peer review, and the advancement of scientific knowledge.

Research Ethics Training & Continuing Development Policies

A commitment to fostering a culture of ethical research is embedded in our approach to learning. Researchers are mandated to undergo comprehensive training in scientific research ethics. This training encompasses active engagement in discussions, interactive activities, and reflective exercises to deepen understanding and develop practical skills that seamlessly integrate into research activities.

Researchers are encouraged to pursue ongoing educational opportunities and professional development in research ethics, ensuring that they stay well-informed of emerging ethical considerations and standards.

Procedures for Research Ethics Training and Continuing Development Policies

By implementing and adhering to these procedures, our organisation aims to create a community of researchers committed to ethical research practices and continuous learning in the evolving field of research ethics.

Mandatory Initial Training

All researchers must undergo mandatory training in scientific research ethics upon joining the organisation. The training will cover foundational principles, relevant regulations, and ethical considerations applicable to the specific field of research.

Training Format

Training sessions will be conducted in a variety of formats, including workshops, seminars, and online modules.

Sessions will involve active engagement through discussions, interactive activities, and reflective exercises to deepen understanding and develop practical skills.


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Frequency of Training

Researchers are required to undergo refresher training regularly to stay updated on evolving ethical standards and considerations.

Additional training may be required in response to significant changes in regulations or ethical guidelines.

Documentation

Records of completed training sessions, including dates and content, will be maintained for each researcher.

Researchers are responsible for keeping track of their training records and ensuring timely completion of required refresher courses.

Monitoring and Compliance

Compliance with the mandatory training policy will be monitored regularly.

Non-compliance may result in consequences, such as restricted access to research facilities or projects until the required training is completed.

Encouragement

Researchers are encouraged to actively seek ongoing educational opportunities and professional development related to research ethics. This may include attending conferences, workshops, webinars, and enrolling in relevant courses.

Financial Support

The Center provides financial support for researchers to attend conferences, workshops, or courses focused on research ethics.

Requests for financial support should be submitted with a clear justification and potential benefits to the researcher's work.

Documentation of Continuous Learning

Researchers are required to document their continuous learning activities, including dates, topics, and outcomes.

Integration into Performance Evaluations

Participation in continuous learning activities will be considered a positive factor during performance evaluations.

Demonstrated commitment to ongoing education and professional development in research ethics will be recognised and rewarded.

Information Sharing

Researchers are encouraged to share insights and knowledge gained from continuing development with their colleagues, contributing to a collaborative and informed research community.


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Participant Rights and Well-being Policies

Ensuring the rights and welfare of research participants is of utmost importance. Researchers should place a high emphasis on securing informed consent and guaranteeing that participants have a comprehensive understanding of the research objectives, methods, and possible hazards. Ethical principles direct the recruitment, treatment, and ongoing care of research subjects, underscoring a dedication to respecting their autonomy and preserving their dignity.

Procedures for Participant Rights and Well-being Policies

By adhering to these Participant Rights and Well-being procedures, our organisation aims to ensure the ethical conduct of research, prioritising the protection of participants and upholding their rights and well-being throughout the research process.

Informed Consent

Prior to participation, researchers must obtain written informed consent from each participant, ensuring comprehension and voluntariness.

Informed consent forms will clearly outline the research purpose, procedures, potential risks, benefits, and the right to withdraw at any time without consequence.

Ethical Recruitment

Recruitment methods will be fair, transparent and avoid any form of coercion or undue influence.

Recruitment materials will accurately represent the nature and purpose of the research to potential participants.

Participant Information

Participants will be provided with comprehensive information about the research, including its goals, procedures, potential risks, and expected duration, in a language and format understandable to them.

Researchers will be available to answer participants' questions and address concerns throughout their involvement in the research.

Autonomy and Dignity

Researchers will uphold the autonomy and dignity of participants throughout the research process.

Participants will be treated respectfully, and their cultural and individual values will be acknowledged and considered in the research design and interactions.

Minimisation of Risks

Researchers will take measures to minimise risks to participants, ensuring that the scientific and societal benefits of the research justify any potential harm.

Continuous monitoring of participant well-being will be conducted, and appropriate actions will be taken if any adverse effects are identified.

Confidentiality

Researchers will implement strict confidentiality measures to protect participants' privacy.

