THE INSTITUTIONAL REVIEW BOARD (IRB) MANUAL

JORDAN UNIVERSITY OF SCIENCE AND TECHNOLOGY

KING ABDULLAH UNIVERSITY HOSPITAL

I, the undersigned hereby declare that I read and understood the following material and agree to comply with its content:

Chairman of committee Prof. Yousef Al-Gaud

Vice chairman Dr. Khaldoon Bashaireh

Name	Date	Signature	Name	Date	Signature

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MANAGEMENT OF JORDAN UNIVEISTY OF SCIENCE AND TECHNOLOGY-KING ABDULLAH UNIVERSIYT HOSPITAL (JUST-KAUH) IRB

IRB Membership Overview:

1. The IRB chairman and members shall be appointed by Jordan University of Science and Technology president. The chairman will manage temporarily the IRB until nominated by the committee. The duration of the appointment will be for two-year period as required by the local regulatory authorities.
2. In the first meeting of the IRB, the committee should nominate a chairman and a vice chairman.
3. The renewal of an appointment will follow the same procedure.
4. In case of resignation of any of the members, immediate replacement will be done.
5. The vice chairman will be delegated to perform all the chairman's duties during his/her absence as described in this manual and the applicable regulations.
6. The IRB may delegate authority to an IRB Coordinator (Administrative Office Coordinator) to initiate the meetings and to handle all study related documents to assure completeness for submission to the board (See Attachment # 01).
7. Nomination and selection processes for IRB members are illustrated below in Institutional Review Board Composition, Authorities and Responsibilities.

IRB Members Training and Orientation:

1. IRB new members shall attend training sessions related to this manual.
2. Additional training through educational seminars and workshops shall be arranged by the IRB administrative office when possible.

Note: Internal/External consultants shall be invited by the IRB chairman or designee for the purpose of training and/or experience in the subjects discussed.

3. Updates in the regulatory authority requirements and other updates shall be communicated to the committee through the IRB administrative office.
4. Chairman shall ensure that new members must complete training on the purposes and functions of the committee and review their duties prior to starting to review protocols.

Note: Attachments # 09 & 10 should be used when any training session or self training were conducted.

Conflict of Interest:

1. Whenever an IRB member has a conflict of interest with a study (whether financial or otherwise), he/she will be prohibited from voting in the meeting for which that particular study was held.
2. It should be clear that this action will not affect the IRB member status with respect to other studies to be reviewed by the IRB.

IRB Interactions and Affairs:

1. JUST-KAUH IRB shall perform its duties independently from the studies Investigators.
2. JUST-KAUH IRB shall work according to the local regulations related to clinical study conduction.
3. The IRB shall report to the Jordan Food and Drug Administration (JFDA), Ministry of Health all Serious/Unexpected Adverse Events.

Facilities and Resources:

1. The IRB members shall perform their meetings in a predetermined meeting room, unless a decision is made to another place.
2. IRB files shall be kept in closed cabinets (Keys shall be kept with the chairman or designee and may be handed to the IRB administrative office as appropriate). This cabinet shall be placed in King Abdullah University Hospital facilities or as appropriate.
3. The IRB shall utilize all the resources provided by King Abdullah University Hospital as appropriate (Filing Space, Photocopier, etc…).

JUST-KAUH INSTITUTIONAL REVIEW BOARD COMPOSITION, AUTHORITIES AND RESPONSIBILITIES

COMPOSITION:

1. The IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities. Those members shall be:
    - Sufficiently qualified through experience and expertise.
    - Of diversity concerning gender, cultural backgrounds and professions.
    - At least one member whose primary concerns is in the scientific area.
    - At least one member whose primary concerns is in the non-scientific area.
    - At least one member from local community and one member is a lawyer.
2. The IRB is formed and established under the authority of local regulations (Clinical Study Conduct, 2001).
3. The term of membership is a two-year period (example: starting July 01, 2004 through June 30, 2006).
4. The IRB shall not allow an IRB member to participate in an initial or continuing review of a project in which the member has a conflict of interest, except to provide information requested by the IRB.

