

Section 18. HOPE CHARISMA Component

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This section describes study-specific procedures for the Community Health clinic model for Agency in Relationships and Safer Microbicide Adherence (CHARISMA). The CHARISMA clinic-based intervention component, hereafter called “CHARISMA” will be conducted at selected HOPE sites. The HOPE site(s) conducting CHARISMA must maintain this section of the Study-Specific Procedures (SSP) Manual in its entirety. All other HOPE sites not participating in CHARISMA are not required to maintain this section of the manual. For clarity of documentation, however, all sites should maintain a reference copy of Version 2.0 of this page (18-1), dated 13 January 2017, in their SSP manuals.

18.1 Introduction

This section specifies the sources of procedural information available to HOPE staff, the responsibilities of the Investigators of Record (IoRs) responsible for CHARISMA at each site, and the process by which each study site is approved to begin implementation of CHARISMA.

Study implementation questions regarding CHARISMA that are not easily addressed within the protocol or this section of the SSP manual should be directed via email to the CHARISMA Management Team (CMT) at mtn-charisma@mtnstopshiv.org.

CHARISMA does not have a separate activation process from HOPE. However, before undertaking any CHARISMA related study procedures, each site must receive notification of completion of all items on the CHARISMA Implementation Readiness Checklist in Appendix 18-1.

18.2 Training, Quality Assurance, and Mentorship for CHARISMA Counselors

18.2.1 Training and certification

To ensure fidelity to the counseling approach in CHARISMA, all staff involved in the study should complete training on basic concepts of gender, Intimate Partner Violence (IPV), and Social Harms (SH). Training will be provided by CMT-designated facilitators following standardized guides (See Appendix 18-2 CHARISMA Facilitator Training Manual).

Each staff member who will be responsible for conducting CHARISMA counseling in MTN-025 must be certified by the CMT at the end of training, before conducting CHARISMA counseling with study participants. For certification, staff will conduct mock counseling sessions in English with a peer, observed by a member of the CMT. Certification will be awarded upon completion of three mock sessions that meet or exceed pre-established quality and fidelity criteria, as defined and evaluated by the CMT using the CHARISMA Counseling Session Observation Form (Appendix 18-3). As indicated in CHARISMA Implementation Readiness Checklist (Appendix 18-1), at least two counselors per site must be certified before the site can begin implementation of CHARISMA.

Once certified, CHARISMA counselors may begin providing CHARISMA counseling when participants come in for their HOPE study visits. Additional details regarding how to conduct counseling sessions can be found in the CHARISMA Agency in Relationships and Empowerment Counseling Manual (CARE Manual) (Appendix 18-5).

18.2.2 Observation and Quality Assurance

Once counselors are certified and begin seeing study participants, CHARISMA counseling mentors will observe and rate three to five of each counsellor's first sessions and at least one in ten sessions thereafter. Additionally, the first three CHARISMA sessions that are triggered via the HOPE SH process will be observed. The CHARISMA Counseling Session Observation Form (See Appendix 18-3) will be used to document these observations. After the each counselor maintains an overall score of at least 50 points, observations can be done once every 20 sessions. For each session observed, counseling mentors are responsible for entering rating information into a weekly statistics report supplied by RTI and sending the report to the CMT once per week. The CHARISMA PI or designee at the site will be responsible with the CHARISMA counsellors for tracking the number of counselling sessions each counsellor has completed, assigning a counseling mentor to observe the relevant sessions, and sharing observation data with RTI.

Before a counseling mentor begins to observe a counseling session, the counselor should ask the participant if they are comfortable with having a mentor sit in on the session for counseling quality assurance purposes. The counseling mentor will observe the session only if the participant agrees to the observation. If the participant declines permission to allow the mentor to sit in, the mentor will seek permission from the next participant whom the counsellor sees. When sitting in on a session, the mentor may introduce themselves to the participant as a counselling mentor and will pre-emptively let the participant know that if any difficult subjects come up, she/he may speak with them separately to follow up on the issue during the same visit.

If a counseling mentor observes a counselor whose scores for quality and fidelity are below-adequate (e.g. 33 or below) during a counseling session with a participant, the mentor should not disrupt the counselling session, but rather conduct mock training sessions with the counselor to improve their counseling techniques. The counselor should continue with mock sessions, rather than actual counselling sessions, until she demonstrates adequate counseling fidelity scores. Upon demonstrating adequate fidelity scores, the counselor can resume CHARISMA counseling sessions with participants. The observer should also discuss a strategy with the IoR to determine whether further counselling should be provided to the participant by the mentor, themselves, before leaving she leaves the clinic. In cases where the observer notices critical errors/ discrepancies during counselling session, the observer should offer the participant further counselling to correct the errors. This should ideally occur on the same day that the counselling occurred, but she may be invited back the following day if same day counselling is not feasible.

