جامعة المنيا
Minia Universitv

MINIA UNIVERSITY

كليـــــــة طب

السيد الأستاذ الدكتور / رئيس الجامعة

تحية طيبة وبعد .....

نحيط سيادتكم علما بان مجلس كلية الطب المنعقد فى تاريخ ٢٠١١/١٢/٢٠ قد وافـــق على إنشاء (لجنة أخلاقيات البحث العلمي) ومرفق طيه تشكيل اللجنة ولائحة اللجنة .

برجاء التكرم بالموافقة على إنشائها والموافقة على إنشاء صندوق خـــاص باســـم (لجنـــة أخلاقيات البحث العلمي) لكلية طب المنيا

وتفضلوا سيادتكم بقبول فائق الاحترام...

عميد الكلية

أ.د/ أبو بكر محمد محيى الدين

القرار:

الموافقة على تشكيل اللجنة واللائحة.

جامعة المنيا
امانة مجلس الجامعة
مجلس جامعة (٩)
بتاريخ : ٢٠١٢/٦/٦

Tel: (0862347460) Fax: (0862342813) E-mail : Minia --med @ yahoo.com

السيد الأستاذ الدكتور/ رئيس الجامعة

تحيه طيبه وبعد

نحيط سيادتكم علما بان مجلس الكلية المنعقد بتاريخ ٢٠١١/١٢/٢٥ قد وافق على تشكيل لجنه أخلاقيات البحث العلمي من كلا من :

١- أ.د /منال اسماعيل عبدالغنى	استاذ مساعد الباثولوجى رئيسا
٢-أ.د /بليغ حمدى عبد الحق	وكيل الكلية للدراسات العليا والبحوث
٣-أ.د/محمد عبدالمحسن هاشم	رئيس قسم الطب الشرعى
٤-د /أمل أنور	مدرس علم النفس-كلية التربية
٥-أ.د/طارق خلف	ممثلا لنقابه الاطباء
٦-د /محمود نصار	مدرس الرمد
٧-أ.د/على عمر	رئيس قسم الفارماكولوجى
٨- أ.د/رفعت محفوظ	استاذ الطب النفسى
٩-أ.د/ابراهيم يحيى	رئيس قسم الفسيولوجي
١٠-أ.د/اشرف عبدالعظيم	استاذ مساعد الصحه العامه

برجا التكرم بالاحاطه والعلم

وتفضلوا بقبول وافر التحيه والتقدير

عميد الكليه

ا.د ابوبكر محى الدين

١٢/١٦/١٦

وقار

كلية الطب
مكتب العميد

جامعة المنيا
Minia University

تشكيل لجنة أخلاقيات البحث العلمي

د / منال إسماعيل عبد الغني	أستاذ مساعد الباثولوجي (رئيساً للجنة)
أ.د/ عصام إبراهيم	أستاذ النساء والتوليد (عضوا)
أ.د/ محمد عبد المحسن هاشم	أستاذ الطب الشرعي (عضوا)
أ.د / عمرو أحمد فؤاد	أستاذ الفارماكولوجي (عضوا)
أ.د/ إيهاب رفعت توفيق	أستاذ المسالك البولية (عضوا)
أ.د / يوسف إسماعيل	أستاذ المسالك البولية (عضوا)
د/ إبتسام إسماعيل	مدرس الصحة العامة (عضوا)
د/	(ممثل نقابة الأطباء – عضو من خارج الكلية)
– ممثل المجتمع المدني	عضو لا ينتمي لمجال الطب

Tel: (086)2347460 Fax: (086)2342813 E-mail :Minia-med@yahoo.com

Date ٢٠١٨/٠٢/

Standard Operating Procedures (SOPs)
Faculty of Medicine,
Minia University, Research Ethics committee

A. INTRODUCTION

Faculty of Medicine, Minia University is committed to high quality scientific research in all aspects of the health and behavior of people and such research depend principally on the participation of humans as subjects in conducted research.

While the primary goal of research is to enhance the well-being of society, an important objective of research involving human subjects is protection of the rights and welfare of subjects who participate in research. Faculty of Medicine, Minia University REC was constituted and operating & guided by the ethical principles embraced by:

1. The "Declaration of Helsinki",
2. "Belmont Report",
3. "CIOMS" &
4. "ICH-GCP" guidelines.

Such principles include autonomy (respect for persons), beneficence (protecting subject welfare), non-malfeasance (minimizing potential harms of research) and justice (avoidance of exploitation). Justice also requires that the benefits and burdens of research be distributed fairly among all groups and classes in a society, as well as between the different countries who are participating in the research.

