Maroof Research Department

Research Policies Manual

TABLE OF CONTENTS

MISSION STATEMENT

Maroof Research Department (MRD) is committed to patient-centered translational research, through capacity building and conduct of ethical studies, bridging bench, bedside and the community at large, leading to improved health outcomes.(Ilman Nafiah)

1.0 STATEMENT OF PURPOSE

a)To contribute to the advancement of knowledge in health sciences through participation in research programs and to provide educational opportunities for multi-disciplinary health professionals of Maroof International hospital.

b)The purpose of the Maroof Research Department includes review of all research proposals and to make recommendations for amendments and/or approval.

2.0 APPLICABILITY

Applicable to all personnel of Maroof International hospital.

3.0 REFERENCES

3.1 International Ethical Guidelines for Biomedical Research Involving Human Subjects Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva 1993.

3.2 Institutional Review Board Guidebook, National Institutes of Health, USA Year 2000.

3.3 Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization, Geneva 2000.

3.4 Conduct of clinical trials guidelines: Doc No GL no. DRAP/PS-002/01, Ist Edition Nov, 8, 2019

3.5 International conference for Harmonization/ good Clinical Principles ICH-GCP: Ver E6 (R2) Update 15/12/2016

3.6 Pakistan Good Clinical Principles /Pakistan GCP (Drug Regulatory Authority of Pakistan)

4.0 DEFINITIONS

4.1 *Research Proposal*

A scientific research study submitted to the Research department for review and initial approval and/or recommend amendments and final approval through IRB.

4.2 *Principal Investigator/Sponsor*

An individual or group of individuals who prepares, develop and submit Research Proposal(s) for review by the MRD.

4.3 *Research Protocol*

The term used for all Research Proposal, which was reviewed, approved, amended and have been assigned a Protocol Number by the MRD.

5.0 MAROOF POLICY

Research has been recognized as an important goal within MIH. It is the task of the MRD to assist actively to provide the environment for optimum translational research. Clinical, applied, social and translational research is recognized as essential parts of the delivery of optimum medical care and the continuing process in developing new and better methods of diagnosis, treatment and prevention of disease. Educational research shall also be governed by this policy

6.0 IRB COMPOSITION

6.1 *Membership*

The Medical Director will appoint members with two years office term and with possible reappointment for subsequent terms:

6.1.1 Chairman of IRB
6.1.2 Chair, Research Department
6.1.4 Representative from Nursing Services
6.1.5 Representative from Pharmaceutical Care Services
6.1.6 Two Department/Division Heads
6.1.7 Two Members-at-Large including a community representative

6.2 *Accountability*

Accountable to the Medical Director/designee To contribute to the advancement of knowledge in health sciences through participation in research programs and to provide educational opportunities for multi-disciplinary health professionals of Maroof International hospital.

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6.3 *Authority*

6.3.1 To make recommendations regarding issues related to research.

6.3.2 To receive and review reports, policies, procedures, proposals and make recommendations appropriate and in accordance with the Policies of the MRD on Guidelines/Procedures and General Instruction for Submission of a Research Proposal.

6.4 *Responsibilities*

6.4.1 To make recommendations concerning research carried out within the MIH.

6.4.2 To review all Research proposals for MIH and make recommendations for amendment and/or approval.

6.4.3 To encourage the development of clinical and basic science research projects in accordance to the policies and procedures, coordinate their logistic requirements and foster their progress in an ongoing manner.

6.4.3 To promote the organization of multi-disciplinary groups and research teams.

6.4.5 **DELETE :** To oversee the recruitment of academic clinicians and scientists in accordance with the provisions of the Medical Staff Bylaws and in coordination with the Recruitment Department.

6.4.6 To assist in recommending space, infrastructure, staffing, equipment for clinical/translational researchers.

6.4.7 To coordinate with the Pharmacy and Therapeutics Committee/ Pharmacy supervisor and Medical directorate for final approval of any investigational drugs that might be used in specific research proposals.