All CHARISMA Counseling Session Observation Forms should be batched and emailed to mtn-charisma@mtnstopshiv.org prior to the scheduled intervention team call (or on another designated day of the week). Separate files should be maintained for each observed session and should be named using the following convention: [site]_CSO_[visit type]_[counselor name]_[date of completion] (e.g. WRHI_CSO_Portia Duma_M1_20DEC2016). Hard copies should be filed in the CHARISMA site training file.

18.2.3 CHARISMA Debriefing Meetings and Psychological Support

Weekly debriefing meetings will be offered to the CHARISMA counselors with mentorship from the Study Coordinator, who ideally has a background in psychology, and peer support. Debriefing meetings, which may be in group or individual format, will include discussion of feedback from the session observations and discussion of challenges and lessons learned in delivering the counseling, including counselor recommendations for any future counseling module modifications to strengthen the intervention or streamline it. In addition, because responding to the issue of IPV can lead to burnout, compassion fatigue, and vicarious trauma, meetings with an external service provider – either in group or individual format – will be offered as needed, but on a minimum of a monthly basis, to provide a mechanism for staff to address their own needs for self-care. These latter meetings should offer opportunities for staff to discuss the emotional challenges of hearing about and responding to violence on a regular basis and to support one another. Meeting notes taken by the moderator or assistant moderator should document challenges and lessons learned, along with recommendations for module modifications. These notes will be reported to the CMT on a weekly basis via the Weekly Implementation Statistics Report (Appendix 18-14). In all discussions, both participant and staff autonomy and confidentiality will be upheld to the extent possible without hindering the support process.

18.3 Access to suitable referrals for CHARISMA participants experiencing IPV/SH

When a HOPE/CHARISMA site determines that a participant is experiencing IPV/SH, staff will provide a referral to an organization that can provide appropriate care. This will happen within the context of the CHARISMA lay counselling session designed to address IPV (Module C). Each site will establish (if needed) and maintain a network of local referral organizations that provide reliable, local services meeting the foreseeable needs that may be identified during administration of the CHARISMA intervention. Referral networks must include mental health and trauma, counseling, medical and legal services; shelters and hotlines. Referral organization names, addresses and contact details should be listed in the site's HOPE Referral SOP. Procedures for the Community Liaison Officer/Manager plans around maintaining relationships with key referral agencies and for following up on quality of care should also be included in the site's HOPE Referral SOP. Best practices for establishing referral networks will also be included in staff training. This will include setting up appointments with key referral agencies to introduce CHARISMA, understand referral agency capacity, and establish relationships with key and emergency contacts within the agencies. A CHARISMA staff member should be responsible for quarterly follow-up with key agencies to ensure that capacity and contact information has not changed. Counsellors should also follow-up with CHARISMA participants who take up referrals to determine their assessment of the quality of services received. This will happen during the participant follow-up session and will be recorded on CHARISMA Worksheets (Appendix 18-12-13).

18.4 Documentation Requirements

Essential documents pertaining to CHARISMA, e.g. IRB correspondence, should be filed in accordance with site specific procedures for other HOPE Essential Documents. Study sites must maintain adequate and accurate participant file records containing all information pertinent to participation in CHARISMA for each study participant. To support continuity in the counseling over time, effort should be made to maintain continuity in who provides the counseling (i.e. ideally participants will see the same counsellor at each session) and in documentation of each counseling session (i.e. sufficient information and detail should be documented on CHARISMA worksheets, Appendices 18-11-13, and/or in HOPE chart notes to inform subsequent counseling sessions).

18.4.1 Participant File Contents

In addition to the file elements outlined in Section 3, files for those participating in CHARISMA should contain:

- A record of all counseling-related activities, including printed Social Benefit and Harm Harms Tool (SBHT) results and counseling worksheets, as well as notes
- Referrals made (including for social harms or adverse events reported) as a result of CHARISMA intervention.

