URINARY INCONTINENCE TREATMENT NETWORK (UITN)

PHASE II QUALITY ASSURANCE PLAN
Version 02/27/09

A. INTRODUCTION

The UITN Investigators will assure for the standard administration of all UITN protocols and research procedures across all Continence Treatment Centers (CTC) through the implementation of a comprehensive Quality Assurance (QA) Plan. When properly implemented, the QA Plan protects the scientific integrity of the UITN protocols by maximizing the reliability and validity of the treatments delivered and the evaluation measurements conducted. The accuracy of reports and results produced and published by UITN Investigators is dependent on the quality of the data submitted by the staff at the primary and satellite CTCs. The Data Coordinating Center (DCC) staff are also obligated to employ the highest standards for data processing and data analysis.

The main objective of the QA Plan is to provide a means by which Investigators can demonstrate that interventions (including surgeries) are conducted in a standardized manner and that complete and accurate data are gathered to evaluate the interventions. The QA Plan ensures that all intervention procedures and all evaluation measurements are performed in the same manner regardless of the CTC, Interventionist or Evaluator.

Standard application of UITN protocols will be accomplished by the following methods:

1. Development of the Manuals of Operations as well as Procedures Manuals for each intervention, and each evaluation measure;
2. Development of user-friendly Data Forms and Question-by Question (QxQ) Specification Guides clearly linked to the research objectives documented in UITN protocols;
3. Steering Committee sign-off procedures for all study Data Forms;
4. Centralized baseline training for all research staff;
5. Certification of all sites and research staff using a combination of standardized Site Certification Requirements checklists, Attestations of Compliance and QC Observation Checklists, Protocol Signature Pages, and Site Staff List and Signature Page documents;
6. Verification of patient eligibility;
7. Regular, collaborative communications between the Site Coordinators and the DCC;
8. On-going monitoring of all protocols including intervention and evaluation activities;
9. QA Site Visits to and/or remote monitoring of all CTC's to meet pre-specified monitoring goals.

Each of these methods is described in the following sections.

B. QA METHODS

B.1 Manual of Operations

The development of the Manual of Operations (MOO) takes place in three steps:

1. The Protocol and working drafts of protocol-specific Procedure Manuals are first produced as Training Manuals for use during baseline training and study start-up. These drafts, with intermittent updates, are used as the primary reference documents for all protocol-specific intervention and evaluation activities conducted in the earliest phase of patient recruitment, enrollment and eligibility screening.
2. Final Procedure Manuals are produced, incorporating all revisions made in response to the findings and experiences of baseline training and enrollment of the first several patients.
3. Subsequent revisions or updates should be minimal and consist of revised pages for replacement in the Manuals.

The UITN Manual of Operations is considered the complete reference for all UITN activities and is available on the UITN study website. It consists of a primary volume containing an overview of the Network's goals and structure; policies and procedures for publications, presentations and ancillary studies; this QA Plan; and a master Data Management Manual. In addition, a protocol-specific Manual is available for each UITN study; such Manuals include the unique Protocol, Intervention and Evaluation Procedure Manuals as required, and study-specific Data Forms, QxQ Specification Guides (QxQs) and Data Management Manual.

The DCC is responsible for updating UITN Manuals, Procedures, Data Forms and QxQs in collaboration with the UITN Steering Committee (SC) and/or assigned Protocol Committees and Work Groups. Selected Committees and Work Groups may assume primary responsibility for updates or revisions to assigned Procedures Manuals, e.g. UDS Work Group members will direct/approve changes or updates made to the UDS Procedures Manual; such changes will still be brought to the SC as a point of information and/or for formal approval.

Current versions of all UITN documents are posted as PDF files on the website to prevent unauthorized alteration of master documents. A limited number of hard copies should be maintained locally in binders in the event that internet access is interrupted. Official notification of updates to Manuals will be distributed by the DCC. To ensure complete updating of all Manuals in the field, Study Coordinators must keep a record of all hard copy Manuals in use at their respective CTC and should conduct routine audits of these reference materials. DCC staff may conduct reviews of CTC Manuals during Site Visits.

Study Coordinators and all research staff members should review the Protocol, Procedure Manuals, Data Forms and QxQs after baseline training, intermittently as needed, and when questions regarding the protocol arise.

UITN study materials, including Data Forms, should not be reproduced or distributed, in whole or in part, beyond UITN study staff without Steering Committee approval.