6.4.8 To address and establish guidelines, policies and procedures, and to keep MRD policies up to date periodically as indicated (every three years).

6.4.9 To forward all committees recommendations to the Medical Director, MIH for final review and approval.

6.5 ***Meetings***

Institutional Review Board (IRB)/ethics committee (EC) will meet at the call of the Chair. A minimum of 6 meetings annually for committee will be called.

6.6 ***Quorum and Manner of Action***

6.6.1 A quorum is defined as the Chairman plus 50% of the voting members in attendance at the meeting.

6.6.2 Manner of Action is defined as a simple majority.

7.0 PROCEDURES/GUIDELINES

7.1 *Submission of a Scientific Research Proposal*

7.1.1 A scientific research proposal will describe one of the following biomedical research activities in humans:

7.1.1.1 USE OF CATEGORY I DRUG: A Formulary drug for an unlabelled indication or in a combination or dosage different from that recommended by the manufacturer.

7.1.1.2 USE OF CATEGORY II DRUG: A non-Formulary drug in a Phase II/III trial.

7.1.1.3 USE OF A DEVICE.

7.1.1.4 A PROCEDURE.

7.1.1.5 A CLINICAL DIAGNOSTIC PROBLEM.

7.1.1.6 A PHYSIOLOGICAL FUNCTION OR EFFECTS.

7.1.1.7 THE AETIOPATHOLOGY OF A DISEASE.

7.1.1.8 A RESEARCH PROJECT ON ANY AREA OF HEALTH CARE/ SCIENCES.

7.1.2 All protocols shall be written according to the research proposal format of the MRD.

7.1.3 The Principal Investigator(s) shall submit the completed protocol, through their Department Chief/section head, to the Chair- MRD.

7.1.4 After a detailed review, the IRB shall take one of the following actions:

7.1.4.1 Recommend the protocol for approval by the Chair, research, MIH.

7.1.4.2 Recommend that changes be made and request the Principal Investigator to submit a rewritten protocol for further review.

7.1.4.3 Recommend that the protocol be rejected, indicating specific rationale.

7.1.4.4 The Institutional Review Board (IRB) Committee approval should be documented in order to start any project.

7.1.5 Important

Annual Reports on the progress of the study should be sent to the MRD, or more frequently if so specified. On completion/discontinuation of the study, a Final Report should be sent to the MRD.

7.2 *General Instructions For The Principal Investigator*

7.2.1 The research proposal should be carefully planned before commencing writing.

7.2.2 Establishment of deadlines for the preparation of the proposal is important particularly in collaborative investigations.

7.2.3 When writing a research proposal, the following format should be followed:

7.2.3.1 Use Basic English.

7.2.3.2 Avoid jargon and spell out acronyms when used initially.

7.2.3.3 Number ALL pages consecutively beginning with the first page of the proposal and continuing to the last page.

7.2.4 Whenever possible, research proposals should be reviewed and proofread by an objective colleague. More often than not, the colleague will draw the attention to some minor points in the proposal that may have been overlooked.

7.2.5 If an investigator wishes to participate in a multi-center study which has been initiated and previously approved by an acknowledged academic, medical or research institution; he/she must submit a copy of that proposal, together with the approval letter from the associated institution. The MIH IRB will review such proposals in an expedited fashion.

7.2.6 If an outside company is sponsoring any research a letter of agreement between the pharmaceutical company/sponsor and the hospital must be attached to the protocol.

7.2.7 Investigational drugs should be kept always in the pharmacy at the specified temperature and a temperature log recording device and refrigeration facility should be provided by SPONSOR The hospital pharmacy should inform the MRD in writing once the drugs are received by the hospital.

7.2.8 The principal investigator should submit the proposal with all relevant forms completed, and a covering memo; through the concerned department chairman or head, to the Director of the MRD.