18.4.2 Source Documentation

For the CHARISMA component of HOPE, participant files must contain the following source documents:

- **SBHT:** Documentation of each implementation of the SBHT, including responses to questions and the participant score, will be included in the participant file. If the tool is implemented via a tablet, a print out of the responses will be placed in the file and stamped as a true copy of the original to certify it.

- **CHARISMA Worksheets:** Worksheets (Appendices 18-11-13) used to target and document the counseling content covered will be filed in participant files after each visit during which CHARISMA procedures take place. Like the SBHT, if worksheets are implemented via a tablet, a print out of the responses will be placed in the file and stamped as a true copy of the original to certify it. These will be used in tandem with HOPE Visit Checklists contained in HOPE SSP Section 3: Documentation. Every item in the left column of each worksheet should be ticked or marked 'NA'. If the HOPE visit procedures deviate from what is outlined in the checklist in regards to CHARISMA implementation, documentation of this should be in the comments section at the bottom of the checklist or in chart notes.
- **HOPE Chart Notes:** Chart notes should be used to document any other visit information not otherwise captured through other source documentation.

18.4.3 Record Retention Requirements

Please refer to Section 14: Data Collection of the MTN-025 SSP. The documents for CHARISMA will be part of the HOPE study files and therefore must be maintained for the same timeframe. No documents may be destroyed without written permission from DAIDS, RTI or local IRBs.

18.5 Participant Accrual

This section provides information on requirements and procedures for participation in CHARISMA.

18.5.1 Study Accrual Plan and Site-Specific Accrual Targets

All HOPE participants at CHARISMA sites are targeted to be included in CHARISMA activities.

18.5.2 CHARISMA Progress Reports

Upon activation, the CHARISMA Study PI or designee should begin weekly reporting of the number of participants who came in for enrollment, were administered the SBHT, were provided counseling (by module type provided), and referred for additional services. A template report for this will be provided by the CMT (Appendix 18-14). If tablets are used, data may be aggregated from an electronic database of the SBHT and CHARISMA worksheet responses.

18.6 Informed Consent

The CHARISMA intervention itself will require informed consent separate from the HOPE enrollment consent form (Appendix 18-15). The consent form must be administered before the conduct of any CHARISMA related procedures. Please refer to Section 5 of this manual for additional instructions around informed consent procedures.

18.7 CHARISMA Procedures

As an overview, the intervention, including the administration of the SBHT, will follow the CARE manual (Appendix 18-5) and worksheet outline (Appendices 18-11-13), but will allow for probing and digression on relevant topics as indicated by the participant's needs. Supplemental counselling materials are included in Appendices 18-6-9 (e.g. counselling flipchart and referral related resources). Counselling flowcharts are available in Appendix 18-10.

CHARISMA counselors will administer the SBHT to each participant at the HOPE enrollment visit. However, if staff are unable to administer at enrollment, participants may be invited to come into the clinic for an interim visit at another time, ideally before their month 1 visit. Administering the SBHT will help to identify participants' counseling needs, so that counseling related to ring use, partner disclosure options and other topics can be tailored to each participant's needs. [CHARISMA counsellors should ideally administer the SGBH via tablet, and as such as screen-shot of completed forms should be printed following each counseling session.](#)

CHARISMA counselors will document select Baseline Behavioral Assessment (BBA) questions on a CHARISMA Baseline Worksheet (Appendix 18-11) via tablet, which in combination with the SBHT, will target the provision of at least one of three tailored counseling modules to all HOPE participants per the CARE Manual (Appendix 18-5). While the tablet will guide the counsellor in module selection, the counsellor will need to use their best judgement based on their training and interaction with the participant to select the appropriate counselling module/s. Should the counsellor require support from the study PI or Mentor to choose these modules, she may consult as required prior to module administration.

Subsequent HOPE visits should be facilitated by the CHARISMA Month 1 and Unscheduled Visits Worksheet (Appendix 18-12) and CHARISMA Quarterly Follow-Up Visit Worksheet (Appendix 18-12-13). All worksheets should ideally be administered via tablet, and as such a screen-shot of completed forms should be printed following each counseling session. If paper forms are used, those will be filed in the participant records and the data will be captured electronically according to procedures outlined in the site data management procedures.

