



THAI VACCINE

STUDY TITLE:	A Randomised, Placebo-Controlled, Double-Blind, Phase I Clinical Trial to Evaluate the Safety and Immunogenicity of a Candidate Prophylactic pHIS-HIV-AE DNA Prime and rFPV-HIV-AE Boost HIV Vaccination Strategy.
STUDY OBJECTIVE:	To assess the safety and immunogenicity of a candidate prophylactic human immunodeficiency virus (HIV) vaccine strategy, specifically designed for HIV-negative Thai individuals.
STUDY DESIGN:	A single centre, randomised, double blind, placebo-controlled 52 week study. Volunteers will receive three intramuscular injections with the DNA vaccine (pHIS-HIV-AE) at weeks 0, 4 and 8, or the same volume of relevant placebo. At week 12, volunteers will receive one intramuscular injections with the fowlpox vaccine (rFPV-HIV-AE).
IS THE STUDY OPEN TO PATIENT ENROLLMENT:	The study will be open to enrolment in March 2006. We are seeking healthy adult volunteers, aged 18-55 years, with no identifiable risk behaviour for HIV-1 infection in Bangkok.
ENROLLMENT TARGET:	24 at Chulalongkorn Hospital, Bangkok
STUDY COMPLETION DATE:	September 2006
STUDY DRUGS:	pHIS-HIV-AE DNA and a non-replicating, recombinant fowlpox virus (rFPV-HIV-AE), each encoding the HIV-1 AE antigens, modified Gag, Pol, Tat/Rev and Env. Both agents will be delivered by intramuscular (IM) injection.
SPONSOR:	NCHECR
COLLABORATOR SITES:	HIV-NAT, HIV Netherlands Australia Thailand Research Collaboration
CONTACT PERSON:	Rebekah Puls, NCHECR (+61 2) 9385 0900