7.2.9 The proposal sent to MRD will be screened for compliance with submission criteria.

7.2.10 Completed proposals will receive a reference number (e.g., 2020.01)

7.2.11 The MRD will arrange for the proposal to be forwarded to IRB/ethics committee (EC) for discussion.

7.2.12 The Principal Investigator will be contacted if either IRB/EC requires any clarifications or recommendations.

7.2.13 It is requested from the principal investigator to regularly update the MRD in writing of the progress of the research

7.2.14 IRB/EC will either approve or disapprove the proposal or any amendments as submitted/requested for approval. No research participant should be recruited before IRB approval or during a request for approval of protocol amendment

7.2.15 The Chair of IRB will communicate the final decision to the Principal Investigator and MRD (Chair/Designee).

7.2.16 A deadline will be set by the MRD for studies, which have exceeded the time frame set by the principal investigator.

7.3 ***Detailed Instructions For Preparing Research Proposal***

7.3.1 Complete proposal (including the original copy) and electronic submission, i.e., by email, USB or equivalent must be submitted to MRD.

7.3.2 Incomplete proposals will be returned for revision.

7.3.3 Research proposals should be prepared under the following headings:

7.3.3.1 Cover Page

7.3.3.2 Abstract

7.3.3.3 Purpose of Proposed Investigation and its Significance

7.3.3.4 Background Information

7.3.3.5 Methodology

7.3.3.6 References

7.3.3.7 Budget

7.3.3.8 Facilities to be used

7.3.3.9 Work Plan

7.3.3.10 Organization and Management

7.3.3.11 Informed Consent

7.3.3.12 Department Approval

7.3.3.13 Potential Hazards

7.3.3.14 Curriculum Vitae of all research investigators

7.3.3.15 Institutional approval where applicable

7.3.4 Cover Page: The content of the Cover Page includes the following:

7.3.4.1 Title of Proposal.

7.3.4.2 Type of Project (Chart review, Human study, Diagnostic, Therapeutic, Epidemiologic, Other).

7.3.4.3 Starting Date.

7.3.4.4 Duration.

7.3.4.5 Total requested fund.

7.3.4.6 Information regarding the Principal Investigator.

7.3.4.7 Information regarding the Co-investigator(s).

7.3.4.8 Principal Investigator's assurance to accept responsibility for the ethical , scientific and technical conduct of the proposed research.

7.3.5 Abstract Of Proposed Research. It briefly outlines the objectives, methods and significance of a study. The length of the abstract should not exceed 200 words.

7.3.6 Purpose Of Proposed Investigation And Its Significance. A brief description of the immediate and long term goals and purpose of the research, and its significance to human health in general, and to health problems in Pakistan in particular *(maximum 1 page).*

7.3.7 Background Information Should Include The Following:

7.3.7.1 Relevant information about the disease *(maximum 2 pages).*

7.3.7.2 Current status of research on this problem, including literature reviews *(maximum 3 pages).*

7.3.7.3 Any previous work done by the investigator *(maximum 1 page).*

7.3.8 This is a very important section for a proper evaluation of the scientific merit and feasibility of the proposal. Please include adequate and concise information on the items listed below *(maximum 4 pages).*

7.3.8.1 For Clinical Studies

7.3.8.1.1 Subject selection: inclusion and exclusion criteria.

7.3.8.1.2 Methods and procedures of the study, treatment schedule, safety precautions.

7.3.8.1.3 Pre-treatment evaluation.

7.3.8.1.4 Evaluation during and after study.

7.3.8.1.5 Criteria for removal from study.

7.3.8.1.6 Attach flow sheet and data-gathering forms.

7.3.8.2 For Laboratory Studies

7.3.8.2.1 Experimental plan and design.

7.3.8.2.2 Analytic and other methods to be used.

7.3.8.3 Statistical Methods

7.3.8.3.1 State number of subjects/patients or experiments required.

7.3.8.3.2 End point of study.

7.3.8.3.3 Method of analysis.

7.3.9 References to be listed. The principal investigator should select a set of the most relevant references to the research and make it available to the MRD members.

