TMDA/DLS/POL/002

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR CONDUCTING RESEARCH

October, 2020

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ACKNOWLEDGEMENTS

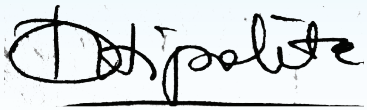
The first version of this document was developed under the then Tanzania Food and Drugs Authority (TFDA). However, following shift of control of food and cosmetics from TFDA to Tanzania Bureau of Standards (TBS) through the Miscellaneous Finance Bill No: 8 of 2019, Tanzania Medicines and Medical Devices Authority (TMDA) was established. Hence, this second version was developed to cater for the new Authority.

My sincere gratitude goes to the original contributors of the first version who were Dr. Adelard Mtenga, Dr. Yonah Hebron, Mr. Salum Kindoli, Dr. Joseph Mwashiuya, Ms. Catherine Luanda, Ms. Jeniva Jasson, Ms. Marcelina Mtalo and Ms. Oliva Andrew. They laid down the foundation for this reviewed version. Special thanks are also extended to Dr. Julius Ntwenya from University of Dodoma (UDOM) for providing technical expertise and experience.

For the development of this second version for TMDA, I am highly indebted to Dr. Gloria C. Omari for her experience and valuable time she devoted to review the first version. The job is well done.

Muhimbili University of Health and Allied Sciences (MUHAS), in Dar es Salaam, Sokoine University of Agriculture (SUA), in Morogoro and National Institute for Medical Research (NIMR) in Dar es Salaam are also acknowledged for making their research guidelines available for reference.

Last but not the least, TMDA Management is acknowledged for constructive comments and inputs during deliberation and approval of this document.



Dr. Danstan Hipolite Shewiyo
Director, Laboratory Services

ABBREVIATIONS

IPR	Intellectual Property Right
IRC	Institutional Review Committee
MoHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MoU	Memorandum of Understanding
TMDA	Tanzania Medicines and Medical Devices Authority
TMDA-RC	Tanzania Medicines and Medical Devices Authority – Review Committee
TMDCA	Tanzania Medicines and Medical Devices Authority Act, Cap 219
DG	Director General
TBS	Tanzania Bureau of Standard
M and E	Monitoring and Evaluating
KPI	Key Performance Indicators

FOREWORD

Tanzania Medicines and Medical Devices Authority (TMDA) is the regulatory authority under the Ministry of Health, Community Development, Gender, Elderly and Children responsible for regulating the quality, safety and efficacy of medicines, medical devices, diagnostics and other health related products. Its Mission is to *Protect and promote public health by ensuring quality safety and efficacy of medicine, medical devices, diagnostics and other health related products*.

In achieving its Mission and Vision, TMDA performs various functions including conducting researches related to the products it regulates. Such research provide findings that enable formulation of interventions and innovations that contribute towards research-based regulatory decisions. In this regard, it is important that researches on areas relevant to TMDA functions are carried out in an organized; scientifically sound manner and abiding to Authority's guidance to enable collection of credible data that can be interpreted to useful information.

For these reasons, this document was therefore developed and is organized into four (4) main parts. The first part covers the research policy which provides a framework to guide researchers on the whole business regarding research. The second part represents research focus areas derived from the five years Strategic Plan (*Revised Edition May, 2020*) for TMDA for 2017/18 - 2021/22. The third part covers strategies for implementation of research. The last part presents guidelines

governing research activities to be undertaken.

It is my anticipation that the document will guide and promote research undertakings at TMDA and/or in collaboration with stakeholders. TMDA staff are hereby encouraged to read, understand and follow this guidance document when looking for solutions to science based regulatory issues which aim to benefit the Authority and also to those that advance their careers. It is envisaged that research activities at TMDA will now increase and gradually contribute towards informed regulatory decision making.

Adam Mitangu Fimbo
Director General

INTRODUCTION

Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children, responsible for regulating safety, quality and effectiveness of medicines, medical devices and *in vitro* diagnostics. Section 14 subsection 2 (c) of The Tanzania Food and Drugs Authority Act of 2003 mandates the Authority to carry out research on matters related to the safety, quality and effectiveness of the regulated products.

