HRSA Response to OMB Questions for the Sickle Cell Demonstration Project
October 6, 2008

- ***Is there a reason why HRSA isn't doing a pre-post for all of the instruments? It seems like it would be useful to see, for example, how the SF-36 scores change before and after the demonstration program. Right now, it looks like only the utilization questionnaire will be fielded at baseline and 12 months later.***

We apologize for the lack of clarity. All of the instruments will be administered at baseline and at the 12 month follow-up as indicated in the table below.

Common Data Instruments for the SCDTDP Data Collection

Instrument Name	Dimension(s) Measured	Target Population	Frequency of Administration
SF 36	Quality of Life	Adults	Baseline at enrollment & Once a year
PedsQL	Quality of Life	Children and adolescents (5-18 years) Parents of children and adolescents (18 years and younger)	Baseline at enrollment & Follow-up at 12 months
Family Index (part of the Medical Home Assessment Tool)	Patient Satisfaction	Adults Parents of children and adolescents (18 years and younger)	Baseline at enrollment & Follow-up at 12 months
Individual Utilization Data Form	Demographics Health care utilization	Adults Parents of children and adolescents (18 years and younger)	Baseline at enrollment & Follow-up at 12 months

- ***If the grantees are going to be involved in reviewing medical charts/records, is a HIPAA authorization required?***

Since grantees may need to obtain health information contained in medical charts/records held by a covered entity a HIPAA authorization may be required. We have amended the consent form to allow the subject to authorize their provider (the covered entity) to release health information to the study team. We will work with the individual grantees and respect their preferences to use this dual consent form or a separate HIPAA authorization form per their institutional policies and procedures.

- ***On the child assent form, when are the words in italics applicable? It seems to me that some of the italicized language should be read to the children regardless (for example, why wouldn't the interviewer want to tell the child that refusal to participate will not affect any benefits?).***

We have removed the "if applicable" exceptions. All of the italicized text will be read to the subject.

- ***On the consent form, please add the phrase "private to the extent permitted by law" or something to that effect. If HRSA thinks that would be confusing to participants, it would be OK to spell out what some of the "exceptions" might be (just as you do on the assent form: i.e., telling someone if the participant is at risk of harm).***

We have amended the adult and parent consent forms by inserting the phrase "private to the extent allowed by law".