7.3.10 Facilities to be used. It is a statement describing whether facilities are available and what additional facilities are required *(maximum one page).*

7.3.11 Work Plan. The work plan should clearly state, in graphic terms if necessary, the sequence of major events during the progress of the research. This should include a projected time frame and utilization of personnel and support, and the methods to be used for monitoring and evaluating the progress of this project. *(maximum one page).*

7.3.12 Organization and Management. The plan should clearly state the organizational structure and the role and responsibilities of the key personnel and the methods of supervision (there could be more than one person involved in the research). *(maximum one page).*

(ETHICS REVIEW)

7.3.13 If no major contradiction with the ethical standard regulations, this issue will be under the responsibility of IRB.

7.3.14 Budget

7.3.14.1 Sponsor / Pharmaceutical companies should pay the actual costs needed over and above that which are offered routinely to a patient with the same medical condition who is not a study participant.

7.3.14.2 It is appropriate to request a financial donation per patient, if feasible, for those studies where additional cost are not required, as highlighted above (7.3.14.1).

7.3.14.3 If financial support is required, the budget form should include information of detailed expenses.

7.3.14.4 The request for the budget should be justified.

7.3.14.5 Requirement for personnel and time required needs explanation, and if personnel are on site, approval of supervisor should be obtained.

7.3.14.6 If an outside academic institution or pharmaceutical company is sponsoring any research, a letter of agreement between the academic institution/ pharmaceutical company and the hospital must be attached to the protocol.

7.3.15 Department/Division Approval. Approval of department chairmen/divison heads of the concerned personnel and facilities involved in the research is a prerequisite for accepting the research proposal. The department chairman/section head approval serves not only as a proof of his awareness of the research studies, but also indicates that the investigation is worthwhile to be carried out. *(see attached form).*

7.3.16 Potential Hazards And Toxicity *(see attached form).*

7.3.17 Curriculum Vitae (including publications) of Principal Investigator and Co-investigator(s) should be attached. *(See "Investigator Personal Data Form").*

7.4 *Processing Research Proposals*

7.4.1 There has to be a set of rules and guidelines by which the IRB/EC members evaluate and handle research proposals (see Appendix I & II, Evaluation Forms). These guidelines should lead to the following:

7.4.1.1 It will reflect the objectivity of the IRB/EC.

7.4.1.2 It will accelerate finalizing protocols.

7.4.1.3 It will give scientific merit to the proposal.

7.4.1.4 It will judge the layout, design, and adherence to the research proposal form and guidelines.

7.4.1.5 It will flag immediately, even before being presented to the IRB/EC, those proposals, which are incomplete or have major deficits.

7.4.2 When the IRB/EC reaches a decision to accept and support drug investigation research proposals, matters arising from this issue should be concentrated on in evaluation of funding and judgment of scientific merits.

7.4.3 The following is a list of the guidelines for processing Research Proposals:

7.4.4.1 All research applications must make use of the forms as established by the MRD.

7.4.4.2 The Chairman/Division head of the principal investigator's department must sign all research application forms.

7.4.4.3 Two (2) copies of the application forms (including the original copy) plus electronic submission, i.e., by email, USB or equivalent , should be presented to the MRD.

7.4.4.4 The MRD will assign the proposal an identification number (e.g. 2020 .001).

7.4.4.5 The MRD will report back to the Principal Investigator(s) that:

7.4.4.5.1 The proposal has been given an identification number, which should be used during further correspondence.

7.4.4.5.2 The MRD will give its advice within 6-8 weeks.

7.4.4.6 Departments are encouraged to establish an internal review process prior to submission of research projects to the MRD. This will eliminate the need for department representation at the MRD meeting.

7.4.4.8 In the event that internal reviewers are not available, the MRD of the MIH, if indicated, may select a minimum of 2 external members to review the proposal.

7.4.4.9 The proposal should be placed on the Agenda of the first meeting of the IRB/EC.

7.4.4.10 The IRB/EC will decide on the proposal after having been informed of the opinions of the reviewers and after a thorough discussion of the protocol.