Importance of research cannot be over emphasized owing to the increasing demands for regulatory authorities to respond to current and emerging health challenges such as introduction of gene therapy, genetically engineered products use of synthetic medicines, incidences of new and re-emerging diseases, complex product formulations, and authenticity of information in social media, falsified and substandard products. It is in this line that TMDA being a regulatory authority is equally affected in such a global trend.

This document has therefore been developed to guide research activities at TMDA in a manner that ensures effective and efficient regulatory functions towards achieving envisaged goal of promoting and protecting public health. It is the first TMDA research guide to be developed and formally embraced by the broader discipline of research. It creates conducive environment

that will facilitate undertaking of research activities within the areas of regulated products in order to cope up with the situation highlighted above.

The document narrates TMDA Research Policy that stresses Management commitment in promoting and supporting research and use of findings thereof in discharging its regulatory duties. Management commitment is crucial for the successful utilization of this guide. This document is an update of the previous version under TFDA and it also highlights research focus areas for the Authority that have been developed from the first version to call for research activities towards improvement of mechanisms for achieving Strategic Objectives as laid down in the current Strategic Plan for 2017/18 – 2021/22 from the then TFDA. Focus areas are important in order to streamline direction of researchers and allocation of resources for the benefit of the Authority and the country. Strategies to enhance such implementation of researches are provided for the purpose of achieving the envisaged research goals in a more structured way.

Other pertinent issues such as formation of TMDA Research Committee, Research approval procedure, handling of collaborative work, management of research funds, ethical considerations, intellectual property rights, dissemination of research findings, authorship of research work, research monitoring and evaluation, disposal of research resources and rewards are guided based on best common practices in research institutions. Appendices of

various forms and formats to capture all research activities are attached with in this document.

It is envisaged that this document will facilitate more coordination and enhancement of research efforts from research priorities of the individual TMDA staff, directorates, the Authority to the national initiatives; as well as those led by collaborators working with TMDA.

1. RESEARCH POLICY

Research policy is a commitment by the institution to the research undertakings that involve gathering of data or generating information and facts for the advancement of knowledge required to answer specific question(s).

TMDA Research Policy states that, '*TMDA Management is committed to facilitate research activities that contribute to the promotion and protection of public health by ensuring that regulated products are of acceptable quality, safety and effectiveness*".

1.1 TMDA Research Goal

To use research findings in ensuring that TMDA regulatory functions are effective and contribute towards achievement of Strategic Objectives with the aim to promote and protect public health.

1.2 Purpose

This document provides a framework for research undertakings at TMDA in order to strengthen, promote, engage and support regulatory processes.

1.3 Objectives

The overall objective is to keep up to date with the fast changing technological and socio-economic needs applicable to issues related to regulated products in order to ensure effective regulatory decisions.

1.4 Justification

There is a growing need for regulatory authorities to make decisions based on scientific evidence following growth in scientific innovation and increasing complexity in public needs. This is evidenced in cases such as the introduction of gene therapy, genetically engineered health, use of synthetic medicines, incidences of new and re- emerging diseases, complex product formulations, authenticity of information in social media, falsified and substandard products.

TMDA being a regulatory authority cannot avoid such a global trend. For these reasons TMDA must ensure that it creates conducive environment that will facilitate undertaking of research activities within the area of regulated products in order to cope up with the situation highlighted above. In doing so, TMDA will be meeting its moral obligation of promoting and protecting public health. This guiding document is instrumental in streamlining research activities at TMDA.

1.5 Scope

This document shall be applied in all research activities conducted by TMDA, or TMDA in collaboration with other institutions. This research policy, focus areas and strategies, shall be reviewed every five years or as need arises.

2. RESEARCH FOCUS AREAS

Research Focus Areas shall serve as guide through which various researches to be conducted will be aligned to. It defines study areas which, shall be periodically formulated in line with the TMDA Strategic Plan. In this document research focus areas have been derived from three (3) of the eight current Strategic Plan objectives which are;

a) Quality, safety and effectiveness of medicines, medical devices and in vitro diagnostics assured;
b) Laboratory services improved; and
c) Public education strengthened and customer services improved

Research areas that fall outside the institutional focus areas but relevant to core functions will be accommodated upon approval by the Director General. It is envisioned that TMDA shall continue to direct resources in research activities; it will also focus its research in areas of importance to generate sufficient evidence so as to contribute in making effective and efficient regulatory decisions.