Note: The IRB may request individuals with special competence to assist in the review of studies beyond the expertise of the Committee members. These individuals will not vote.

5. The IRB shall maintain an IRB Membership List showing name, degree, Position within the board, indications of experience, and relationships with the CRO(s).

AUTHORITY:

1. Approve, modify or disapprove the conduct of a study upon consideration of human subjects' rights protection aspects.

   Note: The IRB has the authority to place restrictions on a study for the favour of subjects' rights and safety.
2. Observe, or have a third party to observe, the consent process and the research, if needed.
3. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements.

RESPONSIBILITIES:

1. To review the scientific basis of the study protocol.
2. To review and approve research Study protocol at convened meeting.

3. To ensure adequacy and qualifications of the clinical study team in conducting these studies.
4. To monitor all study aspects concerning safety and rights of subjects.
5. To ensure that the participation of the study subjects was voluntarily.
6. To ensure that the study was conducted according to Good Clinical practice (GCP) guidelines.
7. To contact the Special Committee (of the ministry of Health) in case of serious/unexpected adverse events that may occur during or after conduction of the study.
8. To ensure prompt reporting of King Abdullah University Hospital to the IRB of changes in research activities.
9. Ensures that changes in approved study, during the period for which IRB approval has already been given, not to be initiated without IRB review and approval except where necessary to eliminate hazards.

JUST-KAUH INSTITUTIONAL REVIEW BOARD FUNCTIONS, OPERATIONS AND RECORDS

1. The IRB shall operate in announced meetings at a frequency that depends on the number of trial studies to be reviewed.
2. The studies related documents (Study protocol and its related documents, copy of the informed consent form and the Investigator Brochure (or package insert)) will be received by each IRB members in a reasonable time before the meeting.
3. During the introductory meeting of the IRB, the responsibilities of the members shall be determined. This is done by electing the chairman, vice chairman, and the responsibilities of each.
4. The IRB shall follow written procedures to:
    - Conduct its review whether initially or continually and reporting its findings and actions to the Principal investigator
    - Ensure prompt reporting to the IRB and regulatory authorities of any unanticipated problems involving risks to human subjects, serious non-compliance and any suspension or termination of the IRB approval.
5. The IRB must notify in writing its decision to approve, disapprove or request modifications in a proposed research activity using Institutional Review Board Approval letter (See Attachment # 02). This correspondence will be made available to the sponsor by the Principal Investigator.
6. IRB Records:

- The Principal Investigator (or any person assigned by him) shall supply each IRB member a copy of the following documents for revision prior to a scheduled meeting :
- Clinical trial protocol and its amendments (if any).

  - Written Informed Consent

  - Subject recruitment procedure (if any).

  - Investigator's Brochure (or package insert).

  - Others as requested by the committee or the applicable regulations.
- The Principal Investigator shall supply a copy of the Investigators/sub investigators current CVs and/ or other documentation evidencing their qualification which will be kept within the IRB records.
- Minutes of meetings shall be prepared to be in sufficient details to show attendance, actions taken by the IRB (if any), the votes on these actions and the basis for requiring changes in or disapproving research.

Note: Copy of the List of IRB members' signatures shall be attached to each voting form (See Attachment # 03).

- IRB shall prepare records of continuing review activities (if applicable).
- IRB shall retain a copy of study closeout supplied from the Principal Investigator or designee upon completion of the study (final report submission, termination or suspension).
- IRB shall prepare a list of IRB members (including affiliated members) identified by names; earned degrees, representative capacity; indications of experience, and their CVs (whenever required).

Note: CVs and other qualification indicators.

7. IRB shall retain any document that describes written procedures.
8. Records shall be retained for at least 3 years after completion of the research and shall be accessible for inspection by the regulatory authorities and any authority to which the study is submitted to.
9. Criteria for approval of a research:
    - Risks to subjects are minimized.
    - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects.
    - Selection of subjects is equitable.
    - Informed Consent will be sought from each prospective subject or the subject's legally authorized representative.
    - Informed consent will be appropriately documented.
    - Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
    - Where appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.
    - Whenever applicable, additional safeguards have been included in the study to protect the rights and welfare of special cases of subjects (e.g., mentally disabled persons and economically or educationally disadvantaged persons).
10. Criteria for IRB voting:
    - All IRB members have the same voting rights.
    - Proxy voting is not allowed (By telephone or faxed).
    - Quorum is needed for approval or disapproval; otherwise the decision will not be accredited.
    - Conflict of interest voting is prohibited.