7.4.4.11 If the IRB/EC cannot reach a decision, the applicant will be asked to give additional information in writing. The IRB/EC can also decide to hear the applicant and can advise that 2 or more members of the Committee do this. A final decision on the proposal must then be taken at the next regular meeting of the MIH IRB/EC.

7.4.4.12 If the decision of the MIH IRB is to reject the proposal, the applicant is thereby informed and should receive a summary of the reasons for rejection.

7.4.4.13 The PI has the right to appeal by resubmitting the proposal after accommodating the communicated recommendations of RC/IRB.

7.4.4.14 If the MRD approves the proposal, the Medical Director will be asked for his approval and the Committee's support will be given in writing.

7.4.4.15 The principal investigator(s) will be asked to report on the progress of the research by submitting a research in-progress report on a 3-6 month basis, depending upon the length of research.

7.4.4.15 The principal investigator(s) will be asked to submit the research final report within 3 or 6 months of the proposed deadline of finishing the study.

7.4.4.17 A reprint of any publication arising from the research project should be presented to the MRD.

7.4.4.18 The MRD will maintain a follow up system for each approved proposal. If the principal investigator does not report according to 15 and 16, the MRD will remind the principal investigator in writing.

7.4.4.19 When a final report has been presented to the MRD, the follow-up tracking system will be closed.

7.4.4.20 A closed file of any research proposal should be kept in the MRD for 2 years.

7.4.4.21 A database should be established for research proposals and activities at MIH.

7.5 *Internal Protocol On Processing Research Proposals*

7.5.1 Whenever a proposal is submitted to the MRD with no obvious deficits, it will be placed on the Agenda of both IRB/EC for review and discussion. The task of the MRD is then to decide if the proposal can continue as it stands or not. The following are the steps the MRD can take:

7.5.1.1 The IRB/EC protocol is accepted as it stands. The MRD prepares a letter to the PI through the office of the Medical Director. In addition, the following should be considered:

7.5.1.1.1 If there are investigational drugs or special equipment* required for the trial, the sponsor will be responsible for all regulatory processes/approvals/ customs clearance at DRAP/Ministry of Health. If required, MRD will submit a supporting letter to the sponsor.

7.5.1.1.2 The investigator or pharmacy department should inform the MRD in writing once the investigational drugs are officially received by the hospital. This will assist the MRD to establish the approximate time to the project initiation.

7.5.2 The Proposal is approved pending clarification. Questions are formulated and brought to the attention of the principal investigator(s) through the MRD. The principal investigator(s) will also be informed that the study cannot be initiated until final approval has been granted. After receiving the reply of the principal investigator(s) one of the following two options will be followed:

7.5.2.1 The Chair of the MRD judges the answers to be sufficient and in line with the discussions of the IRB/EC. He reports through the office of the MRD that permission can be granted. The correspondence is placed on the Agenda of the next IRB/EC meeting; or

7.5.2.2 The Chair of MRD expresses a wish to have the Proposal and the correspondence between the MRD and the principal investigator(s) back on the Agenda before it decides on formal approval. Once formal approval is given, this is done through the office of the Medical Director.

7.5.3 The MRD concludes that the protocol is to be rejected. The grounds for the rejection are formulated, written down in the **minutes** of the meeting and the grounds are also presented in writing to the principal investigator(s).

7.5.4 The principal investigator(s) after having studied the comments made by the MRD can decide to redraft and resubmit the Proposal. This Proposal is to be looked upon by the MRD as a new proposal.

8.0 GUIDELINES FOR COST ESTIMATION AND FUND MANAGEMENT

8.1 *Budget*

8.1.1 All research proposals incur (overhead) costs subject to the use of various hospital facilities during the course of the project (It is very unusual for any research project that involves human subjects requiring clinical care to carry *Zero* budget!).

8.1.2 These expenses are the consequence of using various hospital services needed over and above that which are offered routinely to a patient with the same medical condition who is not a study participant.