B. ASSURANCES

The "Dean" and "Vice Dean of post-graduate studies and research" will oversee the research practices in the Faculty of Medicine and assures that these practices will conform to the principles of research ethics. Part of this assurance includes the development and

The Research Ethics Committee of Faculty of Medicine, Minia University is constituted and operating according to declaration of Helsinki, CIOMS & ICH-GCP guidelines and applicable local and institutional Regulations and guidelines which governs EC operations.

establishment of a well organized, characterized and an independent Research Ethics Committee (REC) which will have the responsibility to review and monitor research involving human subjects.

C. REC MISSION AND AUTHORITY

1. Scope and Purpose

The purpose of the REC is to protect the rights, safety, and welfare of all research subjects. To achieve this, the REC must advise investigators in designing research projects in a manner to minimize potential harm to human subjects, review submitted planned research involving human subjects prior to initiation of the research, approve research that meets established criteria for protection of human subjects, and monitor approved research to ascertain that human subjects protection is sustained.

2. REC responsibility and authority

The human subjects' research carried out at Faculty of Medicine and the university hospitals must be reviewed and approved or determined exempt by the REC prior to the involvement of human subjects in research. Accordingly, the REC has the following responsibilities and authority:

- The REC will review and have authority to approve, require modifications (to secure approval), or disapprove initial and continuing reviews of all research activities;
- The REC will have authority to suspend or terminate an already approved research that is not being conducted in accordance with the REC's requirements or that has been associated with unexpected serious harm to subjects.
- The REC must report to the Dean and Vice Dean unanticipated problems involving risks to subjects and others or serious or continuing noncompliance by investigators.

D. CONSTITUTION OF THE REC

The REC will be constituted to ensure:

a) Competent review of the ethical aspects of the research and

b) Independence from influences that could affect the performance of unbiased reviews.

1. *Chairperson and vice chair*

a. Appointment:

On developing a new committee, the chairperson will be appointed directly by the Dean. Neither the Dean or Vice-Dean can be involved in the committee to ensure independence of the REC from institutional influence.

b. Qualifications of the chair and vice chair:

The chairperson shall have the following qualifications:

i. A medical staff affiliated to the Faculty of Medicine holding at least MD or PhD degree.
ii. Good experience in performing research
iii. Basic training in research ethics, research methodology & design, statistics & scientific writing.
iv. Good communication skills and leadership characteristics.
v. Committed to the protection of human subjects in research

c. Terms of appointment:

The chairperson will serve for a period of three-years. Afterwards, the appointment of the chairperson could be renewed by re-appointed by the Dean. The chairperson shall not serve for more than two consecutive three-year terms.

d. Vice-Chair (coordinator or general secretary):

The chairperson will choose a vice-chair to help him (or her) in carrying out his or her responsibilities. The vice-chair will carry out the chairperson duties in his/her absence upon written permission from the chairperson.

2. *Members of the RECs*

a. **Members:** Members of the RECs will reflect a multidisciplinary and multi-sectorial composition, including relevant scientific expertise (i.e., appropriate to the types of protocols that will be reviewed), balanced age and gender distribution, a mix of junior and senior staff members, a mix of medical/non-medical scientific

and non-scientific persons including nonaffiliated lay representatives (e.g., lawyer, journalist) to reflect the differed viewpoints of the community.

b. **Numbers:** The number of persons in the REC should be kept fairly reasonable e.g. 9 members. It is generally accepted that a minimum of five persons is required to compose the committee. There is no specific recommendation for a widely acceptable maximum number of persons, but it should be kept in mind that too large REC will make it difficult in reaching consensus. Hence, 11 is the maximum recommended number if necessary.

c. **Qualifications and criteria of selection:**

1. Affiliated Members should:
   i. Hold at least a doctorate degree
   ii. Have an interest in research issues and research ethics
   iii. Be reputable and trustworthy
   iv. Be willing to volunteer their time and effort
   v. Be willing to sign a confidentiality agreement regarding meeting deliberations, applications, information on research subjects and other related matters
   vi. Have a basic background on bio and research ethics, research design & methodology,

2. The non-affiliated community representative:
   Is exempted from having a doctorate degree to ensure proper representation of a large sector of the community who might not have such qualification. However, it 's necessary to have a general awareness as well as clear understanding on regulations, laws and rules applied on reviewing scientific proposals ethically

d. **Conditions of Appointment:** Each member will:
   i. Agree to meet all education and training requirements
   ii. Accomplish all the specified duties upon enrolment in the REC e.g. attendance of meetings, review protocols within the allocated time...etc
   iii. Sign a confidentiality agreement regarding meeting deliberations and information on research subjects, applications and submitted protocols.

