

SOP-02 人體試驗委員會之組成(Version 6.1)

SOP-02 Organization of the Institutional Review Board(Version 6.1)

5.3 委員遴選資格的要求

5.3 Qualification of the IRB members

- 5.3.1 主任委員由院長指派，副主任委員、執行秘書及副執行秘書由主任委員指派，委員會之委員由主任委員聘任之。
- 5.3.1 The Chairman is designated by the superintendent. The vice-chairman, executive secretary and vice executive secretary are designated by the Chairman. IRB members are appointed by the Chairman.
- 5.3.2 醫事專業人員，由主任委員遴選，需有參與藥品、新醫療技術、新醫療器材或臨床研究經驗者。
- 5.3.2 Scientific expertise is selected by the Chairman from the personnel experienced in the medicine, new medical technique, new medical device or clinical research area.
- 5.3.3 非醫事專業人員，由主任委員遴選，需熟悉生物科技法規；社會公正人士或曾擔任臨床試驗受試者。
- 5.3.3 Non-scientific expertise is selected by the Chairman from the persons great at biotechnology related laws and regulations, impartial citizens or previous participants of clinical trial.
- 5.3.4 委員的任用是依據個人能力，興趣，倫理和/或科學的知識與專業，必須願意對委員會的工作付出時間和心力。
- 5.3.4 IRB members shall be appointed with reference to their competency, intention, ethic and/or scientific knowledge and expertise. They shall make mental and physical effort for the tasks of the IRB.
- 5.3.5 在計畫審查時，委員們必須以書面的方式揭露有關的利益衝突，包括財務、專業或其他方面。

5.3.5 When reviewing a plan, IRB members shall disclose their conflict of interest related to the plan in writing, including financial, professional or other aspects.

5.3.6 委員會決定當委員的利益衝突程度，是否可參與說明意見和討論。

5.3.6 Whether an IRB member is allowed to give comments or participate in discussion is determined by the IRB in consideration of the conflict of interest and its effect.

5.3.7 在新的任期開始前，委員會委員需要簽署一份應聘書（包含利益揭露，利益衝突迴避原則及保密協議）(IRB-TPEVGH SOP-02-03)。當相關的資訊可能會在委員會工作進行的過程中被公開的情況下，保密協議確保各方的隱私和機密性。

5.3.7 The IRB member shall sign an acceptance of appointment (containing disclosure of interest, conflict of interest avoidance principle and non-disclosure agreement) (IRB-TPEVGH SOP-02-03) before the new term of office begins. The non-disclosure agreement may protect the privacy and confidentiality of all parts in the circumstances in which relevant information may be open during execution of IRB tasks.

5.3.8 委員任用以 2 年為一任期，連聘得連任。但每次改聘人數以不超過委員總人數二分之一為原則。

5.3.8 IRM member's term of office is 2 years and can be renewed upon reappointment. The number of the members whose appointment is changed in each term of office shall not exceed 1/2 of the total IRB members.

5.3.9 負責營業發展（例如籌募研究經費）之主管不可擔任人體試驗委員會委員及人體試驗委員會日常運作等職務。

5.3.9 Individuals who are responsible for business development are prohibited from:

- **Serving as members or ex-officio members on the IRB.**

- **Carrying out day-to-day operations of the review process.**

5.3.10 本院院長可以更新主任委員的任期，主任委員得連任，主任委員可以更新委員的任期，委員得連任。

5.3.10 The superintendent of TPEVGH may renew the Chairman's term of office by reappointment, and the Chairman may renew the member's term of office by reappointment.

5.3.11 委員會在委員任期屆滿改聘時，需確保作業的連續性。

5.3.11 The continuity of IRB business shall be ensured when the appointment of any member is changed upon termination of his/her term of office.

5.4 委員聘任及評核之程序

5.4 IRB member appointment and evaluation procedure

5.4.1 新任委員：

5.4.1 New members:

除主任委員為當然委員外，其餘委員之任期為兩年，連聘得連任之。新任委員簽署應聘書 (IRB-TPEVGH SOP-02-03) 承諾遵守保密協定後發予聘書 (IRB-TPEVGH SOP-02-04)，並報請中央衛生主管機關備查。惟新任委員必須接受委員會之組織、功能及相關規定之講習，並列席審議會審查至少乙次(原擔任本院其他人體試驗委員會委員者可免)，以了解計畫審查之精神、程序及所需注意事項後始得執行委員職務。

Except for the Chairman who is the ex officio member, all IRB members have a two-year term of office and the term may be renewed upon reappointment. New members shall sign an acceptance of appointment (IRB-TPEVGH SOP-02-03) and a letter of appointment (IRB-TPEVGH SOP-02-04) will be issued after they undertake to comply with the non-disclosure agreement. The letter of appointment will be submitted to the central competent health authority for reference. Before doing their duties, new members shall participate in the workshops regarding

the organization, function and relevant regulations of the IRB, and attend at least one review meeting as an observer (not applicable to the members who have served as a member in any TPEVGH Institutional Review Board) to understand the intentions, procedures and matters needing attention in the review of protocols.