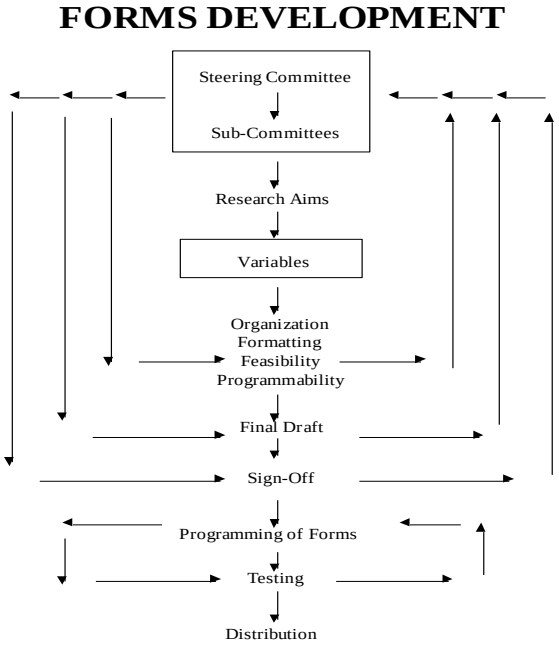
B.2 User Friendly Data Forms and Question by Question Specification Guides

Most importantly, study Data Forms and QxQs are developed to address a study's scientific aims. Of equal importance, forms are designed to be user-friendly for study staff and, in the case of the self-administered instruments, research participants. Every effort is made to design forms that minimize potential errors during data collection, recording and/or entry. Key formatting issues that help to ensure high quality data include: minimal use of open-ended questions; clear skip patterns; standard typeset conventions to distinguish verbatim questions from interviewer instructions; standard introductions and transitions within interviews; subsections organized by topic, and standard coding conventions.

Sign-Off Procedures: Data Forms are developed by the DCC, reviewed and approved by SC-appointed Work Groups, and ultimately approved by the SC (signed-off). UITN forms development includes the following activities:

1. DCC staff draft Data Forms in accordance with the protocols developed by the UITN SC;
2. A Work Group(s) is commissioned to review and revise draft forms in preparation for SC review;
3. Final drafts are distributed to the SC for review and **sign-off** prior to the start of data collection for a UITN protocol.

This process is summarized in the figure below.



B.3 Protocol Signature Page

Once a Network protocol is finalized, the PI is responsible for completing a final, thorough review of this version and completing the accompanying Protocol Signature Page. Signing this document confirms that the PI will comply with all policies and procedures as written, both protocol-specific and UITN-wide. Further, this signature indicates an understanding of the critical importance of appropriate delegation of study responsibilities. With that in mind, the PI

will complete a Site Staff Document and Signature Page that delineates all such delegation of study responsibilities. These documents are developed per protocol with appropriate categories pre-coded for ease of assignment; if additional documentation is required (e.g. Attestation, QC Checklist, etc., that information will be noted). All listed persons must also read the protocol, and in providing their signature and initials, they too are confirming their willingness to comply with all policies and procedures as written, both protocol-specific and UITN-wide.

Finally, the Protocol Signature Page confirms understanding that prior to any site staff beginning any research activities, both IRB approval **and** confirmation from the DCC regarding achievement "site certification" is required. The latter requirement is achieved by staff attending required trainings and completion of certification exercises and documentation as specified. Site certification is explained in more detail in Section B.8.1.

B.4 Baseline Training

A major factor to ensuring data quality and consistency across multiple clinical sites is centralized training at start-up. Per designations on Site Staff Documents, ideally staff from all CTCs will attend a central training to review and discuss the protocol, study procedures including intervention and evaluation measurements and standards, Data Forms completion, data editing procedures and data management. If applicable, intervention and evaluation sessions are offered as separate sessions as intervention and evaluation staff may be blinded to selected components of the protocol. If/when in-person training is not feasible, central training via conference call and/or Webinar will be conducted.

In general, training sessions begin with a didactic review and discussion of the study protocol including all primary and secondary outcome measures. This portion of training is typically led by the Protocol WG Chair. Then, the group reviews each intervention or evaluation element in detail including a thorough review of associated Data Forms. Demonstrations of interventions and measurements are conducted when applicable wherever possible. Videotapes may be used to augment central training. When applicable, central training concludes with return demonstration sessions to allow participants to practice and perfect intervention/evaluation skills.

If a research staff member joins the study after central training has taken place, an alternative training plan must be established in conjunction with the DCC.

B.5 Certification

Minimal performance standards are determined by the UITN SC for every staff category. A rigorous certification program serves to reduce errors and variability in the performance of intervention and evaluation measurement procedures. UITN study staff are obligated to complete certification requirements before they engage in any study activities with UITN patients.