e. Appointment Process

i. Initial Constitution of the REC

An initial core group of members will be selected directly by the Dean that got the mandate to develop and establish a REC. The core committee will identify, interview, and then choose, by consensus the subsequent members of the committee.

ii. Subsequent appointment of members

The REC will identify prospective members and review with them the nature and demands of serving on the REC giving the priority to previous experience and training in research ethics. The full REC will, by consensus, approve the selection of the prospective member.

iii. Conflicts of interest should be avoided when appointments are made. There should be transparency and management of the conflict of interest which should be dealt with on case by case basis.

f. Terms of Appointment

i. **Duration:** Each member will be appointed for a cycle of 3 years in duration.

ii. **Renewal**: At the end of each cycle of appointment, members wishing to stay on should make a written request to the chairperson. Subsequent renewal will depend on prior quality of work, expanding experience in research ethics and attendance performance and be determined by a consensus of the full committee.

iii. **Resignation:** Members wishing to terminate their appointment prior to the 3 year cycle shall send a written letter of resignation to the chairperson 2 months in advance in order to have enough time to appoint another member.

iv. **Disqualification:** Members may be asked to leave the REC if any of the following occurs:

1. Failure to attend two consecutive meetings without permission or more than half of the meetings.
2. Negligence in reviewing protocols
3. Breach of confidentiality agreement
4. Termination will be decided by a majority vote of the full REC.

g. Orientation and training of REC members:

• Initial Education: Following appointment the new member will go through the REC orientation, which consists of an introductory lecture followed by an informational session on practical matters with the REC chair. Subsequent education may take one of the following types:

i. Comprehensive workshops in research ethics
ii. Completion of a training website in research ethics.

• Continuing education: The REC should set standards for continuing education of its members every three years (e.g., regularly scheduled review of published articles in research ethics, attendance at workshops, etc.)

h. Conflicts of Interest:

No REC may have a member participate in the REC's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the REC. Examples of such conflicts of interest could include: a member of the REC who serves as an investigator on research under consideration by that REC; or a member who holds a significant financial interest in a sponsor or product under study.

3. Independent Consultants

The REC may, at the discretion of the chair or its members, invite individuals with competence in research ethics as well as special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REC. These individuals may not vote with the REC. Consultants are not included in determining or establishing a quorum at the meetings. REC meeting minutes reflect the presence of consultants.

E. REC RESEARCH REVIEW EVALUATIONS PROCEDURES, CRITERIA AND ACTIONS

The REC is charged with the responsibility for reviewing and monitoring human subject research conducted under the mandate of Faculty of medicine. Therefore, the first question with respect to REC review of a research proposal is a determination of whether such proposal fits the definition of research.

a. Is it research?

Research is defined as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Thus, a key aspect of research is that there be a systematic design in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge. Research can encompass a wide variety of activities, including: experiments, observational studies, surveys, tests, and recordings.

b. Does it involve human subjects?

A human subject is defined as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." Identifiable private information "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," (such as a public restroom) "and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record)." Intervention includes physical procedures, manipulations of the subject or manipulations of the subject's environment for research purposes. Interaction includes communication between the investigator and the subject. This includes face-to-face, mail and phone interaction as well as any other mode of communication.

Meeting Frequency

The REC will meet at regular time intervals in accordance to the needs of the workloads, but generally the REC should meet at least once a month on a regularly scheduled day. For example, every two weeks, every month, etc. In certain circumstances, RECs can meet on an "as needed" basis.

Scheduled meetings may be cancelled by the chair due to a) insufficient number of applications requiring review at a convened meeting, b) inability to secure a quorum for attendance, or c) other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate.

Quorum Requirements

a. The number required to compose a meeting will be half of the members with a minimum of five.
b. No quorum will consist entirely of members of one profession (e.g., medicine)

Submission of Applications for New Studies

a. **Persons Submitting:** An application form for review of the proposed research project shall be submitted by the principal investigator of the research. It should be noted that an extra form should be filled in case of clinical trials.
b. **Materials Submitted:** Each application should consist of the following:
    1. A signed and dated application form (developed by the REC)
    2. Full protocol
    3. Summarized protocol (not more than 350 words)
    4. Consent form (Arabic and/or English). An additional form is required in cases of future storage.
    5. Product brochure for new drug/device
    6. Time plan for the study
    7. CVs for the principal and co-investigators
    8. Copies of actual questionnaires to be used in the study
    9. Copies of materials to be used (e.g., advertisements) for the recruitment of potential research subjects.
    10. Signed investigator assurance agreement to comply with ethical principles and legal requirements set out in relevant laws and guidelines. If the application is incomplete or otherwise not fully prepared for review, it is returned to the investigator or a request is made for necessary changes or to provide additional information.
    11. Extra information are listed in cases of clinical trials.

c. **Deadline**
    1. Submission: The deadline for submission will be at least 15 days prior to the meeting at which the protocol will be reviewed by the REC.