- Override of disapproval (make ineffective) is completely prohibited.
- Voting shall proceed openly after an opportunity for full discussion has been approved.

JUST-KAUH IRB CLINICAL SITE VISITS PROCEDURE AND RECORDS

1. The IRB committee is informed by Pharmaceutical Research Center (PRC)/Investigator of the study expected dates.

Note: This informing is to be communicated to the IRB chairman or designee by written document, telephone, fax or e-mail and record of this communication shall be kept within IRB and PRC files, the following information should be available in this record:

- Study Name (strength/drug name/dosage form).
- Study Code/Protocol Code.
- Dates of the study periods (consent procedures and clinical periods).
- Location of the study periods.
- Other information as required.

2. The committee shall nominate member(s) during an IRB meeting to perform an audit in any of the study phases.
3. During the site visit the IRB member may interview one or more of the study subjects to check for the compliance of the study protocol and to monitor all study aspects concerning safety and rights of subjects.
4. Attachments # 04 & 05 is used to record the findings per visit. Whenever applicable, findings shall be reported to PRC or the Principal Investigator or designee for follow-up.

Note: Additional page of comments may be added to the checklist when needed.

5. Whenever needed, the IRB Chairman or designee shall follow up these findings until complete resolution is reached.
6. Audit records related to the study under investigation shall be retained as appropriate and a copy shall be kept within PRC correspondence file.

JUST-KAUH IRB REVIEW PROCEDURES

1. The IRB meeting will be conducted as described in this manual.
2. Role of the IRB in Ethical Review:

Guided by the Declaration of Helsinki, principles of ICH guidelines, FDA and local regulations, the IRB shall ensure that risks to subjects are minimized and are reasonable in relation to the anticipated benefits of the conducted research (study) as follows:

- Selection of subjects is equitable;
- Documented, informed consent is obtained from each prospective subject or the subject's legal representative;
- Informed consent is appropriately documented;
- Provisions are made for the protection of the privacy of subjects and that confidentiality of data is maintained;
- Provisions are made for monitoring the safety of subjects; and
- Safeguards are included to protect members of vulnerable population groups (if applicable).

3. Scope of Review:

- **Any research that uses human subjects, tissues/specimens from humans, data/records from human subjects, or surveys of human subjects requires review and approval from the IRB.**

Note: Activities that do not fall under the purview of the IRB include operational activities such as: medical care, quality assurance, quality improvement, certain aspects of public health practice such as routine outbreak investigations and disease monitoring, program evaluation, program audits, journalism, history, biography, philosophy, "fact-finding" inquiries such as criminal, civil and congressional investigations, and intelligence gathering.

- This list does not include all possible activities, so the IRB should be consulted to verify that an activity does not fall under the purview of the IRB.

4. Determining the Type of Evaluation:

There are two levels of IRB evaluation that a research study may undergo, depending on the level of risk to human subjects. These levels are: Full Board (convened) review and Expedited IRB review.

Note: The level of evaluation can only be determined by the IRB, in accordance with Clinical Research guidelines. Even if an investigator believes a study is exempt, no research should begin

until the IRB reviews the protocol and makes the final determination. All research studies require full (convened) Board review and approval.

- Full (Convened) Board Review

Types of Research Requiring Full Board Review:

1. Therapeutic and non-therapeutic studies, in addition to research studies that involve greater than minimal risk for human subjects. This includes:
    - Some research involving children or other vulnerable populations.
    - Research that involves experimental drugs or devices.
    - Research that involves invasive procedures, for example blood donation.
    - Some survey research or interviews that involve sensitive questions, information about HIV, or result in stress for human subjects.
    - Research studies requesting waiver of consent.
2. Research studies that might require a frequent review which has to be done at least annually.