18.7.1 Eligibility Criteria

All HOPE participants at the CHARISMA site will be invited to participate in CHARISMA in order to assess empowerment and relationship counselling and referral needs of the individual. There are no additional exclusion or inclusion criteria unique to CHARISMA within the context of HOPE. However, should there be reports of SH to the CHARISMA counsellors and not the primary HOPE team, these incidents will be relayed immediately to the HOPE study IoR, study coordinator and/or study clinician to manage further and report within the context of HOPE. The CHARISMA Counsellor should document all details related to the reported SH in the HOPE chart notes and ensure that the case is taken to the key staff on HOPE listed above for onward management.

18.7.2 Study Visit Timing

The CHARISMA intervention will be integrated into selected HOPE visits. The activities to be completed at each visit are summarized in Table 18-1. Specifically, those at enrollment (or at an interim visit), month 1, month 3, and month 6; and participants experiencing SH may also need a second follow-up at month 2. No separate appointments will be scheduled for the CHARISMA intervention unless such additional visits are deemed necessary for individual participants or upon the request of a participant. If participants present themselves for unscheduled visits, they will be accommodated at the clinic. An example where this may apply is if a participant presents at an interim or non-quarterly scheduled visit reporting an experience of IPV or social harms. They will then be referred to the CHARISMA Counsellors for initial management followed by the HOPE study clinician/IoR/ SC. They will also receive referral, and support from the HOPE study team as needed.

If at any point the HOPE BA CRF identifies a participant with a new primary partner, this will trigger CHARISMA staff to re-administer the SBHT to assess the new partner’s level of support. HOPE visit checklists will serve as the mechanism to trigger this transfer of information to CHARISMA staff. Additional details on CHARISMA procedures for counseling and referral are detailed in the CARE Manual (Appendix 18-5).

18.7.3 Enrollment

At the HOPE **enrollment visit** (or during an interim visit, as described in section 18.7.6), all participants will have the SBHT administered post informed consent. All participants will be introduced to CHARISMA and the concept of healthy relationships (i.e. the introductory module). The counselor will then check-in with them about their current relationship context before proceeding with the remainder of the counseling session. Using several responses to the HOPE BBA, CHARISMA staff will complete a CHARISMA Baseline Worksheet (Appendix 1818-11). Based on the worksheet, CHARISMA staff will then provide one or more of the following three counseling modules:

Module A: General Partner Communication and Relationship Skills

- **Module B: Partner Disclosure and Communication around Ring Use**
- **Module C: Responding to Intimate Partner Violence and Safety Planning**

If a participant reveals that they are in a violent relationship at any time during counselling administration that they did not reveal during the BBA or SBHT, counsellors should pause their counselling activities and offer Module C activities regardless of where they are with the counselling. The counsellor will document the reason for this shift in activities on the CHARISMA worksheet.

Additional details of all modules are available in the CARE Manual (Appendix 1818-5).

18.7.4 Subsequent Visits

At the **Month 1 visit**, CHARISMA counselors will follow-up with participants on how well they have succeeded with their action plan and provide an abbreviated “booster” session of the counseling module(s) as needed. They will also re-administer the SBHT if the participant has a new partner. For more serious cases, a second follow-up will occur at the **Month 2 visit** or earlier if requested or indicated.

At the **Month 3 and Month 6 visits**, counselors will re-administer the SBHT and provide additional counseling if requested by the participant or deemed necessary during SBHT process.

Table 18-1. CHARISMA Counseling Plan Summary

Visit	Tasks	Documents to Facilitate Visit
Enrollment (or at an interim visit)	<ul style="list-style-type: none"> • CHARISMA introduction • CHARISMA ICF • SBHT administration • Administration of counseling module selected based on Baseline worksheet • Provide written referrals as needed 	SBHT CHARISMA Worksheet – Baseline
Month 1	<ul style="list-style-type: none"> • Check-in on progress or action plan or uptake of any referrals given 	CHARISMA Worksheet – Month 1 and Unscheduled Visits

	<ul style="list-style-type: none"> • Check the BA - Re-administration of SBHT if participant has a new partner • Administration of counseling module if deemed necessary or requested by participant • Provide written referrals as needed 	
Month 3	<ul style="list-style-type: none"> • Re-administration of SBHT • Administration of counseling module if deemed necessary or requested by participant • Provide written referrals as needed 	SBHT CHARISMA Worksheet – Quarterly Follow-up Visit
Month 6	<ul style="list-style-type: none"> • Re-administration of SBHT • Administration of counseling module if deemed necessary or requested by participant 	SBHT CHARISMA Worksheet – Quarterly Follow-up Visit
Additional visits as needed	<ul style="list-style-type: none"> • Referrals and counseling as needed • Re-administration of SBHT if participant has a new partner 	CHARISMA Worksheet – Month 1 and Unscheduled Visits

18.7.5 Interim Visits

At any other HOPE visit, if a participant reports a social harm related to partner-related problems, including IPV, or other violence-related events (irrespective of relation to study or partner) she should be referred to the CHARISMA team to provide appropriate components of CHARISMA counseling and referrals.