2.1 Focus areas

Focus areas under each strategic objective are as follows;

2.1.1 Quality, safety and effectiveness of medicines, medical devices and in vitro diagnostics assured;

i. Increasing access to quality, safe and effective medicines, medical devices and *in vitro* diagnostics.

ii. Assessing the effectiveness and efficiency of the existing regulatory processes in assuring quality, safety and effectiveness of medicines, medical devices and diagnostics.

iii. Determining and recommend interventions measures for the risks associated with use of medicines, medical devices and in vitro diagnostics.

iv. Responding to emerging issues of public health concerns related to medicines, medical devices and *in vitro* diagnostics.

1.1.2 ***Laboratory services improved;***

i. Development and validation of analytical methods to assure the quality, safety and effectiveness of the regulated products.

ii. Determining competence and effectiveness of TMDA laboratories and quality assurance centers.

1.1.3 ***Public education strengthened and customer services improved;***

i. Raising public awareness, compliance and participation into TMDA regulatory activities.

ii. Improving service delivery mechanisms and customer satisfaction level.

3. STRATEGIES

A myriad of approaches will be utilized to execute research activities in an organized and effective manner.

3.1 Identification of sources of funds and resource mobilization

The source of funds for execution of TMDA functions are as stipulated in the Tanzania Medicines and Medical Devices Fee and Charges Regulations, 2015 and their subsequent amendments

The Authority shall thus apply part of these funds for the purposes of carrying out research to such capacity that is sustainable and as described in its annual business plan and budget. In addition to these sources of funds, the Authority shall solicit funds from funding organizations, development partners and private sectors. All research funds shall be managed as per approved Government procedures.

3.2 Engagement of relevant actors, stakeholders and end users

A relevance-based approach will be employed to identify and forge mutual beneficial partnership with stakeholders who are engaged in research. Networking and participation will be embraced to foster effective collaborations. As much as possible demand driven research will be thought of in the design of research studies in-line with the TMDA research focus areas. Depending on the national and global needs, emerging issues will be accommodated. There shall be an effective communication to allow sharing of research findings

and exchange of experience between and within the parties. It is envisaged that there shall be joint grant application, research management and publication where necessary.

3.3 Influencing policy and policy makers

TMDA shall conduct regular research findings dissemination workshops, to address public health concerns related to regulated products and inform the Government on the positive and critical role of research and the need for increased funding.

3.4 Communication, up-scaling and out-scaling

It is envisaged that research findings shall be properly communicated to relevant stakeholders and wherever required up-scaling and scaling down will be properly addressed. It is also important to enhance access of TMDA staff to reliable and current information. TMDA shall also establish a networking platform with other information resource centers and strengthen linkages with academic institutions, research institutions, private sectors, international organizations, relevant ministries and Government agencies.

4. RESEARCH GUIDELINES

Good practices in conducting research require any research to be preceded by development of research proposal before formal applications are made to the Management. Applications review and approvals shall follow standardized path to enhance transparency, fairness and ensure that only scientifically sound research ideas are executed to enable achievement of the envisaged outcome. From the reasons above, these guidelines have been developed.

4.1 Application to conduct research

4.1.1 Proposal Development

i. Any TMDA staff, a team, Section/Directorate or an individual from collaborating institution or an institution itself may develop a research proposal and ensure its completeness and scientific soundness. The applicant shall also be responsible for identifying possible source of funding and if already secured it should be indicated in the proposal.

ii. The proposal shall be developed as per format **(Appendix I)** or as prescribed by funding agency(s).

iii. The proposal shall be submitted to the approving organ through the respective Directorate.

