November 20, 2009

TO: Allison Schmidt, OMB

FROM: Nidhi Singh, HRSA Reports Clearance Officer

SUBJECT: HRSA HIV/AIDS Bureau– Response to OMB Comments on the Intervention Trials to Retain HIV-Positive Patients in Medical Care (New ICR)

A1) Please include these materials ("a theme slogan for the intervention, brochures, posters with messages to patients, brief verbal retention in care messages from clinicians and clinic staff to patients, and appointment reminder cards") **in ICR package.**

HRSA Response: Attached to this memo are the following materials to include in the ICR package: Tab 1 which consists of a) brochure b) pocket guide for verbal retention in care messages (for clinic staff and for clinicians) c) posters (for exam room and for waiting for room). Since submission of this ICR, it was decided that appointment reminder cards will be the same cards that are used at each specific site. The supporting statement has been revised to reflect that the appointment cards are no longer considered components of the clinic-wide intervention and that each of the six participating sites will continue to utilize their own, pre- existing appointment reminder cards.

A2) "One hundred will be new patients and 200 will be patients with inconsistent attendance (missed at least one visit) for HIV primary care in the prior 12 months": **Why surveying new patients? During analysis, will these two groups be distinguished?**

HRSA Response: This project is surveying new as well as existing/established patients because both types of patients are at risk of falling out of HIV primary care. There is a high no-return rate for new patients, as high as 40% in some clinics, and so it is important to survey new patients as well. The two groups will be pooled in the primary analysis of Phase I and II. During secondary analyses, these two groups will be distinguished to see if there is any important difference in the effect of the interventions for new vs. established patients.

A3) Please include in ICR package: "In both intervention arms, patients will receive information about the importance of regular clinic attendance, motivational messages to stay in care, and modules designed to help patients increase specific skills that may improve clinic attendance"

HRSA Response: Attached to this memo is detailed information on the components of the Phase 2 intervention including modules and messages patients will receive. These materials (Tab 2-4) are to be included in the ICR package.

A4) If this is not direct "remuneration" for expenses, for instance, for travel expenses, please change language to "incentive." Please adjust language on consent form as well.

HRSA Response: HRSA will revise the Supporting Statement Question A9 title to "Incentives for Respondents" and replace "Renumeration". HRSA has also revised the language on consent form accordingly.

A5) OMB does not approve a $30 incentive (only $20, regardless of whether it is cash or gift card). We are trying to maintain equity across studies and across agencies in the Federal government. And we think that there should be equity across the sites within a single study if you are planning to pool the results. Please adjust amount on consent form as well.

HRSA Response: HRSA agrees that there should be equity across sites and has revised the Supporting Statement to state that "Patients will receive $20 in cash equivalent" and has adjusted the language in the consent form.

A6) What is the status of this application? ("Participating sites collectively applying for a Federal Certificate of Confidentiality.")

HRSA Response: The Certificate request is currently in process and is expected to be approved sometime in January, 2010.

A7) "Patients who have attended at least one visit for HIV primary care in each of two consecutive 6-month intervals will be coded "1" (consistent attendees) and those who do not fulfill this definition will be coded "0" (inconsistent attendees)."
Are these (consistent attendees) by default all the new patients (in the recruitment process of 100 new and 200 "inconsistent" patients)? Or could the recruited "inconsistent" patients (who missed at least one visit before recruitment) also qualify here as "consistent," as long as they had attended at least one visit later on?

HRSA Response: The reference to the 200 inconsistent patients in OMB's comment above refers to the **eligibility** to enter into the trial. Once entered into the trial the attendance behavior will be observed of all study participants over a 12 month period to see if they are well engaged (did not miss an appointment in that 12 month period) or not (they missed an appointment in the past 12 months). To further clarify, the Supporting Statement has been revised to state "Patients who have attended at least one visit for HIV primary care in each of two consecutive 6-month intervals will be coded "1" (well engaged in care) and those who do not fulfill this definition will be coded "0" (not well engaged in care)."

The results for the 100 new and the 200 inconsistent patients will be kept separate during the analysis of the trial data.

A8) Please also provide a brief discussion of the limitations of this study, with a note that such limitations will be discussed in any presentation of the data.

HRSA Response: The clinic-wide intervention was a one-group before-after design, and could be subject to secular trends in patient behavior unrelated to the intervention. We believe the danger of this bias is minimized by the short duration of the before and after periods (one year each). The multi-site study enables us to see if trends are consistent in different patient populations and geographical areas. The Phase II clinical trial has limitations typical to a clinical trial including generalization of results from our clinical trial to actual clinical practice. We have strived to design this study to reflect actual clinic practices as much as possible.

These statements will be included as part of a limitations paragraph in any study results manuscript, posters and presentations at meetings.

A9) Each pilot activity will involve 10 patients at each site for a total of 60 ACASI survey pilots. Please add to burden table and discussion.

HRSA Response: As requested, information regarding the ACASI survey pilot activities is now added to the burden table and discussion of the Supporting Statement. It is now revised to include the additional 30 burden hours for this pilot activity.

HRSA correction: One additional correction was made to the burden table to decrease the Number of Responses per Respondent and Total Number of Burden hours for the Risk Retention Screener. Since submitting this ICR to OMB, researchers determined that the Skills Domains modules will provide more in-depth information that would lead to identification of new or ongoing barriers and attitudes that may prevent a patient from staying in care. Therefore, the information obtained from the structured retention risk screener will only be needed at one time during the study in Phase II.