8.1.3 Identifying an estimated budget cost will enable sponsors/ companies supporting research to fund the project appropriately. For this reason it is very important to get advice regarding the overhead cost estimation, which should include also the various hospital services, used for the study.

8.2 *Funding Sources*

8.2.1 MRD offers limited seed funding for the research projects. The other potential sponsors are:

8.2.1.1 Pharmacetical companies (for-profit institutions).

8.2.1.2 Grants awarding bodies in Pakistan and abroad.

8.2.1.3 Other donor/sponsorship sources (non-profit organizations).

8.2.1.4 Individuals (e.g. private patients).

8.3 *Receipt and disbursement of Research funds*

8.3.1 For self directed research with no contractual obligation for defined outcomes, grant money should go to the account for disbursement to the PI and indirect costs be charged at 10% and rest given on as needed basis to PI but no direct remuneration to PI.

8.3.2 If the grant is contractual (government, private sector) setting specific terms regarding research outcomes and proprietary rights, then a 30% overhead will be charged and rest should be used for direct costs and remuneration to PI at a predetermined rate (e.g. 70/30).

8.3.3 The revenue from overheads should be distributed to hospital administration, research department, and department to which PI belong at a rate of 40%, 30% and 30% respectively.

8.3 ***Cost Estimation and Funding***

In order to know ways how to handle overhead costs for a research project estimation of overhead cost and subsequent management of generated funds for a research proposal should include:

8.3.1 Pathology and laboratory investigations.

8.3.2 Other diagnostic studies (Cardiopulmonary, EEG, ECHO, etc.).

8.3.3 Medical imaging procedures.

8.3.4 Pharmacy-including drug dispensing costs.

8.3.5 Clinic visits.

8.3.6 PI/ Co- PI :Physician's time and input at hourly prorated value.

8.3.7 Nursing Services.

8.3.8 MRC costs.

8.3.9 Patient related costs (transportation, etc.).

8.3.10 Other costs.(MRD Admin support: Chair, AD/ CRA, IRB fees , IT, Telephone, Data storage, electricity and miscellaneous like publication costs)

8.3.11 An approved price list for the above will be available at the MRD office. In addition the list will be available for each Dept/Division head.

8.3.12 The cost of various procedures relevant to the proposed research will be provided to the principal investigator on request through the chairman or head of his/her section.

8.3.13 Research proposals not funded by external donor organizations should be charged at actual cost of consumables and incurred cost born by the sponsor (see please next point).

8.4 ***Research Fund Management***

To allow the MRD to monitor funds made available by funding agencies, the following policies and procedures should be considered:

8.4.1 All funds generated through industry or other donor bodies should be received and accounted for by an assigned Research budget/accounts office (financial audit).

8.4.2 A MIH MRD account shall be established for this reason.

8.4.3 Generated funds from support services will be utilized to support the costs of such services *(future researchers and/or needs for the services i.e. equipment).*

9.0 GUIDELINES FOR AUTHORSHIP

9.1 Introduction:

The goal of research and scholarly publication is the timely dissemination of information to scholars, healthcare professionals, and the general public in order to engage them in the challenge of discovery, enhancement of knowledge and the improvement of life. In turn, authorship to a scholarly and research publication has come to serve the academic profession as a highly dependable recognition of merit.

Academic recognition/ promotions are judged by the number of quality publications in peer-reviewed journals. These are considered to be the main determinants of academic grading in higher education. Therefore, the pressure to publish is such that researchers are often tempted to be co-authors in a paper without having made substantial intellectual and scientific contribution.