Documentation required for full (Convened) Board review includes:

Protocol – include sufficient information to permit the IRB to assess the rationale, scientific merit, potential risks to subjects, and benefits to subjects, what the subject is being asked to do, how the data will be analyzed, and alternatives available to the subject. The following must be provided:

1. Title of the study
2. Objectives of the study
3. Background and rationale, including literature review
4. Sponsor of the study.
5. Description of procedures to be performed
6. Description of subject population with justification for this selection
7. Identification of inclusion/exclusion criteria
8. Detailed research methodology
9. Data collection and statistical analysis
10. Results of previous related research (if any).
11. Curriculum vitae of Principal Investigator or other documents that clarify the qualification of the Principal Investigator.

10. The following should also be included (as appropriate), depending on the type of protocol:

❒ Safety information

❒ Adverse Event management and reporting

❒ Record management

❒ Investigator Brochure or package insert

❒ Progress reports (if any).

❒ Certificate of insurance

11. Others as required.

Informed Consent: The Subject Consent Form – the process and procedures of documenting compensation for subjects should be provided to IRB. Basic content of the Consent Form shall be reviewed as illustrated below.

Case Report Form or Data Collection Sheet – when appropriate, include a copy of materials used to record data, indicating whether variables identify participants or not.

Amendments to Consent and Case Report Forms, if any Copies: at least one copy for every IRB member

Employee statement – Investigators planning to recruit employees as research subjects must indicate so on the Consent form. Investigators should be particularly careful to ensure that no coercion is used in the recruitment of this population.

Identified Tissue/Specimen For Future Research. Investigators planning to use/collect tissue for future research that is part of the "main study" should indicate so in the Study protocol and the Subject Consent Form.

Advertisements and Informational Material – copies of brochures, advertisements, videos, or any other informational material that are used in the recruitment of subjects must be submitted to the IRB for approval prior to publication or use because direct advertising for study subjects starts the informed consent and subject selection process.

Numeric values of compensation or gratuity should not be listed on advertisements.

When appropriately worded, the following items may be included in advertisements:

- The name and address of the Principal Investigator or research facility,
- The condition under study and/or the purpose of the research,
- In summary form, the criteria that will be used to determine eligibility for the study,
- A brief list of participation benefits, if any,
- The time or other commitment required of the subjects, and
- The location of the research and the person or office to contact for further information.

- Expedited Review

  Type of Research Qualifying for Expedited Review:

In research studies qualifying for expedited review, human subjects incur no more than minimal risk. Special abbreviated consent form formats are available for tissue collections that meet criteria for expedited review. Research activities that may qualify for expedited review are:

1. Certain kinds of research on drugs and devices;
2. Collecting blood by stick or venipuncture with limits for age, health status; etc.
3. The prospective collection of specimens for research purposes by non-invasive means;
4. Data collected through non-invasive means (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding X-rays and microwaves;
5. Materials that have been collected solely for non-research purposes;
6. Voice, video, digital or image recording made for research purposes;
7. Research on individual or group characteristics or behaviour or research employing survey, interview, oral history, focus group, program or human services evaluation, and quality assurance methodologies.

<u>Documentation Required for Expedited Review</u>

The application process for consideration of expedited review is the same as that for full (convened) Board review.

<u>IRB Evaluation of Expedited Review Studies</u>

Applications for expedited review will be reviewed by the IRB chairman or by one or more experienced IRB Board members designated by the chairman. The assigned reviewers may exercise all of the authorities of the IRB, except that they may not disapprove the research. Only the full Board may disapprove a study.

If the study qualifies for expedited review and is approved, a notice confirming approval for the study will be sent to the Principal Investigator and his/her institution is notified via the IRB Minutes.

It is the responsibility of the Principal Investigator to notify the sponsor about IRB decisions.

5. At least one copy of the above mentioned documents shall be supplied for every IRB member.
6. Decision obtained by the IRB committee shall be documented in an approval letter.