4.1.2 Review and Approval

i. There shall be an Institutional Review Committee (IRC) that will be named as TMDA – Review committee (TMDA-RC) comprising of seven (7) members in which four (4) shall be TMDA staff and

3 from research/academic institutions.

ii. The members shall be appointed by the Director General (DG) on the basis of their academic qualifications and experiences in research work and shall include Director responsible for overseeing research activities at TMDA.

iii. The members shall elect a chairperson who shall preside in all committee meetings and the Director responsible for research shall be the Secretary.

iv. The TMDA-RC shall meet once every six (6) months or as need arises.

v. All research proposals shall be presented before the TMDA-RC. Subject to the nature of the proposal submitted, the Director responsible for research may co-opt a maximum of two (2) individuals to support the TMDA-RC.

vi. The TMDA-RC shall review all proposals and provide recommendation as per the checklist **(Appendix II)**. The TMDA-RC may also recommend on potential funding institution.

vii. In case the proposal needs minor improvement/ corrections in some areas, the Review Committee shall recommend approval with corrections.

viii. In case the proposal needs major improvements, the applicant shall make the necessary corrections and return the proposal within the timeframe prescribed by the Review Committee.

ix. If TMDA-RC is not satisfied with the proposal, it may recommend for rejection.

x. Recommendations from the TMDA-RC shall

be submitted to the DG through the directorate responsible for research using TMDA-RC Recommendation Submission Note **(Appendix III)**.

xi. The Director General upon receiving recommendations from the TMDA-RC may approve the proposal and notify the applicant in writing on the outcome of the review process within one month after the Review Committee meeting.

xii. Where TMDA or TMDA staff has a collaborative proposal which has been jointly developed and approved by a collaborating institution, the same shall be forwarded to TMDA-RC for noting.

4.1.3 Ethical Consideration

i. Where necessary, ethical clearance must be obtained from the respective body.

ii. The research shall not be allowed to commence until when ethical clearance has been obtained from the directorate responsible for research.

4.1.4 Registration of Research Proposal

All approved research proposals shall be duly registered in a prescribed format **(Appendix IV)** and issued with a proposal number with format: TMDA xx/DIR/QM/RP/zz, (where, first section refers to Institution and last two digits refer to the year, second section refers to Source Directorate, third section refers to quality management section, fourth section refers to Research project and last section indicates serial number assigned to the proposal) which will be used in all future correspondences.

4.2 Intellectual Property Rights (IPR)

i. TMDA shall be the owner of research outputs emanating from research work initiated by TMDA by using its own resources. Staff involved in carrying out the research shall be acknowledged.

ii. There shall be a co-ownership of research outputs in a situation where a TMDA staff has initiated a research activity, conducted within TMDAs' focused research areas using funds from TMDA budget/funding agent.

iii. TMDA staff or collaborator shall own IPR for research work conducted within TMDAs' focus research areas using funds from his/her own source and initiated by that staff/collaborator.

iv. In case permission has been granted to a researcher who is not a TMDA staff to use TMDA premises/ facilities, the researcher shall own the research output, but acknowledge TMDA in his report/ manuscript.

v. In collaborative research, ownership shall be as provided in the agreement between TMDA and respective parties.

4.3 Research Implementation

i. The lead researcher shall prepare Progress Report(s) against the approved research work-plan stating implementation status, challenges encountered and corrective actions among others as per format **(Appendix V)** and submit to respective Directorates for evaluation. The evaluation report will be sent to

the Director responsible for research. The progress report shall be sent to the funding agency where applicable.

ii. Failure to submit progress report within the agreed timeframe with no reasonable justification, shall lead to suspension of fund disbursement until such a report is submitted.

iii. Externally funded researches shall be evaluated based on the agreement between TMDA and the funding agency.

4.4 Final Report

i. The lead researcher shall prepare final research report within agreed timeframe after completion of research work.

ii. The report shall be in a prescribed format **(Appendix VI**) or as provided by the funding agency and shall be submitted to the respective Directorate. The report shall also be submitted to the Director responsible for overseeing research.

4.5 Dissemination of Research Findings and Authorship

4.5.1 Dissemination

In ensuring that the outcomes of research work are made available to the stakeholders, and general public, TMDA researchers and collaborators shall be required to disseminate the research findings upon obtaining authorization from Director General through various means which include publications in peer review journals, public education programs

by using audio visual, radio, television, press releases, fliers, newspapers, drama, seminars, workshops, conferences and newsletters. However, it is encouraged that all research works be published in relevant peer review journals.

