

## Procedural Rules (as amended on September 2, 2003)

### I Purpose

The International Medical & Dental Ethics Commission (IMDEC) offers independent ethical and legal reviews of drug, medical-device and other healthcare and consumer-product studies on behalf of sponsors and investigators responsible for carrying out such studies in the pharmaceutical, medical-device, healthcare and consumer-product industries.

IMDEC's primary objective in conducting its reviews is to protect the rights and dignity of those persons who volunteer to participate in clinical research. In seeking to meet this objective, the commission takes special care to ensure that the studies it reviews are carried out in conformity with all applicable national and international rules and recommendations. With regard to drug and medical-device studies, IMDEC is also guided in its decision making by the consideration of whether the risks for individual volunteers associated with participation in a clinical study are medically acceptable in light of the study's expected benefits for medical science.

IMDEC is registered at the **German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte)** and operates in accordance with **ICH Guidelines for Good Clinical Practice** and **U.S. Food and Drug Administration Regulations**.

IMDEC is also registered under **IRB Identifier IRB00002010** at the **Office of Human Research Protections of the U.S. Department of Health and Human Services**.

### II Membership

1. IMDEC's membership comprises at least 12 individuals from various countries and of diverse professional and cultural backgrounds. The members include both medical and legal experts of both sexes as well as laypersons of both sexes.
2. Through the experience, expertise and diversity of its members, IMDEC possesses the competence necessary to review specific research activities, ascertain the acceptability of proposed research in light of national and international regulations and standards of professional practice, and safeguard the rights and welfare of human subjects.
3. To avoid conflicts of interest, members who are themselves involved in the carrying out of a clinical study may not participate - beyond the supplying of information - in the review of the same clinical study.
4. IMDEC may solicit the advice of appropriately qualified referees. While such

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referees may participate at committee meetings, they may not vote on specific study proposals.

5. All members active in the review of study proposals are sworn to secrecy.
6. Committee meetings are led by the committee chairperson. The chairperson may be represented by another committee member who assumes the role of acting chairperson. The chairperson is appointed for a period of two years. At the end of this period, it is the responsibility of the remaining committee members to either reappoint the chairperson or to appoint a replacement.
7. It is open to any interested individual to submit an application in writing to IMDEC to become a committee member. New member appointments are made with an eye to maintaining the committee's independence, expertise, interdisciplinary nature and cultural balance. Members are appointed for a period of two years by the chairperson in consultation with the existing committee members. Reappointment is regarded as desirable for the sake of continuity.
8. Committee members are remunerated for their work. This remuneration corresponds to that of experts appointed by the courts.
9. In the interest of maintaining independence, the role of IMDEC's management and ownership is restricted to the provision of basic administrative support and basic resources such as an office, a conference room, computer equipment and filing space. Those persons responsible for managing IMDEC's business affairs and any of IMDEC's owners may not function as committee members.

### III Regulatory Canon

IMDEC reviews study proposals in accordance with the following regulatory documents.

- Declaration of Helsinki
- ICH Guidelines for Good Clinical Practice
- U.S. Food and Drug Administration Regulations
- German Drug Law
- German Medical Device Law
- EN-540
- European Cosmetic, Toiletry and Perfumery Association (COLIPA) Guidelines
- Cosmetic, Toiletry and Fragrance Association (CTFA) Safety Testing Guidelines

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- The Belmont Report
- Health Insurance Portability and Accountability Act (HIPAA Privacy Rule)
- ISO 14155 Clinical Investigation of Medical Devices for Human Subjects

### **IV Submitting a Study Proposal to IMDEC**

1. The study sponsor or the study investigator submits a copy of all required documentation in English or German to IMDEC by mail, fax or e-mail. The required documentation includes:
  - A short written request for commission review (1 copy)
  - Study protocol (6 copies)
  - Test-subject information sheets and informed-consent form (6 copies)
  - Investigator's brochure (if not previously made available to the commission) (3 copies)
  - Principal investigator's CV (1 copy)
  - Other investigators' CVs (for multicenter studies; may be submitted after initial request) (1 copy)
  - List of proposed study centers (1 copy)
  - Description of subject recruitment procedures including information about compensation as well as any advertisements used for recruiting purposes (1 copy)
  - Verification of insurance coverage or copy of CE-certificate (1 copy)
  - Case report forms (may be submitted after initial request for review) (2 copies)
  - If applicable, a statement justifying the use of any vulnerable subject populations (6 copies)
  - If applicable, a statement outlining special informed consent procedures used for study subjects (e.g., foreign nationals) who show signs of insufficient language comprehension (6 copies)
2. Requests for review may be supplemented or withdrawn.
3. As a rule, research proposals are reviewed within 9 days of their receipt (on

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condition that all relevant documentation has indeed been received).