Note: It shall be agreed that changes or modifications to the Study protocol shall be reported to the committee as described later in this manual.

7. The Principal Investigator remains responsible for ensuring that proper informed consent is provided for each subject in the study
8. The Principal Investigator is responsible for training any named individual(s) in the process of consent and making sure that they are knowledgeable about the study, the process and can answer questions about the scientific basis of the protocol.
9. The Principal Investigator is responsible for obtaining review from all appropriate specialty areas or for including a co-investigator(s) from all areas included in the study
    - When a study is proposed that involves an aspect of medicine generally considered to be outside the traditional training and practice of the Principal Investigator, the Principal Investigator must include colleagues with appropriate expertise as co-investigators.
    - The Principal Investigator may be asked to provide the IRB with written confirmation that the investigatory team possesses the level of training and expertise to adequately conduct the study and to ensure subject safety.

JUST-KAUH IRB STUDY CLOSURE REPORTING

1. At the completion of each approved study (submission of the final report to the sponsor or study suspension/termination), the Principal Investigator will prepare a study closure report for the IRB that includes the following information about the entirety of the study from beginning through completion:
    - Summary information about the study including: study name/Code, Protocol code no., IRB approval Date, study dates (Screening and clinical periods), final report submission date or termination/suspension dates, etc.
    - CRO name and address, Principal Investigator name and address, Sponsor name and address and other study related parties when applicable.
    - Participants: number of subjects enrolled and withdrawals, generally, reasons shall be specified.
    - A listing of serious and unexpected adverse events that occurred during the study.
    - Comments on the conduct of the study (Deviations).
    - A statement that the study is completed, terminated or suspended.
    - Any conclusion the Principal Investigator may have regarding the study.
2. A copy of this report will be kept within the CRO/Investigator and IRB correspondence files.
3. This report shall be kept within the IRB files and retained as described in this manual.

MODIFICATIONS TO THE STUDY PROTOCOL OR ITS RELATED DOCUMENTS AFTER APPROVAL

1. The Principal Investigator should not implement any deviation from, or changes of, the protocol without prior review and documented approval/favourable opinion from the IRB of an amendment, except where necessary to eliminate an immediate hazard(s) to study subjects, or when the change(s) involves only logistical or administrative aspects of the study (e.g., change of monitor(s), change of telephone numbers). Following are some points which are considered to be ethically acceptable and there's always a chance to happen:
    - A decrease in the number of blood draws and /or volume of blood per draw and total.
    - Any other procedural change which does not adversely affect safety (e.g., analytical methodology, handling of samples, changes in sampling tubes additives, additional clinical laboratory tests, etc,)
    - Edits of the wording of the Informed consent Form or protocol which do not alter the meaning of the text (e.g., typographical errors, changes in grammar, etc.)
    - Change in length of retention of drug supplies or archiving report.
    - Change in statistical method used.
    - Widening weight restrictions of up to ±15% of ideal weight based on Metropolitan Life Insurance Table.
    - Change in the identification of the test or reference product, but not in the product itself.
    - Addition of vital signs measurement, ECG examination and any other safety measures including samples collected for laboratory tests, e.g., blood withdrawal taking into consideration that the total volume of blood to be withdrawn will be within the acceptable limits defined by the IRB committee.
    - Modification of the meals timing with an acceptable justification.
    - Increasing the washout period.
    - Other logistical and/or administrative issues that do not affect subjects' safety.
2. The Principal Investigator or designee should inform the IRB Chairman of the above listed changes within 24 hours.

3. Following are some of the modifications that should not be implemented without prior written approval of the IRB committee:
    - An increase in the number of blood draws and/or volume of blood per draw and total.
    - Decreasing the frequency of vital signs measurement and/or deleting ECG examination or other safety measures.
    - Increasing the administered dose and consequently altering some procedures.
    - Decreasing the washout period.
    - Other actions that are related to the safety and rights of the study subjects.
4. A copy of the approval letter and the signed amendment shall be kept within the IRB files.

