| **Transfer Checklist (Transferring Site)** | | | |
| --- | --- | --- | --- |
| **Procedure** | | **Staff Initials and Date** | **Comments:** |
|  | **Discuss willingness/ability of the participant to transfer to the receiving site.** |  |  |
|  | **Notify the receiving site and MTN-034 study management team of the transfer.** |  |  |
|  | **Discuss and agree upon logistical details of the transfer with the receiving site** (e.g. next target visit date, qualitative participation status, special needs of participant, ongoing AEs, language fluency, participants new contact information and location transport needs/directions to receiving site, etc.). |  |  |
|  | **Resolve all outstanding QCs within Rave.** SCHARP will notify the transferring site of all outstanding data QC notes and missing eCRFs for the transferring participant. |  |  |
|  | If applicable, resolve all outstanding QCs of any qualitative documents and complete handoff to receiving site per QMT guidance (behavioral team should 1) write memo describing participant’s involvement to date in qualitative component and 2) email QMT to inform them of situation and solicit guidance) |  |  |
|  | **IoR to sign off on all CRFs in the Medidata Rave study database that have been completed for the participant at their site.** *(Note: A transfer cannot happen until all CRFs are signed off.)* |  |  |
|  | **Explain the transfer arrangements to the participant and obtain her written permission to provide copies of her study records to the receiving site. Provide contact details of receiving site.** *(NOTE: If the participant has already moved and cannot return to sign the records release, this may be accomplished by the transferring site faxing the release to the receiving site for completion by the participant.)* |  |  |
|  | **Prepare certified copies, using Good Documentation Practices (GDP), of all of the participant’s paper study records** (i.e. all informed consent forms, coversheets, and comprehension checklists/assessments, locator forms, and study visit documentation including chart notes, counseling notes, visit checklists, lab reports, external medical reports, lab testing logs, paper CRFs, tracking logs/tools, pharmacy logs/forms, worksheets, IDI certified transcripts, IDI notes, etc.).  *Optional: complete inventory log.* |  |  |
|  | **Ship certified copies of the participant study records to the receiving site via courier or overnight mail service.** (NOTE: Copies of participant-specific records maintained in the transferring site pharmacy must be sent to the receiving site pharmacy in a separate file clearly marked “Pharmacy Only” and may be delivered in the same shipping envelope or carton as the clinic records). The transferring site (clinic and pharmacy) will document all materials sent to the receiving site and inform the receiving site of the shipment date and expected arrival date. The receiving site (clinic and pharmacy) will confirm receipt of the shipment. |  |  |
|  | **Complete Participant Transfer eCRF.** (NOTE: SDMC makes the appropriate database updates to reflect the change in site follow-up responsibility. The participant’s original PTID and follow-up visit schedule remain unchanged, as does the participant’s random assignment) |  |  |

\*\*Note: The transferring site should maintain all original study documents on site according to study record retention requirements. The transferring site will retain responsibility for storage, and shipment to the MTN Laboratory Center (LC), if applicable, of all specimens collected from the participant prior to her transfer, unless otherwise instructed by the MTN LC.