2. Investigator notification: investigators will be notified of an REC decision within 3 days after a decision has been reached.

Review of Applications of New Studies

The REC will use a primary & secondary reviewer system in which two members will be assigned to lead the review and present the protocol for discussion at the convened meeting. All REC members will be provided with detailed materials describing the research so that each member will be able to discuss the protocol at the meeting.

Member review:

- A member will be selected to be the primary reviewer of the protocol and will be responsible for:
- Completing the primary reviewer form
- Presenting the protocol for discussion at the meeting
- All members will receive protocols for review at least 2 week prior to the review meeting
- All members are required to review all submitted materials and be prepared to discuss all protocols at the convened meeting.

REC Evaluation Criteria:

The REC will assess the following review criteria:

- Acceptable Social Value to the community/country
- Scientific Design: The REC will consider the assessment of scientific design as determined by a separate Research Committee. The REC will consider elements of scientific design not reviewed by the Research Committee (e.g., justification of the use of placebo control arms, inclusion and exclusion criteria, etc.).
- Recruitment of Research Subjects: In accordance with Belmont principles, both the burdens and benefits of research should be distributed equitably. Selection of subjects is one important means of ensuring that the burdens and benefits of research shall be distributed equitably. In making this assessment the REC will

take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. If such vulnerable populations will be potentially enrolled in research, then the REC will determine the appropriateness of additional safeguards to provide added protection to vulnerable populations.

- Analysis of Risks and Benefits: The REC will identify all risks (physical, psychological, social, and economic) involved in the research. Risks to subjects must be minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by relying on procedures already being performed on the subjects for diagnostic or treatment purposes. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- Privacy of Subjects and Confidentiality Procedures to Protect Subjects' Data: The REC will determine the appropriateness of procedures in place to ensure subject privacy and to ensure the confidentiality of data obtained from the subjects.
- Procedures to Monitor Subjects During the Study: The REC will consider the appropriateness of criteria for prematurely withdrawing research subjects for safety considerations (if applicable); the adequacy of provisions to monitor safety of research subjects; and the determination of whether a Data Safety Monitoring Board (DSMB) is required.
- Informed Consent: Unless specifically waived by the REC, informed consent must be sought from each prospective subject or the subject's legally authorized representative.

Externally Sponsored Studies/Projects:

Sometimes research is undertaken in Egypt but sponsored, financed, and sometimes entirely or partly carried out by an external international or national organization or pharmaceutical company with the collaboration or agreement of the appropriate authorities, institutions and personnel of Egypt. In such externally sponsored research, the REC in the Faculty of Medicine and in the country of the sponsor will have responsibility for conducting both scientific and ethical review, as well as the authority to withhold approval of research proposals that fail to meet their scientific or ethical standards.

The REC at Faculty of Medicine will have the following special responsibilities:

- determine whether the objectives of the research are responsive to the health needs and priorities of Egypt to avoid exploitation of underprivileged communities
- Obtain information regarding the type of post-trial benefits to the community and Egypt to determine that the burdens and potential benefits of the research have been fairly distributed between the participating countries.
- Should determine whether the research plan conflicts with the involved community's customs and traditions.

o Review of the adequacy, completeness, and understandability of written and oral information Determination of whether signed, written informed consent can be waived and the validity of alternative procedures to document the provision of informed consent

o The determination of whether informed consent could be obtained from the subject's legally acceptable representative.

o Determination of whether the informed consent document contains the required basic elements of consent (see checklist).

Expedited Review

o Certain minimal risk protocols may receive expedited review by the chairperson. All expedited decisions shall be communicated to the next convened meeting of the REC. The REC shall establish criteria by which protocols can be reviewed by such an expedited procedure.

o b. "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Voting and Decision making

- All members who attended the meeting while the protocol was discussed will participate in the voting unless a member has a conflict of interest. Those members physically present for the vote should be recorded as either voting for, against, or abstaining. Members who are excused from the vote (e.g. due to conflict of interest)

should physically leave the room, would not be counted in the aforementioned tally, and should be identified by name in the minutes.