CONDUCTING JUST-KAUH IRB MEETINGS

1. IRB meetings are regularly scheduled at a specific day/time every week as been set by the committee at the first meeting.
2. The prescheduled appointment may be altered by the IRB administrative office based on the request of the IRB chairman or other members or due to the complete submissions of protocols to be reviewed.
3. Complete IRB submissions will be reviewed within at least 3 working days after the day of recepit.
4. IRB administrative office shall accordingly arrange date/time and location on the meeting agenda that will be distributed to the members (See Attachment # 06).
5. Each meeting is expected to be of maximum 2 hours or as appropriate.
6. Before each meeting, each member will receive all pertinent material prior to the meeting and - can actively and equally participate in the discussion of all studies.
7. Minutes of such meetings (See Attachment # 07) must clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements:

   - Attendees;

   - Initial and continued presence of at least two thirds of members including at least one non-scientific member (or as required by the applicable regulations).

   - Actions taken by the IRB;

   - Votes on such actions;

   - Discussion and resolution of controverter issues.

   - Letter of Recommendations/Others as appropriate.
8. The IRB meeting is a closed meeting and is not open to attendance by visitors. A visitor wishing to attend a meeting should send a letter to the Board that includes a rationale for attending this meeting. The Board decides whether to allow the visitor to attend on a case-by-case basis. Visitors are required to sign a confidentiality statement (See Attachment # 08).

BASIC ELEMENTS OF INFORMED CONSENT FORM (ICF)

The following points are the basic elements of the ICF and must be present in any ICF:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the regulatory bodies for which the study is submitted may inspect the records.
- For research involving more than minimal risk, an explanation as to whether any compensation and whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to any related questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled as been specified by the Informed Consent Form.
- Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

-A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.

- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

- Any additional costs to the subject that may result from participation in the research.

- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- The approximate number of subject involved in the study.
- Others as requested by the local regulatory authorities, and as proposed by the IRB committee.

ATTACHMENT # 01

AUTHORIZATION LETTER

DATE:
TO:
TITLE:

Dear Mr/Ms: _____

I would be pleased if you would as an IRB Administrative Office Staff take care of the tasks stated below:

- Coordinate the IRB office activities to meet all applicable regulations and ensure compliance of the committee procedures (prepare and update SOPs, coordinate training sessions, update the regulatory files whenever applicable, etc...).
- Organize the correspondence between the committee and the Principal Investigator. This may include but not limited to all of the following:
    1. Study protocols and study related documents.
    2. IRB requests for additional information.
    3. Amendments.
    4. Local unanticipated problems and adverse event reports.
    5. Study Closure Reports.
    6. Others as appropriate.
- Distribute of study related documents required for the board review and ensure that all necessary documents are provided at the time of submission.
- Prepare the agenda for each meeting.
- Attend all IRB meetings to take care of related administrative issues (prepare the approval letters, documentation of the accurate and complete minutes of the meeting which serve

as the official, permanent record of IRB actions, distribution of IRB recommendation letters to King Abdullah University Hospital departments, etc, ….).

- Provide consultation to the Board at the meetings in areas of regulatory compliance.
- Prepare and update list of IRB members identified by name, earned degree, qualification and certification if any and, position in the committee.
- Maintain all IRB files, including CVs, training records and standard operating procedures, study closure reports, safety reports, minutes of the meetings and relevant letters of recommendations, approval letters specifying IRB action and decision, audit checklists, others as appropriate.
- Manage other related administrative activities as assigned.

Regards,

IRB Chairman

_____

Date: _____

ATTACHMENT # 02

IRB APPROVAL LETTER

TITLE OF THE STUDY:
PROTOCOL CODE NO.:
DAY/DATE OF MEETING:
TIME OF MEETING (INITIATION - TERMINATION):

ATTENDANCE:

MEMBER NAME*	QUALIFICATION

ABSENCE:

MEMBER NAME*	QUALIFICATION

QUORUM IS: ❒ REACHED ❒NOT REACHED (SPECIFY THE DATE OF THE NEXT MEETING**)**

** Number of signatures may be expanded.*

TITLE OF THE STUDY:
PROTOCOL CODE NO.:

OTHER ATTENDANTS:

MEMBER NAME*	QUALIFICATION

PROTOCOL VERSION / DATE OF APPROVAL	
NUMBER OF PROTOCOL AMENDMENTS SUBMITTED	
SPONSOR NAME AND ADDRESS	
SPONSOR NAME	
SPONSOR ADDRESS	
PRINCIPAL INVESTIGATOR NAME AND ADDRESS	
PRINCIPAL INVESTIGATOR NAME	
PRINCIPAL INVESTIGATOR ADDRESS	

** Number of signatures may be expanded.*

TITLE OF THE STUDY:
PROTOCOL CODE NO.:

THE FOLLOWING DOCUMENTS HAVE BEEN SUBMITTED TO IRB (✓) FOR APPROVAL ON THE STUDY MENTIONED ABOVE

DOCUMENT	DATE OF SUBMISSION
❒ PROTOCOL # _____	
❒ PROTOCOL AMENDMENTS (AS ABOVE)	
❒ CASE REPORT FORM	
❒ INFORMED CONSENT	
❒ INVESTIGATORS BROCHURE (IB) / PACKAGE INSERT	
❒ OTHERS:	

IRB CHAIRMAN SIGNATURE: _____ DATE: _____

MEMBERS VOTING FORM

TITLE OF THE STUDY:
PROTOCOL CODE NO.:

IN THIS MEETING THE FOLLOWING DOCUMENTS WERE REVIEWED:
☐ **CLINICAL PROTOCOL**
☐ **CASE REPORT FORM**
☐ **INFORMED CONSENT FORM**
❒ **INVESTIGATORS BROCHURE (IB) / PACKAGE INSERT**
☐ **OTHERS: _____**
THE IRB INVITED _____ TITLE _____
TO PROVIDE FURTHER INFORMATION ON THE STUDY UNDER DISCUSSION.
(SEE ATTACHED INFORMATION SHEETS WHEN APPLICABLE)
SIGNATURE*: _____ DATE: _____
AT THE END OF THE DISCUSSION, EACH MEMBER WAS ASKED TO VOTE ON THE SUBJECT. THE VOTING RESULT WAS AS FOLLOWS:

MEMBER NAME*	YES	NO	SIGNATURES
	❒	❒	
	❒	❒	
	❒	❒	
	❒	❒	
	❒	❒	
	❒	❒	
	❒	❒	
	❒	❒	
	❒	❒	
	❒	❒	

FINAL DECISION:

ALL THE MATERIALS WE SUBMITTED TO THE IRB, INCLUDING THE INFORMED CONSENT FORMS REVIEWED BY THE IRB AND:

❒ **APPROVED** ❒ **CONTINGENTLY APPROVED:** SEE ATTACHED LETTER OF RECOMMENDATIONS

❒ **DISAPPROVED DUE TO THE FOLLOWING REASONS:**

_____

_____

_____

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** Number of signatures may be expanded.*

ATTACHMENT # 03

ATTACHMENT # 04

CONSENT PROCEDURES AUDIT CHECKLIST

IRB MEMBERS SIGNATURE LIST*

NAME:	SEX:
QUALIFICATION:	TITLE:
SIGNATURE:	DATE:
NAME:	SEX:
QUALIFICATION:	TITLE:
SIGNATURE:	DATE:
NAME:	SEX:
QUALIFICATION:	TITLE:
SIGNATURE:	DATE:
NAME:	SEX:
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NAME:	SEX:
QUALIFICATION:	TITLE:
SIGNATURE:	DATE:
NAME:	SEX:
QUALIFICATION:	TITLE:
SIGNATURE:	DATE:
NAME:	SEX:
QUALIFICATION:	TITLE:
SIGNATURE:	DATE:

PAGE I OF I

** Number of signatures may be expanded.*

NAME OF THE STUDY:	
PROTOCOL CODE NO.:	
STUDY CODE:	