### **V Committee Procedure**

1. Meetings take place every Tuesday evening. Ad hoc meetings may also be arranged.
2. With ample time in advance of committee meetings, study materials are made available to at least five committee members and one alternate.
3. Each committee member slated to participate at the next meeting examines all documents received and drafts notes for the purpose of more effective discussion.
4. At least five committee members (at these two of these physicians) take part in person at the committee meeting. A quorum is five members.
5. Each study proposal is discussed from ethical and legal points of view, with discussion culminating in a vote on the study proposal's acceptability. While IMDEC endeavors to reach unanimous decisions, a simple majority is deemed sufficient to issue an opinion. In the case of ties, the vote of the chairperson is decisive.
6. Minutes are kept for each meeting. These minutes specify: place; date; time of day; members present; subject of review; result of review; and specific voting tally.
7. The result of committee review shall declare one of the following:
  - a) approval
  - b) conditional approval
  - c) approval denied
  - d) decision postponed
8. Notice of the committee's decision is sent by fax or e-mail to the sponsor or investigator on the day following the committee meeting.
9. An official certificate of review containing the committee's decision, the signatures of the individual members present as well as any dissenting opinions is sent by mail.
10. As a rule, IMDEC drafts its certificates of review in English and in German.
11. In the case of (7b), final approval is granted as soon as the sponsor or investigator demonstrates that the conditions have been met. Alternatively, the

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sponsor may request that the decision be reconsidered. Decisions are reconsidered only upon presentation of a thorough justification for not accepting the conditions.

12. Committee decisions may be postponed. Postponement is deemed necessary whenever important matters must be clarified through further consultation with the sponsor or the investigator or through the submission of additional documents.
13. All study documents are maintained in the commission's archives for a period of at least four years.

### VI Continuing Review

1. At the time of its initial review, the committee will arrive at a decision as to whether the study at hand is subject to interim reporting. This decision is largely based on the type of risk assessed during the review, the proposed enrollment procedures for the study and the proposed length of the study.
2. If the committee determines that the study is subject to interim reporting, it will notify the investigator/sponsor of this fact on its certificate of review. This notification will specify the content of the required reporting and the deadlines by which such reports are to be submitted to the commission.
3. In order to ensure that investigators/sponsors comply with interim reporting requirements, the committee maintains a practice of sending reminders to the investigator/sponsor. These reminders clearly indicate that failure to report in a timely manner will result in the expiration of the commission's approval.
4. While the content of interim reporting may be more narrowly circumscribed, the commission usually requires the submission of a protocol summary and a status report on the progress of research, including (i) the number of additional enrollments, (ii) a summary of any adverse events or unanticipated problems involving risks to subjects, (iii) the number of subject withdrawals and any associated complaints about the research, (iv) a summary of any relevant recent literature, clinical findings, amendments or modifications to the research since the last review and (v) a copy of the current informed consent document.
5. Interim reports are handled by the committee chairperson or a substitute according to an expedited review procedure. The chairperson may decide to pass on such reports to the full committee for review at its next scheduled meeting.

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6. **Amendments** to the study protocol should be presented to IMDEC for approval before their implementation, except when their implementation is necessary to eliminate immediate hazards to the subjects or when they involve only logistical or administrative aspects of the trial (e.g., change of monitors, telephone numbers, etc.).
7. Amendments are handled by the committee chairperson or a substitute according to an expedited review procedure. The chairperson may decide to pass on such amendments to the full committee for review at its next scheduled meeting.
8. **Significant new clinical findings** and all study-related events (especially **serious adverse events**) that could have a bearing on the health and safety of trial subjects are to be reported without delay to IMDEC in writing. These are handled by the committee chairperson or a substitute according to an expedited review procedure. If time permits, they may be passed on for full committee review.
9. The committee may conduct on-site inspections. The committee may also withdraw its approval should it come to have compelling evidence that a study is not being conducted in accordance with good clinical practice or in accordance with any conditions it may have set before issuing its approval.
10. A brief final report should be sent to IMDEC upon study completion.

### VII Fees

The commission receives a fee for its services in order to cover operating costs and the compensation of its members. The fee for the review of a clinical study proposal ranges from € 1,100 to € 3,500 plus the applicable value added tax. The fee for the review of study amendments, unexpected adverse events and new clinical findings ranges from € 100 to € 300 plus the applicable value added tax. In exceptional cases, the fees mentioned may be raised or lowered.