- Decisions should be made at meetings where a quorum is present.
- Decisions should be arrived at through consensus, where possible. In cases where a consensus appears unlikely or when discussions become prolonged, the chairperson shall call for a vote. In such instances, a majority vote will be sufficient to arrive at a decision. In case of a tie, the decision favored by the chairperson shall be determinate.
- When an REC member has a conflict of interest (see D(2)(h):Member conflict of interest) that requires him/her to excuse himself/herself from discussion of and voting on a particular protocol, that member should leave the meeting room for the duration of the discussion and vote, except as requested to address questions raised by other members. If the member's conflict of interest causes a loss of quorum, the vote should be postponed to another meeting. For this reason, REC members should notify the chair prior to the meeting if they have a conflict of interest related to a specific protocol slated for review at the meeting, and every effort should be made to ensure

Types of decisions taken:

- **Approval:** Approval of research In the case of an approval with no changes, the research may proceed once the PI receives written documentation of REC approval.

- **Approval with minor changes:** The REC may determine that a study may be approved with stipulated minor changes or clarifications. Minor changes are those changes that do not involve potential for increased risk or decreased benefit to the human subjects. Some examples of minor changes are: changes in contact information or identity of non-key research personnel, changes in the study title, and changes in the consent form that reflect the minor changes listed earlier. For minor changes, the Chair or a voting REC member(s) designated by the Chair must ensure that the investigator makes the appropriate changes to the research protocol. Such changes must be clearly delineated at the convened meeting and subsequent review requires simple verification of concurrence. The research may proceed after the required changes are verified and the designated reviewer approves the protocol.

- **Deferral:** The term "deferral" is used to describe the situation in which the REC determines that substantive changes must be made before approval may be granted. The investigator's response, including any amended materials, must be reviewed by the convened REC.

- **Disapproved:** The project, as proposed, is disapproved and may not go forward. Disapproval usually indicates that a proposal requires major changes not likely to be feasible without a complete reassessment of the protocol by the investigator and/or sponsor. Suspension and termination of research study by REC: The chair of the REC or the convened REC may suspend a study at any time if it is determined that the study requires further review or evaluation. This determination may be made due to an adverse event, noncompliance or other danger to human subjects. Once a study has been suspended, the convened REC should review the study and either require changes to the protocol, allow the study to restart, or terminate the study.
- Though the chair may suspend a study, only the convened REC can make the decision to terminate a study.

Appeal against REC decisions:

Investigators may appeal against the REC's decisions. At the discretion of the chair, the investigator may make such an appeal in writing to the REC. At the REC's discretion, the investigator may be invited to the REC meeting at which his or her appeal will be considered.

REC Meeting Minutes should be in sufficient details to include the following:

1. Date and time meeting starts and ends
2. Names of members present
3. Names of members absent
4. Names of alternates attending in lieu of specified absent members
5. Names of consultants present
6. Names of investigators present
7. Names of guests present

Actions taken by the REC

Actions taken by the REC at a convened meeting as well as the vote on these actions including the number of members voting for, against and abstaining, and (if

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applicable) notation that any members with a conflict of interest (identified by name) were excused and were absent for the discussion and vote; The basis for requiring changes in or disapproving research; For each protocol in which changes are stipulated by the REC, a determination of whether the changes represent minor modifications that do not require verification by the convened REC, or whether they are significant, requiring convened REC review; and, A written summary of the discussion of controversial issues and their resolution.

REC findings and determinations

The followings are required findings and determinations and must be noted in the minutes with reference to the appropriate federal regulations.

- Determination of the level of risk for human subjects in the research study (no citation required).
- Justification for waiver or alteration of informed consent;
- Justification for the waiver of the requirement for written documentation of consent;
- Justification for approval of research involving children;
- Justification for approval of research planned for an emergency setting; and
- Special protections warranted in specific research projects for groups of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons.
- The secretary of the REC will be responsible for taking the minutes of the meeting. At each meeting, one member of the committee will take notes and review the minutes to ensure accuracy and completeness.

Communication of Decisions

a. A decision of the REC will be communicated to the investigator in writing within three days of the meeting.
b. Each decision will include:
   - A clear statement of the decision reached,
   - Justifications of any disapproval
   - In cases of conditional approval, a list of the conditions needed for approval and its associated justifications
   - In cases of a positive decision, a statement of the responsibilities of the investigator (e.g., confirmation of the acceptance of any requirements imposed by the REC, submission of progress reports, the need to notify the REC in cases of protocol amendments, changes to recruitment materials, changes to the consent form, and the reporting of any unexpected adverse events or unanticipated problems or termination of the study).
   - The date and place of the decision
   - Any advice given by the REC
   - Signature of the chairperson

Investigators' Responsibilities during Conduct of the Study

During the conduct of the study, the investigator shall submit within a specified period of time (to be determined for each category) the following:

- Amendments to the protocol
- Serious and unexpected adverse events
- Safety reports (if applicable)
- Reports of any Data and Safety Monitoring Board
- Unanticipated problems
- Termination of the study

The REC will determine which of the above can be reviewed by an expedited procedure and which requires full committee review

Continuing Review

a. **Submission:** At the time of continuing review, the investigator shall submit the following information for review:
   - Enrollment of subjects: gender and age
   - Number of subjects withdrawn and reasons for such withdrawal
   - Adverse events (Cumulative and type for the previous period since the last review)
   - Modifications to the protocol
   - Changes of investigators
   - Results, if available
   - Current informed consent form
   - RECs should determine which continuing reviews can be reviewed by an expedited process and which continuing protocols require full committee review.

b. **Lapsed studies:** A lapsed study is one for which the approval period has expired prior to the renewal of approval by the REC. If the investigator fails to submit the materials for continuing review prior to the REC meeting that needs to review the study before the expiration date, then the lapsed study will be classified as inactive. Once a study has lapsed notification should be sent to the investigator ordering that all study-related measures must immediately cease except those necessary for welfare of the human subjects. If the investigator desires to continue a study that has lapsed for more than one month, then the investigator must submit a new application for re-review by the REC, and must wait for REC approval before resuming research under the protocol.

F. WAIVER OF INFORMED CONSENT

The REC may approve a consent procedure, that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the REC finds and documents that:

1. The research involves no more than minimal risk to the subjects;

2. The research could not practicably be carried out without the waiver or alteration. Alternatively, the REC may waive the requirement for informed consent involving research in the emergency setting. [RECs must develop criteria under which informed consent may be waived]

G. WAIVER OF WRITTEN CONSENT

The REC may waive the requirement for the investigator to obtain a signed consent form.

Such a waiver is allowable if:

- The consent document is the only link between the subject and the research and the principal risk of harm would come from a breach of confidentiality.
- The research presents no more than a minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.

Dear Applicant,

Please enclose the following **information & documents** on submitting your request to our Research Ethics Committee (FMREC).

Please **sign & date all documents**.

Documents to be submitted (Check if applicable)	Availability
1. Letter of delegation	
2. Approval of the authority of the place where the study will be conducted (in case of prospective studies or review of records & retrospective studies); Approval by the hospital management/department council	
3. Full Protocol (Final version & date)	
4. Arabic Generic Informed Consent (Final version & date) and English Generic Informed Consent (Final version & date, if applicable).	
5. Investigator Application Form	
6. Questionnaire (if applicable) (Final version & date)	
7. CERTIFICATE OF INSURANCE NO. (If applicable)	
8. Arabic Patient ID Card (Version & date) and English Patient ID Card (version & date, if applicable)	
9. Brochures or other printed materials regarding the drug under investigation	
10. Curriculum vitae	

N.B. All documents must be submitted in hard & soft copies (3 copies in three folders including CD in each folder).

Sincerely,

Associate Prof. Manal Ismail Abd-Elghany, PhD (UK), MD (Egypt)
Associate Prof. of Pathology
Chairman of Research Ethics Committee
Faculty of Medicine,
Minia University, Egypt
Email address: manal.abdelghany@hotmail.com/ manalismail2000@yahoo.co.uk

Investigator Application Form

1. Name of Researcher/Principle Investigator: ----------

2. Name of the Department and name of Institution: ----------

3. Contact details of Researcher/Principle Investigator:

- Address: ----------
- E-mail address: ----------
- Phone number (Land line):----------
- Cell phone:----------
- Fax number: ----------

4. Name(s) of Co-Investigator(s)

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5. Grade of Protocol:

a. MD b. MSc c. Other----------

a. Domestic (occurring within the country) b. Multicentre within Egypt c. International

6. Title of the research (Arabic & English)

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7. Type of research (check that applies):

a. Clinical trial	b. Survey Study	c. Review of records
d. Tissue sample	e. Blood sampling	f. Surgical Technique
g. Invasive Technique	h. Device Study	i. Experimental

j. Other----------

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8. Study Design (check that applies):

a. Clinical trial (Phase):	I	II	III	IV
b. Randomization:	Yes:	No:		
c. Placebo:	Yes:	No:		
d. Genetic sampling:	Yes:	No:		

e. Other ----------

9. Subjects (Human participants) of the research:

* **Justification of inclusion & exclusion criteria is evidenced:** Yes: No:
* **This research includes:**

a. Children (< 18 years):	Yes:	No:
b. Adults (> 18 years):	Yes:	No:
c. Other Vulnerable groups:	Yes:	No:

If yes, please discuss the justification of inclusion of vulnerable human subjects (e.g. children, mentally ill, prisoners, pregnant women, orphans,…etc.) :----------

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10. The research includes:

a. Cells & tissues:	Yes:	No:
b. Fetal tissue:	Yes:	No:
c. Biological fluid:	Yes:	No:
d. Genetic material:	Yes:	No:

11. Will the materials collected from patients be transferred outside the country? Yes: No:

If yes, please justify the need for doing that

.....