4.5.2 Authorship

Authorship refers to the listing of names of participants in all communications, both oral and written, of experimental results, and their interpretation to scientific colleagues. Authorship potentially conveys great benefit, as well as responsibility and is based on the significance of contribution to the conceptualization, design, execution and/or interpretation of the research study findings, as well as on drafting or substantively reviewing or revising the research article, and willingness to assume responsibility for the study.

Authorship in publication shall take consideration of the following;

i. TMDA staff engaged in a particular research work shall be an author for a research conducted within TMDA focusing research areas using funds from TMDA/funding agent but initiated by that staff. In this case funding agent(s) shall be acknowledged.
ii. In collaborative research, authorship shall be as provided in the agreement between TMDA and the other party.
iii. Each author shall be responsible to review and support their contributions to the manuscript and be willing to support the general conclusions of the study submitted (originally or in revision) for publication.

iv. There shall be a corresponding author who should be considered the primary author (but is not necessarily the first author), with the additional responsibilities of coordinating the completion and submission of the work, satisfying pertinent rules of submission, and coordinating responses of the group to inquiries or challenges.

v. Order of authorship shall be determined based on the contribution to the research work as prescribed in **(Appendix VII)**.

4.6 Handling of Collaborative Research

TMDA shall collaborate with research institutions in addressing various focused research areas whenever necessary. In all collaborations there shall be a signed Memorandum of Understanding (MoU) as per TMDA set procedures and the research shall be executed in the manner laid down in the MoU.

4.7 Institutional Overhead Costs, Research Funds Management and Procurement

4.7.1 Institutional Overhead Costs

Research not funded by TMDA will be charged institutional overhead cost at the rate of 15% of the total grant value.

4.7.2 Research Funds Management

i. All research funds regardless of their sources shall be channeled through TMDA accounts and handled as per approved budget for the respective research.

ii. Research funds committed by TMDA shall be managed and monitored by the respective Directorate.

iii. Externally solicited research funds shall be managed and monitored by the lead researcher in collaboration with the respective Directorate.

iv. In case of collaborative research activities, the funds shall be managed and monitored as prescribed in the MoU and terms of agreement.

4.7.3 Procurement of Research Needs

Procurement of research needs shall be carried out as per the Public Procurement Act and its Regulations. In case of collaborative research, the procurement will be performed as per the agreement between parties.

4.8 Disposal of Research Project Resources

All resources bought out of research grant (vehicles, laboratory equipment and any supplies) shall be the property of TMDA. In case of collaborative research, tools and equipment shall be disposed as per agreement between parties.

4.9 Research Rewards

A special reward shall be given to an outstanding research work which has contributed in the achievement of the institutional strategic objectives. The outstanding work shall be selected among research works conducted within the period of two (2) years and shall be effected as per the Internal Financial Regulations and Government Standing Orders.

5. MONITORING AND EVALUATION OF RESEARCH PROJECT ACTIVITIES

Monitoring and Evaluation (M&E) are integral and inherent processes that are needed to measure any intervention such as policies, plans, programmes, projects or activities. M&E ensures effective and efficient implementation of planned interventions. A good M&E system should be able to measure, assess and evaluate the level of implementation, performance and achievements of such interventions.

In the context of these guidelines, M&E will focus to:

a) Ascertain whether researches are implemented as planned, i.e. whether or not the researches are on schedule and within allocated resources;
b) Establish whether research outputs are useful and relevant to the TMDA needs;
c) Assess whether efforts are worth continuing with or there is need to adjust procedures accordingly; and
d) Document lessons learnt during research project implementation for both intended and unintended outputs/results and to enable sharing of useful information for future researches of similar nature.

Each research project shall be accompanied by monitoring and evaluation plan that should include among other things the following components: -

a) Brief description of a research project including

objectives and expected outputs/results;

b) Purpose(s) of ME plan;
c) M&E design including data collection tools, techniques and methods of data analysis;
d) M&E matrix in a format provided in **Appendix VIII;**
e) M&E Team (Composition including roles and responsibilities);
f) Prescribed reporting format for M&E findings; and
g) Dissemination and utilization of M&E reports.