This issue is not unique to Pakistan. Groups of researchers and editors all over the world have been suggesting mechanisms and defining criteria to resolve issues related to authorship. The International Committee of Medical Journals Editors, (ICMJE, also known as the Vancouver group) drew up guidelines based on the principal that each author should be able to define-the-work and to defend-the-work publicly. These guidelines may be summarized as:

Authorship should be based only on a substantial contribution to:

i. Conception and design or analysis and interpretation of data,

ii. Drafting the article or revising it critically for important intellectual content and

iii. Final approval of the version to be published.

iv. Taking public responsibility for the content of the publication

All the above criteria must be met. Participation solely in the collection of data, supervision of study activity, or acquisition of funding does not constitute authorship. This can qualify as acknowledgement

New ICMJE criteria (2000) require that 'each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. (see item iv above) One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.'

Fields like Nursing Research and Education have adopted very similar guidelines for authorship. The American Psychological Association Manual (APA Manual) further clarifies that the order of assigned authorship should reflect the relative contributions to the work and not the relative status of the individuals.

9.2 Objectives and Principles:

The institution's Authorship Guidelines seek to establish a clear and sound framework for the encouragement of invention, innovation, creative work and technological development. It provides a framework for managing the institution's authorship policy objectives, which are:

I. Establish and enhance the climate for innovation and invention;

II. Foster a healthy environment for education, research and development;

III. Avoid disputes over attribution of academic credit;

IV. Recognize respective rights of faculty/ consultants/allied health professionals/trainees and research staff to authorship of publishable material towards which they have made significant contributions.

9.3 General principles regarding authorship

9.3.1 Authorship credit must be assigned only to those whose contributions are substantial.

9.3.2 Each author should have participated in formulating the research problem, designing and implementing the study, interpreting the results, writing and reviewing the research paper, and should be

prepared to defend the publication against criticism. (Please refer to section 7.0 for further guidance). All authors are publicly accountable for the content and conclusions of the paper.

9.3.3 The order of authorship should reflect the relative contributions of various participants in the project. The intellectual and substantive contributions of research team members to the project should be stated on all papers and presentations resulting from the project. An editor may request written documentation of each author's contribution.

9.3.4 If participants of a research project have contributed equally, and no one person can be identified as having a more significant role than others, then the group may consider representing themselves by a corporate (collective) title (if acceptable to the relevant journal). The article should then carry a footnote containing the names and contributions of individuals represented by the collective title.

9.3.5 In the case of equal contributions to a publication, authorship may also be assigned by listing names alphabetically, with a qualifying statement that all contributions are equal.

9.3.6 In a project that may lead to multiple publications, each investigator may take turns to be the first author on at least one publication, provided his/her contribution to all publications is equal. This may be determined based on the level of individual involvement and interests in a particular aspect of the study. Please refer to section 7.0 for further guidance.

9.3.7 Individuals who make substantial contributions to a paper but are not project team members may be recognized as an author.

4.8 Gift [1] and ghost [2] authorship are strictly not acceptable.

9.3.9 Contributions of those who are not co-authors (such as those providing technical assistance or those involved in data collection) must be acknowledged.

9.3.10 The investigative team and funding source must be acknowledged on all papers and presentations resulting from the project.

9.3.11 Titles for papers and presentations must be discussed by the research team to avoid overlaps, omissions and controversy.

9.3.12 Before being submitted, the paper should be reviewed by the Principal Investigator (PI) if this person is not an author on the paper.

9.3.13 Authors should notify the editor if they have published or submitted elsewhere for publication the same or a substantially similar manuscript if a transfer of copyright is involved.

9.3.14 All authors should sign the letter of transmittal and copyright release form. (It is not sufficient for one author to do so on behalf of the others).