Identifiable participant information will be securely stored and disclosed only as required by law or with explicit participant consent.

Right to Withdraw

Participants have the right to withdraw from the research at any stage without facing negative consequences.

Researchers will provide clear instructions on how participants can withdraw and emphasise the ongoing respect for their decision.

Treatment and Follow-up

Participants will be treated with fairness, respect, and consideration for their well-being during all interactions related to the research.

Adequate follow-up procedures will be in place to address any lingering concerns or questions participants may have after the completion of the research.

Institutional Review Board Approval

All research protocols involving human participants must undergo ethical review and receive approval from an Institutional Review Board before initiation.

Any modifications to the research design or procedures that may affect participant rights and well-being will require subsequent ethical review and approval.

Procedures for Public Trust Policies

Public Trust policies

Maintaining public trust is integral to our mission. Researchers must maintain ethical conduct in all communications and collaborations with the public, stakeholders, and collaborators, fostering transparency at every stage of the research process.

Transparent disclosure of any potential conflicts of interest is mandatory, reinforcing trust among all stakeholders.

Procedures for Public Trust Policies

By observing these Public Trust Policies and implementing these procedures, our organisation aims to prioritise ethical conduct, foster transparency, and reinforce public trust in our research activities.

Ethical Communication Guidelines

Establish and communicate clear guidelines for ethical communication in all interactions with the public, stakeholders, and collaborators.

Train researchers and staff members on these guidelines to ensure a consistent and responsible approach to communication.

Transparency in Research Communication

Provide regular updates on research progress, methodologies, and findings through accessible channels such as websites, newsletters, and public presentations.

Clearly communicate the societal impact and implications of research, emphasising the organisation's commitment to transparency.

Collaboration with the Public

Encourage researchers to actively engage with the public through outreach programmes, educational initiatives, and community involvement.

Foster a culture of openness and responsiveness to public inquiries, concerns, and feedback.

Stakeholder Engagement

Identify key stakeholders and establish mechanisms for ongoing communication and collaboration.

Conduct regular meetings or forums to discuss research activities, address concerns, and gather input from stakeholders.

Conflict of Interest Disclosure

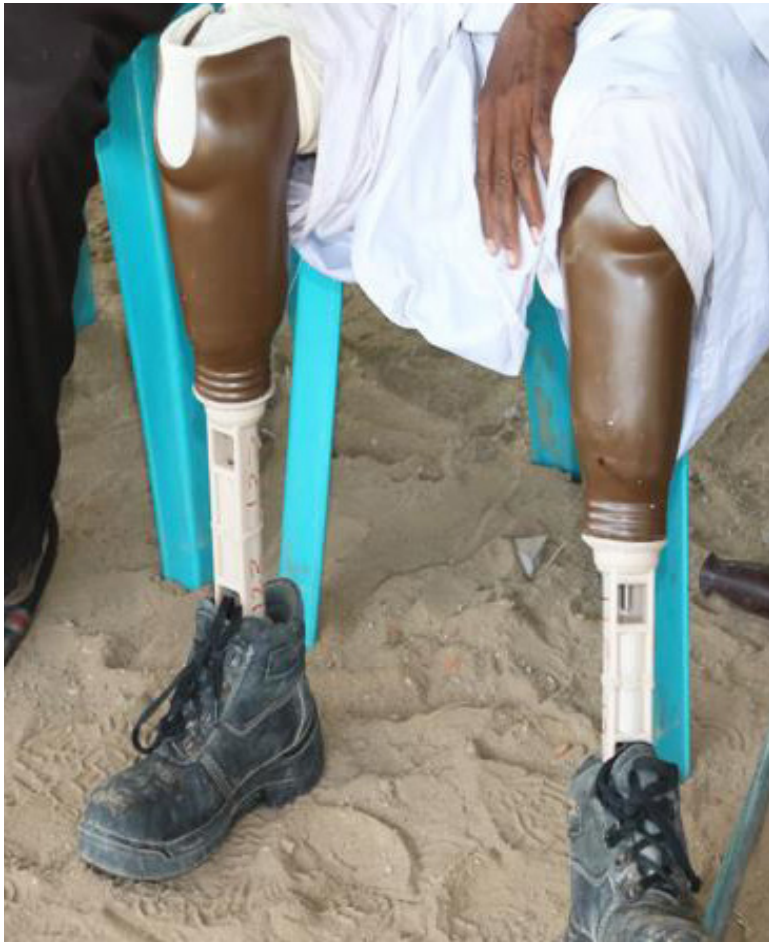
Implement a clear and comprehensive policy on the disclosure of potential conflicts of interest by researchers, staff, and collaborators.