ITEM	YES	NO	N/A	COMMENTS
The IRB has received a copy of the Consent Procedure and approved it.	❒	❒	❒	
The ICF was written in an understandable language to the subjects	❒	❒	❒	
A qualified staff is present to perform the consent procedure	❒	❒	❒	
The subjects were allowed to have a copy of the IRB approved ICF	❒	❒	❒	
The subjects were allowed to read and understand the ICF	❒	❒	❒	
All information written in the ICF were fully explained to the subjects	❒	❒	❒	
All adverse drug reactions were fully explained to the subjects	❒	❒	❒	
The amount and method of payment was fully explained to the subjects	❒	❒	❒	
All subjects questions were answered by the attending staff	❒	❒	❒	
ADDITIONAL COMMENTS				

IRB MEMBER: _____ **DATE:** _____

IRB CHAIRMAN: _____ **DATE:** _____

PAGE ____ OF _____

ATTACHMENT # 05

CLINICAL PERIODS AUDIT CHECKLIST

NAME OF THE STUDY:	
PROTOCOL CODE NO.:	
STUDY CODE:	
STUDY PERIOD:	

ITEM	**YES**	**NO**	**N/A**	**COMMENTS**
The study was conducted in an accredited site	❒	❒	❒	
Adequate space was provided to the subjects	❒	❒	❒	
The space is clean and healthy	❒	❒	❒	
Meals provided were acceptable and adequate to the subjects	❒	❒	❒	
Safety measures (emergency settings) are taken	❒	❒	❒	
Qualified clinical staff and study physician are present.	❒	❒	❒	
Adequate procedure is available to handle adverse events	❒	❒	❒	
Documentation of adverse events is adequate	❒	❒	❒	
The study was done according to the approved protocol (concerning number of samples, clinical staff, etc.).	❒	❒	❒	
The subjects are aware of the study procedures (aims and possible adverse events).	❒	❒	❒	
Study subjects have complaints	❒	❒	❒	
ADDITIONAL COMMENTS				

IRB MEMBER: _____ **DATE:** _____

IRB CHAIRMAN: _____ **DATE:** _____

PAGE ____ **OF** _____

ATTACHMENT # 06

IRB MEETING AGENDA

DATE / DAY		
TIME / DURATION		
LOCATION		
ATTENDEES:		
AGENDA TOPICS:* ***The following topics shall be discussed during the meeting:***		
1.		
2.		
3.		
4.		
5.		
6.		
Meeting Called By:		
Date:		

**Number of Rows may be expanded.*

PAGE ____OF ____

ATTACHMENT # 07

MINUTES OF MEETING

DATE / DAY		
TIME / DURATION		
LOCATION		
ATTENDEES:		
NAME*	**SIGNATURE***	
ABSENTEES:		
NAME*	**SIGNATURE***	
MINUTES OF MEETING:* ***The following topics were discussed during the meeting:***		
1.		
2.		
3.		
Meeting Facilitator:		
Date:		

**Number of Rows may be expanded.*

PAGE ____OF ____

ATTACHMENT # 08

CONFIDENTIALITY STATEMENT

I, _____(*printed name*) hereby agree to handle all information related to studies submitted to the Institutional Review Board of _____(*printed name*) for approval in a fully confidential manner and will not release any piece of it to a third party. Such confidential information deals with, but not restricted to: study activities, study documents and any other information, which is not publicly released. Also, all information related to study subject identity shall be handled as a confidential document.

It is understood that the regulatory authorities are not considered a third party.

_____

NAME:

_____

TITLE:

_____

SIGNATURE:

_____

DATE:

ATTACHMENT # 09
IRB MEMBERS TRAINING FORM

TRAINING MATERIAL DESCRIPTION:

_____

_____

_____

_____

TRAINER: _____ **SIGNATURE:** _____ **DATE:** _____

NAME	SIGNATURE	DATE

ATTACHMENT # 10
IRB MEMBERS SELF -TRAINING FORM

I HAVE READ AND UNDERSTOOD THE FOLLOWING TRAINING MATERIAL AND AGREE TO COMPLY WITH ALL ITS CONTENT:

TRAINING MATERIAL DESCRIPTION:

_____

_____

_____

_____

NAME: _____

TITLE: _____

SIGNATURE: _____

DATE: _____