If participants are deemed at risk or require more counseling than what is feasible during routine HOPE study-scheduled visits, **additional visits** may be scheduled on an as-needed basis to meet additional counseling and referral needs. Counselors should discuss and agree upon a follow-up schedule with the participant during the visit at which the participant is determined to need additional counseling. Staff should follow-up with participants via the participant’s preferred means of contact to ensure the safety and well-being of the participant.

If participants are at risk of immediate physical or sexual violence, they should receive immediate referral to relevant services identified by the site team as being part of the accessible network of care. Staff should offer written or assisted (i.e. where a staff calls a referral agency for participant) referrals to participants for any additional counseling or services from outside organizations to ensure, to the best of the study team’s ability, the safety and well-being of the participant beyond the life of the trial. Participants will encouraged to contact the site should she need to talk to a counsellor in between visits. Either over the phone (if pre-established with the participant as a safe contact method) or at subsequent visits, counselors should follow up with the participant to determine whether she received the services for which she was referred. This will be documented on the CHARISMA worksheets, if during a visit, or via HOPE chart notes, if over the phone.

18.7.6 Language

All materials should be administered in the preferred language of the participant. The counsellor should seek to assess the participant's level of understanding in the language and offer them the choice of their preferred language (isiZulu or English). This may be different than the language in which she provided informed consent for HOPE, as long as fluency is confirmed/documentated in both languages (e.g. on the Enrolment IC coversheet and/or chart notes). Any deviation from this should be documented in the participant chart notes. Visit counseling flowcharts (Appendix 18-10) and worksheets (Appendices 18-11-13) should be used to guide the order of procedures for CHARISMA implementation.

18.7.7 Location

The CHARISMA intervention will be conducted in private counselling rooms that are quiet enough for participant privacy. It is recommended that use of clinical exam rooms be avoided to allow for a more comfortable discussion space.

18.7.8 Data Collection Procedures

Ideally, documentation of the counseling discussion would take place after closing the session. If needed, counsellors can take brief notes during the counseling session (on HOPE chart notes), but should always show the participant what they are writing to promote transparency in their interaction. Sites are encouraged to use flags or alert notes in participant study charts to highlight issues requiring follow-up at subsequent visits or issues that need to be addressed by study team members outside of the counseling sessions (e.g. referral for clinical issues).

Counselors should record all CHARISMA procedures completed for each participant, including relevant notes for counseling based on the quarterly behavioral assessments (BA, as part of HOPE), SBHT administration results, and as-needed counseling and referrals on the CHARISMA worksheets. Copies of all referrals (with the participant's name) must be filed with the Informed Consent/Locator. An amended copy of all referral should be retained in the participant file. All materials should contain the participant's HOPE PTID. All files will be quality controlled on the day of the visit.

Further description of the management of the intervention documents is in Section 18.9.

18.7.9 Male Partners and Couple Counselling

As part of the counseling activities, participants may be offered an opportunity to invite their male partners themselves or have the clinic staff invite their male partners into the clinic, if deemed safe. Counsellors may offer a letter for inviting male partners to the clinic to facilitate this process (Appendix 18-9). Instances where this may not be safe include women who are in violent relationships. Acceptance of these offers will be documented in the CHARISMA worksheets.

If a male partner arrives at the clinic, HOPE Administrative staff should assess the purpose of his visit before referring him to the HOPE IoR/SC, a counsellor or a clinical staff member depending on his needs. If he has come for HIV testing and counselling, he will be referred to a HOPE HIV counsellor and regular HIV voluntary testing and counselling procedures will be followed. All HIV counsellors are cross trained on CHARISMA and they can also assess if there is a need for a CHARISMA counsellor to see a partner despite lack of a direct request. If he has more general questions or concerns, the CHARISMA counsellors will be available to respond as well. All interactions with male partners will be documented in chart notes of the HOPE participants file but indicating clearly that the notes related to "Partner of X participant" for that specific entry.