.....

12. Will the material/s collected from patients be stored for future usage? **Yes:** **No:**

13. Does the research include experiments on genetic material?

14. Request is being made to waive (refrain from demanding) informed consent: Yes No

If yes, please explain why this research doesn't need informed consent----------

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15. The research is for the good of society: Yes: No:

16. Facilities for the research are available: Yes: No:

17. The risks are reasonable to the potential direct benefits to the subjects, if any, or to the knowledge to be gained: Yes: No:

18. List <u>the risks</u> of the study:

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19. List the potential benefits (<u>direct</u> & <u>indirect</u>), if any, to the subjects:

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20. <u>Privacy</u> and <u>confidentiality</u> of subjects are assured: Yes: No:

21. It is clearly stated that the subject of the research could quit at anytime without penalty or loss of any benefits to which they would otherwise be entitled: Yes: No:

22. Informed consent is attached: Yes: No:

23. Full Protocol is attached: Yes: No:

Check if applies:

1) **Study title (English & Arabic)** Yes: No:
2) **Introduction & Background & references** Yes: No:
3) **Duration of the study** Yes: No:
4) **Site of the study** Yes: No:
5) **Materials/Subjects & Methods including all essential details** Yes: No:
6) **Number of included participants (healthy volunteers & patients)** Yes: No:
7) **Criteria of selection of participants (inclusion & exclusion criteria)** Yes: No:
8) **Type, frequency & duration of method of intervention used** Yes: No:

24. C.V. of the researcher/principle investigator is included Yes: No:

Signature of Researcher/Principle Investigator

Date: / / 2018

نموذج الموافقة المستنيرة
لإجراء بحث طبى على مشارك متطوع

الإسم:..... النوع:.....
السن: ..... تاريخ الميلاد:.....
العنوان: ..... التليفون: .....

١. عنوان البحث باللغة العربية	
٢. الخلفية العلمية والهدف من إجراء البحث	
٣. الفوائد المتوقعة من البحث (الفوائد المباشرة والغير مباشرة)	

٤. ماسوف يتم إجراوه بالتفصيل	- مدة البحث: - مكان إجرائه: - عدد المشاركين فى البحث (مرضى وأصحاء): - أسلوب إختيار المشاركين فى البحث وخاصة فى التجارب الاكلينيكية: - تفاصيل خطوات البحث متضمنا نوع وعدد مرات الممارسات المستخدمة (يمكن إضافة سطور إضافية لإستيفاء هذا الجزء) :
٥. هل سيتم الأحتفاظ بعينات (دم أو أنسجة) لأستخدامها مستقبليا	

٦. هل يتضمن البحث تجارب على الحامض النووى DNA	
٧. هل يستدعي إجراء البحث سفر العينات خارج البلاد	
٨. المخاطر المحتملة من إجراء البحث	
٩. التعويضات فى حالة حدوث مخاطر	
١٠. توافر وثيقة التأمين على الشخص المشارك	
١١. البدائل المتاحة فى حالة رفضك الاشتراك فى هذا البحث هى	
١٢. عند وجود أى استفسار للمشارك	يمكن الاتصال: بالباحث الرئيسى ..... تليفون:..... من ينوب عنه: ..... تليفون:..... رئيس/ممثل لجنة الأخلاقيات: ..... تليفون : .....
١٣. إقرار الباحث الرئيسي/الطبيب المشرف على البحث	أتعهد بالحفاظ على سرية المعلومات الخاصة بالشخص محل البحث توقيع الطبيب المشرف: ..... التاريخ : .....

١٤. موافقة المشارك فى البحث (أو موكله)	أقر أننى أوافق على الاشتراك فى البحث وقد اطلعت وفهمت جميع التفاصيل والإجراءات التى ستتم خلال هذا البحث والمذكورة أعلاه ملحوظة هامة : ١ -من حق المتطوع الانسحاب من البحث فى أى وقت دون أى عواقب سلبية ٢ -يجب حصول المتطوع على صورة من الإقرار توقيع الشخص المتطوع محل البحث (أو موكله) : ..... التاريخ: .....

هذا البحث:

- توطئة لرسالة ماجيستير ☐ توطئة لرسالة دكتوراه ☐
- بحث غير ممول ☐
- مشروع بحثى ممول ☐ الجهة الممولة .....
- تجربة أكلينكية ☐ المرحلة .....