6. APPENDICES

Appendix I

RESEARCH PROPOSAL OUTLINE

1. Title of the project
2. Summary (Brief description of the proposed study)
3. Introduction and Literature review
4. Statement of the problem
5. Rationale
6. Objectives: (Main Objective and Specific objectives)
7. Methodology to include data collection instruments
8. Personnel's CV
9. Budget and Budget justification
10. Research work plan
11. Ethical consideration
12. Limitation of the study
13. Dissemination of the research results
14. M&E Plan

Appendix II

CHECKLIST FOR REVIEW OF PROPOSAL

	To be filled by the TMDA - RC		
A	Committee member(s)*	signature	Date
B	Designation		
C	Title of the re-search proposal		
D	**Elements for review process**		Overall score13
1	**TMDA research focus area**		
	Research proposal falls within the TMDA research focus areas		
	Comments		
2	**Research presentation**		
2.1	Research questions and scope appropriate to the proposed study		
	Comments		
2.2	Literature review (*Literature review demonstrates adequate understanding of the research area*)		
	Comments		
3	**Research design and methods appropriate to the project**		

3.1	Sound methodology	
	3.2.1 study design	
	3.2.2 sample size calculation	
	3.2.3 sampling procedure	
	3.2.4 data analysis	
	Comment on whether the researcher demonstrates sound knowledge of the field of research	
3.2	Comment on whether Ethical issues well-articulated	
4	**Resource implications**	
	4.1 Adequate infrastructure and funding	
	4.2 Laboratory access appropriate (if applicable)others , specify	
	4.3 Adequate technical support available	
	4.4 Further training or assistance required	
	Comment	
5	**Dissemination plan**	
	5.1 A Clearly presented plan for sharing results of the project through a variety of mediums	
	Comments	
6	**General comment(s)**	
	Comment on the overall research proposal (*feasibility, aims, significance, originality, the scope of the research should be appropriate for the design*)	
7	**Recommendations**	

	Accept it is	Accept with minor correction(s)	Major correction(s)	Outright Reject
	If rejected, state why			

**The same form will be used for independent review by members and for committee resolution*

Appendix III

RESEARCHCOMMITTEE RECOMMENDATIONS SUBMISSION

NOTE

1. Being satisfied with the review of the research proposal (s) by the TMDA – RC, the Directorate for Laboratory Services (DLS) recommends for approval of ……Proposal (s) (Annex …) that comply with the Research Policy, Focus Area and Guidelines requirements.

2. Being satisfied with the review of the research proposal (s) by the TMDA – RC, the Directorate for Laboratory Services (DLS) recommends the rejection of …….. Proposal (s) (Annex …) that do not comply with the Research Policy, Focus Area and Guidelines requirements.

Prepared by:

Name: ..……

Director, Laboratory Services (DLS)

Signatures: …….

Date: …….

Approved/Not Approved by:

Comments (where applicable)

……
……
……
……..

Name: …….
Director General

Signatures: ……
Date: ……

Appendix IV

RESEARCH PROJECT REGISTRATION FORM

Title of the Research:		
Description of the project		
Date of project approval		
TMDA research focus areas:		
Name of the lead Researcher:		
Collaborating institution:		
Name of Researchers:	TMDA researchers:	
	Collaborating institute researchers:	
Starting date:		
Proposed research duration:		
Expected completion date:		
Main objective		
Specific objectives		
Funding Agency:		
Annual disbursement:		
Total budget:		
Lead researcher:	Signature:	Date:
Remarks by the Director responsible for research		
	Signature:	Date:

Registration number (to be issued by the Directorate responsible for research)	

Appendix V

RESEARCH PROGRESS REPORT

1. Project title:
2. Research focus areas:
3. Researcher(s):
4. Project duration (Year and Date):
5. Period being covered:
6. Directorate:
7. Collaborating institution:
8. Implementation status (Technical & financial):
9. Problems/challenges encountered and proposed solutions/corrective actions to be taken.
10. Name of project leader: …… Signature……. Date……