APPENDIX:

Gift authorship *is defined as co-authorship awarded to a person who has not contributed significantly to the research project. Junior researchers often feel pressured to accept or assign honorary authorship to their supervisors or senior co-workers who have substantial powers over their future career. In addition, young investigators may feel the need to increase their publication list quickly in order to secure their next job or they believe that including more experienced colleagues as authors will increase their chances of publication. Senior researchers assign gift authorship as repayment for favors or for encouraging collaboration and maintaining good working relations. Regardless of the cause, gift authorship is an unacceptable practice for academic publications.*

Ghost authorship *is defined as the failure to award authorship to a person who has contributed significantly to the research project. Ghost authorship may come about because of differences in the criteria that junior and senior researchers use to define authorship, a decline in work ethics during the course of the project or a change in the work environment. Contributors who leave the project before its closure are often deprived of authorship. Regardless of the cause, ghost authorship is an unacceptable practice for academic publications.*

9.5 Co-authorship between Consultants/faculty and Assistant Consultants/ Trainees/medical officers : General principles

Authorship is not presumed to be a right obtained by association with a research project, without significant contribution. It is to everyone's benefit that there is a clear understanding about potential joint authorship roles whenever there is research collaboration among faculty and students, whether the latter are assigned as apprentices, students in a class, hired assistants, or any other role. Initial arrangements can always be re-discussed should circumstances change; for example, if the student contributes more to the project than originally anticipated.

9.5.1 Principal authorship and other publication credits must accurately reflect the relative scientific or professional contributions of the individuals involved, regardless of their relative status.

9.5.2 Under no circumstance may a health professional/trainee at MIH publish data owned by MIH or MIH consultants/faculty without permission from the relevant body or consultant/faculty member for the relevant project.

9.5.3 The person who conceptualized the project, secured the funding, developed the research instruments, etc., should review any publication or other public presentation from the project and give his/her permission if something from the project is to be published without his or her name on it.

9.5.4 A trainee/student is presumed to have authorship of his or her masters thesis and/or doctoral dissertation and is encouraged to publish any part or all of the approved thesis or dissertation unless there have been some prior restrictions to which the student has agreed (e.g. that authorship must be shared with others contributing to the project or to wait for a jointly authored or edited book combining several theses). However, students must inform the supervisors of their intention to publish.

9.5.5 If a trainee/ student expects to be sole author on publications based on all or part of his/her thesis research, this should be discussed in advance with the supervisor and an early agreement in writing must be reached.

9.5.6 When a significant amount of additional research is required to produce publishable material, or when the trainee/student contributes little to the writing of the paper, the supervisor may be the first author.

9.5.7 When a group of students work together on a project and their relative contributions are equal, they should consider representing themselves by a collective title, or list the names alphabetically with a qualifying statement that the contributions are equal. The requirements of the journal itself will determine the relevant option.

9.5.8 Individuals who are not enrolled in a graduate program but are employed as research assistants should not expect joint authorship of their supervisor's publications, unless they have made a significant original contribution to the research program.

9.5.9 Data gathered for a research project or a program of research under a PI (using a grant or otherwise) may not be used by students or collaborators without the PI's permission, unless they have been made part of a public archive. In either case, proper acknowledgements are imperative. For detailed guidelines on 'Ownership of and Access to Data,' please refer to the 'Intellectual Property Rights- Policy Document' section 15.0.

9.5.10 It is impossible to anticipate all potential problems. Mutual respect, trust and clear communication forestall difficulties. Please refer to the 'Dispute Resolution' section below for further direction.

9.6 Dispute Resolution:

If a dispute or concern arises with respect to authorship, the trainee/ student, researcher and his/her supervisor should first try to resolve any differences amicably. If a discussion with the supervisor does not resolve the problem, several avenues of dispute resolution within the trainee/student's/ researcher's section can be approached in the following order:

- Head of the section
- Department Head and then Medical Director as appropriate

- Institutional IRB/Research Committee

The decision of the IRB/ Research committee will be deemed to be final and binding on all parties involved in the dispute.

9.7 Strategy for determining authorship

As scientific research becomes more multi-disciplinary in nature, individual contributions of all authors must be specified and perhaps a strategy for assigning credit when publishing should be adopted. The procedure developed by Digiusto, 1994, and Ahmed et al., 1997 can serve as guidelines and details can be obtained from MRD .

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Accessed on December 15, 2005. Contains research policies and ethics (including authorship guidelines) outlined by McGill University, Canada.

APPENDIX-1

Communication between Principal Investigators and Research Centre