



## PROJECT SUMMARY

### EXPANDED CROSS-SECTIONAL AND PROSPECTIVE STUDY FOR MEASUREMENT OF HIV INCIDENCE IN CHÓKWÈ, MOZAMBIQUE



FHI is sponsoring an HIV incidence study in Chókwè, Gaza Province, Mozambique, funded by USAID. With funding from the Henry Jackson Foundation, affiliated with the U.S. Military HIV Research Program (MHRP) and Walter Reed Army Institute of Research (WRAIR), we propose to expand the study size and duration to demonstrate site capacity, and provide more precise estimates of HIV incidence.

In brief, the prospective phase of the study will be increased from the current N=400 women to N=735 women. In order to enroll this larger cohort of eligible female volunteers for the prospective phase of the study, we anticipate that we will have to screen N=1,800 women in the cross-sectional screening phase.

The observation period in the prospective phase will be lengthened from the current 6-12 months of follow-up to 9-24 months of follow-up, with the earliest enrollees scheduled for the longest follow-up time. The follow-up visit schedule will be changed from the current monthly visits to quarterly (every 3 months) visits. Community engagement efforts will be invigorated and widened to increase enrollment rates, and additional field staff will be hired to mobilize the community, handle the increased number of study visits, and maintain contact with the prospective phase study participants.

The protocol has been amended to the satisfaction of Henry Jackson Foundation, FHI and Mozambique INS staff. FHI will submit the amended protocol to its IRB, the Protection of Human Subjects Committee (PHSC), for expedited review in February 2011. After PHSC review and approval, we will submit the protocol to the WRAIR IRB. After that review, the protocol will be submitted to the national Mozambican IRB, the Comité Nacional de Bioética para a Saúde (CNBS). We expect to have full IRB approval for the protocol amendment by May 2011. Enrollment into the cross-sectional and prospective phases of the current study is already under way; the enrollment period for the expanded study will run through the third quarter of 2012 and the follow-up period will be through the second quarter of 2013. Study close-out, analysis and reporting will take place in late 2013.

Funding from the Henry Jackson Foundation further diversifies the research portfolio at the Chókwè center and provides more funding stability.

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