18.8 Visit Checklists

The study implementation tools section of the MTN-025 website contains examples of checklists detailing the protocol-specified procedures that must be completed at HOPE study visits. These checklists should be modified to include CHARISMA procedures, then reviewed by the MTN CORE (FHI 360) for approval before implementation of CHARISMA. The site will add CHARISMA procedures to the enrollment, month 1, and quarterly visit checklists. Additional triggers to alert CHARISMA staff of changes in partners will be added to other monthly checklists (i.e. those months when CHARISMA activities are not scheduled).

18.9 Data Collection

Only data collection issues unique to the CHARISMA data are covered in this section. For more information on HOPE data collection procedures, see Section 14 of this manual.

For questions about this section or about general data collection policies, procedures, or materials for the HOPE CHARISMA component, please contact the CMT at (mtn-charisma@mtnstopshiv.org).

18.9.1 CHARISMA Participation Statistics

Details about participation in CHARISMA will not be recorded on the site's HOPE Screening and Enrollment Log; however as all HOPE participants at the CHARISMA site will be eligible to participate in CHARISMA and the number enrolled in HOPE will be referenced by an RTI data manager to understand the total number of women reached.

In addition, an electronic database used to capture SBHT and CHARISMA worksheet data will be summarized on a weekly basis using a weekly reporting template provided by the CMT. The database will allow production of summary reports that show how many women were administered the SBHT, how many counselling sessions of each type were completed, how many referrals were provided, and how many male partners were invited to the clinic. This, in combination with a weekly implementation statistics report, which will be completed by the PI/Site Coordinator/ or designee, will be used to keep track of study enrollment and relevant lessons learned (See CHARISMA Weekly Implementation Statistics Report template, Appendix 18-14). The Weekly Implementation Statistics Report should be emailed to mtn-charisma@mtnstopshiv.org prior to the scheduled intervention team call (or on another designated day). It should represent the week preceding the day emailed (e.g. if emailed on a Wednesday, statistics will reflect intervention activities from Wednesday-Wednesday). Files should be named using the following convention: [site]_Weekly Stats_[date of completion] (e.g. WRHI_Weekly Stats_20DEC2016).

18.9.2 Visit Codes

HOPE visit codes should be completed on CHARISMA documentation (notes, SBHT, Worksheets).

18.9.3 Forms and Materials: Supply and Storage

The SBHT, CHARISMA worksheets, and supplemental materials needed for the CHARISMA component of HOPE will be electronically supplied by RTI and available on the MTN website. They should be printed locally. These materials will also be posted within the CHARISMA sub-folder on the www.MTNstopshiv.org MTN 025/HOPE website under Study Implementation Materials. The site is responsible for maintaining an adequate supply of hard copies of the current version of these documents in all languages. One copy of previous versions of guides and materials should be maintained in an archive, and all other copies destroyed.

18.10 CHARISMA Intervention

During CHARISMA intervention visits, the counselor should complete the SBHT (if needed for that visit) and visit worksheet via tablet to document the CHARISMA intervention procedures. These materials will provide a summary of the intervention session that can be used in “real time.” After initial completion, SBHT and worksheet should undergo a site level quality review during which, at a minimum, all staff members who were present at the intervention visit will review the materials for accuracy and completeness. The tablet SBHT and worksheet program will be provided by the CMT. Hard copies of the SBHT and worksheets (i.e. print outs of screen shots) must be maintained in participant files and electronic files resulting from SBHT administration should be uploaded to SharePoint by the site data manager or data supervisor at the end of each day. In cases where paper versions of the tools were administered with participants, staff will need to enter these into the tablet, ideally on the same day that they were administered. Prior to uploading to SharePoint, the data will need to be downloaded to a password protected local computer in a file named using the date of the download. The folder will then need to be compressed by right-clicking the day’s folder, clicking “send to”, and clicking “compressed (zipped) folder”. A compressed file folder will be created. The data supervisor will then navigate to the designated CHARISMA SharePoint folder ([link](#)) and choose to upload the compressed file folder. Data from the electronic database should be summarized in a weekly update. The worksheet and SBHT data should be emailed to RTI (mtn-charisma@mtnstopshiv.org) at the end of each week. Templates for the dataset and weekly update will be provided by the CMT. See section 18.9.1.

18.10.1 Study Monitoring

In addition to reviewing participation logs, counseling observation forms, and debriefing meeting notes described above, the CMT will monitor implementation of CHARISMA through a review of select participant files. This review will occur after the first 10 enrollments are done and then every two months thereafter.