تمت الموافقة على هذا البحث من قبل لجنة أخلاقيات البحث العلمي، كلية الطب-جامعة المنيا بتاريخ

توقيع رئيس لجنة اخلاقيات البحث العلمي

Date: / / 2018

Faculty of Medicine, Minia University

Research Ethics Workshop

Sunday 2nd September 2012

Workshop Instructor : Prof. Mahmoud Abo-Elenin

Workshop Organizer : Dr. Manal Ismail

10.00- 10.30	Opening, Welcome, Introduction Overview of participants expectation Pre –test.
10.30- 11.00	Presentation Why ethics in clinical research? **Dr. Manal Ismail Abd-Elghany**
11.00- 11.30 **11.30-12-30**	Presentation Protection of human subjects in research **Dr. Manal Ismail Abd-Elghany** (Informed consent--group work) **Dr. Manal Ismail, Dr. Hany Sleem**
12.30- 1.00	Break
1.00- 1.30	Presentation Research ethics committees **Dr/ Hany Sleem**

1.30- 2.30	Protocol group work
2.30-3.00	Closing remarks- post-test

Egyptian Society for Healthcare Development (ESHD)
Ministry of Social Solidarity No: 7001

Agenda ESHD Workshop 16th April 2011

Day 1 Session I	Moderator: Dr. Azza Saleh	
Time	Topic	Presenter
8:30 -9:00	Registration / Breakfast	
9:00-9:10	Opening ceremony	Dr. Azza Saleh, Dr. Hany Sleem
9:10-9:25	Today's agenda, Pre-test	Moderator
9:25-9:40	Research Ethics History	Dr. Hany Sleem
9:40-10:05	Ethical Requirements + Principles	Dr. Azza Saleh
10:05-10:25	Analysis of risks& benefits	Dr. Hany Sleem
10:25-10:55	Analysis of risks& benefits exercise	Dr. Hany Sleem
10:55- 11:15	Informed consent	Dr. Azza Saleh
11:15 - 11: 45	Informed consent exercise	Dr. Azza Saleh
11:45 -12:05	REC guidelines	Dr. Hany Sleem
12:05 -12:25	Clinical Trials	Dr. Azza Saleh
12:25-12:40	Ethics of Good Clinical Practice	Dr. Hany Sleem
12:40-12:45	Wrap up and Evaluation sheet	Moderator

WORKSHOP EVALUATION FORM

Please answer the following questions using the following scale:
1 = strongly disagree; 2= disagree; 3= neutral; 4 = agree; 5 = strongly agree; NA (not applicable)
(N.B. Please choose one answer only)

1. **History of Research Ethics: Manal Ismail Abd-Elghany**

Presentation was clear and understandable	1	2	3	4	5
Content was appropriate	1	2	3	4	5

Comments:

2. **Informed Consent:** Manal Ismail Abd-Elghany

Presentation was clear and understandable	1	2	3	4	5
Content was appropriate	1	2	3	4	5

Comments:

3. **Risks and Benefits:** Manal Ismail Abd-Elghany

Presentation was clear and understandable	1	2	3	4	5
Content was appropriate	1	2	3	4	5

Comments:

4. **Informed Consent Exercise**

Exercise provided an excellent learning opportunity	1	2	3	4	5
Content was appropriate	1	2	3	4	5

Comments:

5. **Research Ethics Committees: Roles and Functions: Maha Eshak**

Presentation was clear and understandable	1	2	3	4	5
Content was appropriate	1	2	3	4	5

Comments:

6. **Stored Biological Samples:** Manal Ismail Abd-Elghany & Maha Eshak

Presentation was clear and understandable	1	2	3	4	5
Content was appropriate	1	2	3	4	5

Comments:

What did you like the most about this workshop?

What could be done to enhance this workshop?

Thank You

Number of Reviewed Research Studies (2011-2018)

Year of Revision	Type of Research				
	MSc	MD	Research Study (National)	Research Study (Multi center within Egypt and/or International)	Clinical Trial
2011	-	-	1	1	3
2012	-	-	-	-	Renewal of 2 & end of 1
213	-	-	4	-	Renewal of 2
2014	-	-	1	-	Renewal of 2
2015	1	1	3	-	End of 2
2016	1	-	4	1	-
2017	3	4	16	4	-
2018	4	-	3	-	1

Associate Prof. Manal Ismail Abd-Elghany, PhD (UK), MD (Egypt)

Manal I Abd-Elghany

Chairman of Research Ethics Committee
Faculty of Medicine,
Minia University
Egypt

Date: 18/3/2018