

編號
NUM AS-IRB02-05022
日期
Date 1110'2006

中央研究院醫學研究倫理委員會
研究計畫審查同意書
Certificate of Approval

IRB02
修訂日期
Revised Date : 0315'2006

申請案編號 Application No : AS-IRB01-05022
計畫名稱 Project title : 建立亞太地區人類多樣性基因資料庫 (Pan-Asia SNP Initiative)
申請人 Project Investigator : 陳垣崇
合作機構 Collaborating Institute(s) : Pan-Asia SNP Initiative (PASNPI)
執行期間 Implement Duration : From 2005 / 06 / 01 / to 2007 / 12 / 31 /
(yyyy /mm/dd) (yyyy /mm/dd)
核准日期 Approval Date : 2006 / 11 / 10 / (yyyy / mm/ dd)
有效期限 Due Date : 2007 / 12 / 31 / (yyyy / mm/ dd)
進度或成果報告 Progress Report :

1. 請於96年12月30日前繳交進度或成果報告至本委員會追蹤審查。The progress report should be submitted to the IRB at Academia Sinica before 2007 / 12 / 30 / (yyyy/mm/ dd) for continuing review.
2. 如向衛生署定期提出進度或成果報告，需將完整報告內容副知本委員會。If Progress reports are submitted to the Department of Health, a copy should be submitted to the IRB at Academia Sinica.
3. 如受試者有不良反應，應即時向主管機關報告並副知本委員會。All the adverse events are required to report to the official institute and IRB of Academia Sinica promptly.

附註意見 Additional Opinion :

1. 往後若欲自「台灣地區華人細胞株及基因資料庫」釋出 DNA 資料至 PASNPI，須再提至本委員會審查。The applicant shall submit to this committee for new approval if any other DNA data is to be released from the "Collaborative Study to Establish a Cell Bank and a Genetic Database on Non-Aboriginal Taiwanese."
2. 請申請者建議 PASNPI 訂定「明確」之資料使用條件 (例如用於哪些方向之研究，以預防某族群污名化的可能性) 與審核機制，並於明年年度進度報告時，將 PASNPI 之相關結論副知本委員會。The applicant shall suggest PASNPI set forth clear criteria and establish a mechanism to review any use of PASNPI database. Such criteria and mechanism should be set in a way, among others, to avoid any research project that is likely to stigmatize a specific group of people. The applicant shall inform, in the annual report, this committee of the conclusion of PASNPI on this issue.
3. 請申請者爭取成為 PASNPI 之 Policy IRB 的成員，並建立 Policy IRB 與各國參與成員所代表族群之溝通管道 (使其 IRB 可反應所研究的族群之倫理觀點)，並於明年年度進度報告時，將 PASNPI 之相關結論副知本委員會。The applicant shall petition PASNPI for including the representative from Taiwan to be a member of its Policy IRB, and establishing a communication mechanism between the Policy IRB and the representative of participating group of people. The applicant shall inform, in the annual report, of the conclusion of PASNPI on this issue.
4. 請申請者於 PASNPI Executive Committee 會議中，建議仿效 International Hap Map Project，成立各參與族群之 Community Advisory Group，使其擁有以族群為單位退出 PASNPI 計畫之決定權，並於明年年度進度報告時，將 PASNPI 之相關結論副知本委員會。PI shall propose in PASNPI Executive Committee meeting to establish Community Advisory Groups to represent the interests of each donor community and to serve as liaison between PASNPI and such community. A CAG would have a right to ask that all of the data from that community be withdrawn from further use. PI shall inform this committee of the decision of PANSPI when the request for continuation approval is submitted in 2007.

茲 證明上項醫學研究計畫，包括其受試者之說明同意書，已經本委員會之審核，並同意此計畫書之內容符合本委員會所訂定之醫學研究倫理標準。

The above named study proposal has been reviewed, along with the informed consent, by the committee and found to conform with the guidelines set forth by this committee.

主任委員：
Chairman

日期：
Date

中央研究院醫學研究倫理委員會
Human Subject Research Ethics Committee / IRB
Academia Sinica