5.4.2 新聘：

5.4.2 New appointment:

當有委員出缺時(委員任期屆滿不再續任或因故離職)，由執行秘書尋覓及徵詢委員候選人若干人(至少與出缺委員人數相同)呈主任委員圈選。委員聘任依新任委員程序辦理。於同一年度內，新聘委員人數以不超過全體委員人數 2 分之 1 為原則。委員新聘之任何異動，須主動報請中央衛生主管機關備查並保存完整紀錄(含異動原因)。

When there is a vacancy (due to termination of the term of office without renew or resignation of a member for whatever reasons), the executive secretary looks for and asks a number of candidates (at least equal to the number of vacancies) for their intention, and recommends them to the Chairman for selection. Appointment of new members is subject to the new member appointment procedure. The number of newly appointed members shall basically not exceed 1/2 of the total IRB members in the same year. Any change regarding new appointment of IRB members shall be reported to the central competent health authority for reference, and a complete record (including the reason for the change) shall be maintained.

5.4.3 續聘：

5.4.3 Reappointment:

委員任期屆滿時，主任委員依據委員表現及意願決定是否續聘。

The Chairman may decide the reappointment of a member whose term of office expires in consideration of his/her

performance and intention.

新聘及續聘委員必須簽署明述同意遵守利益揭露，利益衝突迴避原則及保密協議之應聘書後始能繼續執行委員職務。委員續聘之任何異動，須主動報請中央衛生主管機關備查並保存完整紀錄(含異動原因)。

Newly appointed and reappointed members shall sign an acceptance of appointment containing disclosure of interest, conflict of interest avoidance principle and non-disclosure agreement before doing their duties as an IRB member. Any change regarding reappointment of IRB members shall be reported to the central competent health authority for reference, and a complete record (including the reason for the change) shall be maintained.

5.4.4 補聘：

5.4.4 Complemental appointment:

委員於任期屆滿前得因故請辭，惟須於離職前提出辭呈，以便補聘委員，然本會無替代委員(Alternative member)機制。補聘委員依新聘委員程序辦理。委員出缺時，必要時得補聘，以免影響委員會之運作。委員補聘之任何異動，須主動報請中央衛生主管機關備查並保存完整紀錄(含異動原因)。

Members may resign for whatever reasons before expiration of the term of office, and a resignation shall be submitted to make up the number of the members by complemental appointment. The Alternative Member mechanism is not available at IRB. Complemental appointment of members is subject to the new member appointment procedure and may be necessary whenever there is a vacancy left by a member so as not to affect the operation of the IRB. Any change regarding complemental appointment of IRB members shall be reported to the central competent health authority for reference, and a complete record (including the reason for the change) shall be maintained.

5.4.5 解聘：

5.4.5 Dismissal:

委員有以下情況時，委員會將事件發生事實提審議會討論，情節嚴重者(如下列敘述之項目)，予以解聘。

Where any of the following occurs to a member, he/she shall report the occurrence and fact to the review meeting for discussion. The member may be dismissed in case of serious circumstances (as described below).

5.4.5.1 不遵守利益揭露，利益衝突迴避原則及保密協議。

5.4.5.1 The member does not disclose his/her interest, disobeys the conflict of interest avoidance principle or acts in violation of the non-disclosure agreement.

5.4.5.2 任期內審議會出席次數累計無故缺席三次以上或超過應出席次數三分之一以上。

5.4.5.2 The member does not attend the review meeting three times accumulatively without justifiable reasons, or is absent at more than 1/3 of the meetings which he/she should attend.

5.4.5.3 未接受足夠臨床試驗教育規範(含 GCP)訓練之相關規定。

5.4.5.3 The member does not take adequate good clinical practice training (including GCP).

5.4.5.4 三個月內未完成委員訓練者。

5.4.5.4 The member does not finish member training within three months.

5.4.5.5 經二分之一以上委員投票(無記名投票)同意者。委員解聘時需經提會討論通過後，以書面告知。委員辭職或被解聘，可以聘任相關領域或特定的專家遞補。

5.4.5.5 A majority of members agree on the dismissal by voting (balloting). Dismissal of a member shall be proposed to the meeting for discussion and the

member shall be informed by letter. An expert in related areas or a specific expert may be appointed complementally when a member resigns or is dismissed.

5.4.5.6 副主任委員、執行秘書、副執行秘書及委員的評核由主任委員就委員出席會議審查表現及接受教育訓練情形進行評核，每年評核一次，秘書處將於每年底定期統計上述評核項目資料陳核主任委員進行評核(IRB-TPEVGH SOP-02-05)，評核結果須包括回饋及建議事項（IRB-TPEVGH SOP-02-08），以書面交付委員，並做為委員聘任之依據。相關評核資料由承辦人提供相關資料提請主任委員評核並做出續聘、不續聘、停聘及加強訓練或其他處分等之決行。主任委員由院長填寫主任委員評核表(IRB-TPEVGH SOP-02-07) 評核結果須包括回饋及建議事項（IRB-TPEVGH SOP-02-08），以書面交付主任委員，並做為聘任之依據。

5.4.5.6 The vice-chairman, executive secretary, vice executive secretary and member shall be evaluated by the Chairman in consideration of their performance at the review meeting and in the educational training. The evaluation is conducted once every year. The executive secretary regularly summarizes evaluation items and related data at the end of the year, and submits them to the Chairman for evaluation (IRB-TPEVGH SOP-02-05). The result of the evaluation shall contain feedbacks and suggestions (IRB-TPEVGH SOP-02-08). It shall be delivered to the member in writing and used as a basis for appointment of the member. The staff shall provide relevant evaluation data to the Chairman for evaluation, and the Chairman shall make a decision of reappointment, termination of appointment,

enhancement of training or other disposition measures. Evaluation of the Chairman is conducted by the superintendent by filling out the evaluation form (IRB-TPEVGH SOP-02-07). The result of the evaluation shall contain feedback and suggestions (IRB-TPEVGH SOP-02-08). It shall be delivered to the Chairman in writing and used as a basis for the appointment.