Mandate the transparent disclosure of financial interests, professional relationships, or any other factors that could potentially influence the research process.

Review and Approval Process

Establish a review and approval process for potential conflicts of interest, involving an independent committee to assess the impact on research integrity and public trust.

Develop guidelines for managing conflicts of interest to mitigate any potential risks and maintain public confidence.



Documentation of Disclosures

Maintain records of all conflict of interest disclosures and the corresponding review and approval processes.

Ensure that these records are accessible for internal audits and external scrutiny to demonstrate transparency.

Communication of Conflicts of Interest

Clearly communicate any identified conflicts of interest to relevant stakeholders, including the public, in a timely and transparent manner.

Develop a communication plan outlining the steps taken to address conflicts and prevent their impact on the research process.

Training on Ethical Conduct

Incorporate ethical conduct and transparency training into the onboarding process for new researchers and staff members.

Provide regular refresher training to ensure that all members of the organisation remain informed about ethical standards and best practices.

Periodic Public Trust Audits

Conduct periodic assessments of public trust through surveys, focus groups, or other feedback mechanisms.

Use the findings to identify areas for improvement, adjust communication strategies, and reinforce ethical conduct within the organisation.

Continuing Improvement

Establish a continuing improvement process for the organisation's public trust policies, incorporating feedback from stakeholders and staying abreast of evolving ethical standards.

Regularly review and update policies to address emerging challenges and maintain a proactive approach to public trust.

Research Ethics Legal and Professional Standards Policies

Mycetoma Research Centre encourage researchers to adhere to all relevant legal and professional standards governing research ethics, thereby mitigating the risk of disciplinary action and potential legal consequences.

Procedures for Legal and Professional Standards in Research Ethics

Researchers must undergo regular training sessions to stay informed about the latest legal and professional standards governing research ethics.

Training programmes should cover applicable laws, regulations, and professional codes of conduct relevant to the research activities conducted at the Mycetoma Research Centre.

- **Documentation of Legal and Professional Requirements**

  Maintain an up-to-date repository of all relevant laws, regulations, and professional codes of conduct that apply to the Mycetoma Research Centre's research activities.

  Ensure that researchers have access to and are familiar with the documented legal and professional requirements.

- **Regular Legal Compliance Audits**

  Conduct periodic audits to assess researchers' compliance with legal and professional standards.

  Identify any potential areas of non-compliance and take corrective actions promptly.

- **Support Resources**

  Establish a dedicated support system to assist researchers in understanding and navigating legal and professional requirements.

  Provide access to legal counsel or experts to address specific queries or concerns related to research ethics.

- **Reporting Mechanism for Concerns**

  Establish a confidential reporting mechanism for researchers to raise concerns about potential legal or professional violations.

  Ensure that individuals reporting concerns are protected from retaliation and that all reports are thoroughly investigated.

- **Disciplinary Procedures**

  Clearly outline the disciplinary procedures that will be initiated in the event of violations of legal or professional standards.

  Ensure that the procedures are fair, transparent, and in accordance with employment laws and regulations.

- **Legal Support in Case of Allegations**

  In the event of legal allegations against a researcher, the Mycetoma Research Centre will provide legal support, including access to legal counsel.

  The legal team will work in coordination with the researcher to address the allegations and uphold their legal rights.

- **Continuous Monitoring and Updating**

  Regularly review and update these procedures to align with any changes in relevant legal and professional standards.

  Communicate updates to researchers promptly to ensure ongoing compliance.

- **Documentation**

  Maintain comprehensive records of training sessions, audit reports, legal and professional standards documentation, and all disciplinary actions taken.

- **Responsibility**

  The Institutional Review Board in collaboration with the Legal Department, is responsible for overseeing the implementation of these procedures, conducting audits, providing support resources, and ensuring continuous compliance with legal and professional standards. Researchers are individually accountable for understanding and adhering to these standards.

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