Appendix VI

FINAL RESEARCH REPORT FORMAT

1. Research Information

Research Number:		
Research Title:		
Date of registration:		
Date of completion:		
Total budget:		
Final report submission date:		
Directorate:		
Collaborating institution if any:		
Research focuses areas:		
Name of the lead researcher:	Name:	
	Signature:	
	Date:	
Name (s) of the research team: …… …… …… ……		

2. Research Overview:
3. Summary of the implementation of approved work plan:
4. Key findings and outcomes:
5. Conclusion and Recommendation:

Appendix VII

GUIDELINES FOR AUTHORSHIP CONTRIBUTION

Contributions Yes		**Authorship?**		**Comments**
		No		
Conceptualization, design and interpretation of results	Original idea, planning and input Other intellectual contribution			-An idea alone may not warrant authorship, unless highly original and unique -Yes but assuming active involvement

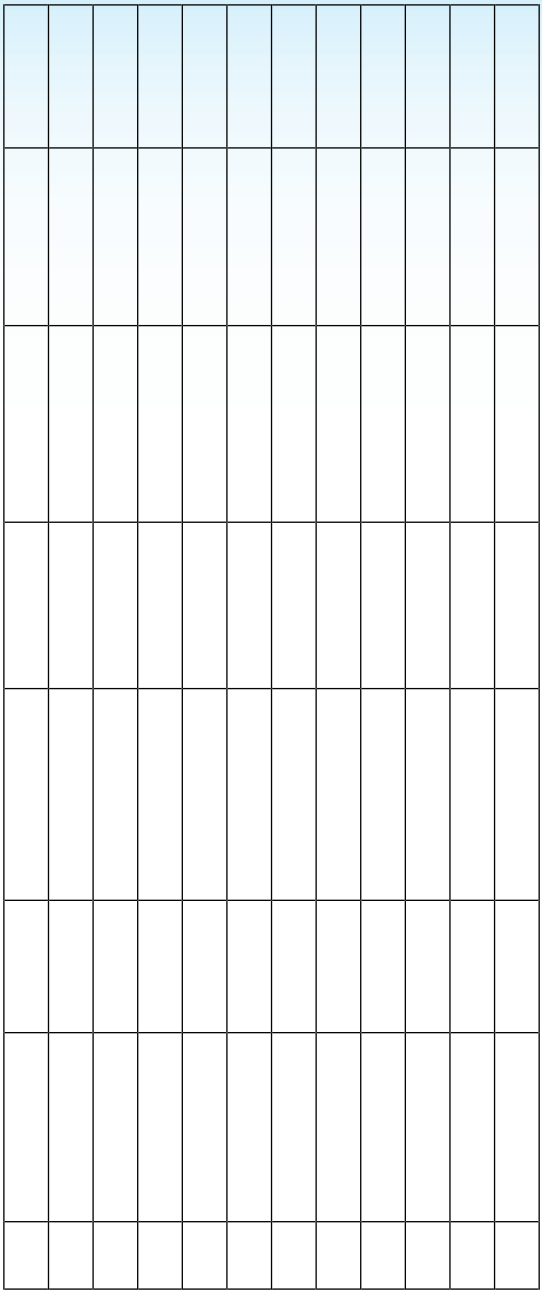
Supervisory role	Supervision of the project			-Yes, but assuming active involvement
	Training, education,			
	Mentoring or first author			-No, unless substantive contribution made to study
Administrative and technical support	Resources: Monetary,			-Acknowledgements yes, authorship no -No if already published; yes if novel -Maybe, depending on circumstances
	Resources: Animals, reagents			
	Resources: Patients			

Data acquisition	Original experimental work			
	Technical experimental work			-No if routine; yes if novel methods added or specific role, e.g., statistics, imaging etc.
	Data analysis (assays)			Yes unless only very basic
	Data analysis (statistics)			-Yes, unless only very basic (t-test)
Writing and other	Drafting of manuscript			Warrants first authorship
	Reading/commenting on manuscript			-substantial feedback can be acknowledged
	None			Includes honorary authorship for lab chiefs,

Appendix VIII

MONITORING AND EVALUATION MATRIX

Sn	Indicator and indicator description	Data collection and methods of analysis				Frequency of reporting	Responsible
		Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		



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