

銘傳大學人體研究倫理委員會設置辦法

Ming Chuan University Human Subject Research Ethics Committee Procedures

民國 99 年 10 月 4 日法規審查委員會通過

民國 99 年 11 月 1 日行政會議通過

Passed at the Regulation Review Committee Meeting on October 4, 2010

Passed at the Administrative Council Meeting on November 1, 2010

第一條 為確保執行以人為對象研究之安全及保障受試者權益，依據行政院衛生署人體研究倫理政策指引及其他相關法律規定，特設立銘傳大學人體研究倫理委員會(以下簡稱本會)，並制訂本辦法。

Article 1 These procedures and the Ming Chuan University Human Subject Research Ethics Committee, herewith called the Committee, were established in accordance with Human Research Ethics Policy Guidelines of the Department of Health, Executive Yuan and other relevant regulations. The purpose of these procedures is to ensure the safety and rights of human subject research.

第二條 本會職掌如下：

- (一) 研議及訂定人體研究作業基準及相關審核辦法。
- (二) 審核及監督人體研究計畫。
- (三) 審核受試者權益與倫理道德法律事項。
- (四) 其他有關與人為研究對象之事項。

Article 2 Matters dealt with at the Committee meetings are as follows:

1. Discussion and establishment of human subject research standards and relevant review procedures.
2. Review and supervision of human subject research projects.
3. Review of legal ethics and rights in human subject research.
4. Other relevant matters concerning human subject research.

第三條 本會置委員七至九人，其中健康科技學院院長、資訊學院院長及體育室主任為當然委員，其餘由校長遴聘之。其中應有三分之一以上為法律專家及其他社會公正人士，並應有二人以上為機構外人士，且應含具備醫師資格者至少一名。

遴聘之校外委員得依相關規定支領出席費及交通費。

Article 3 The Committee is composed of seven to nine members, besides the ex-officio members of the Deans of the School of Health Technology and School of Information Technology, and Director of Physical Education Office, others shall be appointed by the president. At least one third of the committee members shall be legal specialists and other impartial public figures, and at least two persons from outside of the institution that include one physician.

Off-campus committee members may receive attendance fee and transportation fee according to

relevant regulations.

第四條 本會設主任委員一人，由委員互選之，並經校長核定後聘任。
本會委員均屬無給職，任期為二年，得續聘連任。
本會置執行秘書一人，綜理業務，由主任委員指派之。
前項委員因故出缺時，由主任委員補聘之，繼任委員之任期至原任期屆滿之日止。

Article 4 The Committee members shall elect one individual as a chairperson, to be approved by the president before appointment.

The term of Committee members is two years and members are not paid. Members can be re-nominated when the term expires.

An executive secretary is appointed by the chairperson to manage Committee affairs.

When abovementioned Committee positions fall vacant, the chairperson should make up the needed appointments. The term of any successor is based on the remaining time in the original term.

第五條 本會視實際需要召開會議，必要時得邀請與審議事項有關之人員列席。

Article 5 The Committee shall summon meetings depending on actual needs. If necessary, it may invite relevant personnel to attend the meeting.

第六條 研究計畫如屬依醫學理論於人體施行新醫療技術、新藥品、新醫療器材及學名藥生體可用率、生體相等性之試驗研究者，應依醫療法第七十八條規定，與教學醫院或經中央主管機關核准設立之醫療機構共同進行研究。
前項研究計畫應經過共同研究之教學醫院或經中央主管機關核准設立之醫療機構所屬之人體試驗委員會審核通過，始得實施。審核之結果應副知本會。

Article 6 Research of new medical technologies, new medicines, new medical devices, bioavailability and bioequivalence of generic drugs on human subjects based on medical theory should be conducted with teaching hospitals or medical care institutions approved by the central competent authority and registered at court in accordance with the Medical Care Act Article 78.

Upon being passed at the Institutional Review Board Meeting, the abovementioned research can be implemented. A duplicate copy of review results shall be noted to the Committee.

第七條 有關本校人體研究之審核、監督及管理實施細則另訂之。

Article 7 Enforcement rules for reviewing, supervising, and managing university human subject research are stipulated elsewhere.

第八條 本辦法經行政會議通過，校長核定後實施，修正時亦同。

Article 8 Upon being passed at the Administrative Council Meeting and approved by the president, these procedures were implemented. Any revision must follow the same procedure.