Research staff's ability to meet minimum standards is assessed using pre-determined criteria established by assigned Work Groups and by the DCC in accordance with prevailing performance standards in the specialty area of study and in the conduct of NIH trials. Separate criteria are developed for each intervention and evaluation component.

B.5.1. Certification of Staff

Principal Investigators identify study staff and their roles and responsibilities for each UITN study. Accordingly, the PI and assigned staff persons must attest to the completion of several performance standards established specifically for the intervention or measurement. By signing the Protocol Signature Page, Site Staff List and Signature Page and/or Certification Attestation document, the staff person and the PI assure that the person meets all required elements of the standards established by the SC. The following represents a generic list of elements included in most Certification Attestation documents:

1. Registered/licensed to meet state requirements for practitioners completing the **intervention or measures** (e.g. MD, NP, PA, RN, PT, other technician category, etc.);
2. Certified by or membership in a professional specialty group (may be required);
3. Regularly and frequently performs **the intervention or measure** in his/her practice;
4. Attended (completed) all elements of the baseline training curriculum for **the intervention or measure;**
5. Completed a comprehensive review of the UITN protocol;
6. Completed a comprehensive review of **the intervention or measurement** Procedure Manuals, Data Form(s) and QxQ Specifications Guide(s);
7. Reviewed any other materials that may be adopted as standards by the SC for **the intervention or measure** such as published standards or videotapes of **the interventions or measures**, e.g. the ICS POP-Q standards published in the *Am J Obstet Gynec (1996) 175:10-17;* and the Duke University Medical Center POP-Q videotape;
8. Demonstrated compliance in the performance of **the intervention or measure** per UITN protocol and procedures as observed by an authorized QA Observer completing a QC Observation Checklist (**NOTE**: For all clinical measures, the PI or the Co-PI is the authorized QA Observer);
9. Submitted an Attestation of Compliance signed by the PI for attainment of certification to the DCC.

To achieve baseline certification, staff must complete certification requirements and submit required materials (e.g. Attestations, QC Observation Checklists, etc.) to the DCC for review and processing. The DCC promptly reviews these materials for quality and completeness and notifies the CTC of the results in writing.

B.5.2. QA Observations and the QC Observation Checklists

One of the most important components of certification is the staff member's ability to demonstrate compliance in the performance of the intervention or measure per UITN standards as observed by an authorized QA Observer completing a QC Observation Checklist. Observation Checklists are developed for all critical interventions and measurement procedures. All performance elements included on the Checklists are taken directly from the protocol and procedures approved by the UITN SC. Criteria are scored as "yes" or "no" with the opportunity to record comments for each criterion.

QC Observation Checklists are a key mechanism to ensuring a standardized process within and across sites for assessing research staff's ability to perform in accordance with established criteria. Variability amongst QA observers within and across sites is minimized or eliminated by the use of such tools. Checklists also provide the QA Observer with an objective guide of measurable behaviors that guarantees that all critical components of performance are evaluated during the

observed session. Finally, Checklists can be used to structure post-observation reviews of the observed session.

For clinical measures, the CTC Principal Investigator or Co-Principal Investigator will be required to complete the QA Observation and QC Observation Checklist for the intervention or measure. For example, the PI or Co-PI is required to complete the QA Observation and QC Checklist for certification of Surgeons in the SISTEr protocol. For other research measures, the authorized QA Observer will be either a DCC staff person or a CTC colleague already certified in the intervention or measure. For example, a DCC staff person will complete the QA Observation and QC Checklist for certification in research interviewing. Each Checklist will specify who is authorized to act as the QA Observer for the observation.

QC Observation Checklists for all intervention and evaluation procedures can be found in the QA section of the specific protocol's page on the UITN website.

B.5.3 Maintenance of Certification Status through Recertification

Standards for the ongoing maintenance of research staff proficiency in the conduct of study procedures are designed to prevent/minimize "drift" in performance over time. The Steering Committee has established a requirement for annual recertification for most staff categories. To recertify, research staff must demonstrate compliance with UITN protocols and procedures during observed sessions at designated intervals from the date of one's initial certification. Recertification should be completed prior to the expiration of one's certification status, as data from non-certified staff will not be accepted by the UITN Data Management System (DMS). To that end, Coordinators should review study-specific Certification Reports at least monthly to ensure that plans for recertification are made accordingly.

Authorized QA Observers must complete a QC Observation Checklist at the time of the recertification observation. NOTE: Attestations of Compliance should not be completed as a part of recertification. Recertification requirements differ by protocol, intervention and measurement category; for study-specific details, refer to the protocol-specific QA Plan.

Completed QC Observation Checklists should be sent to the DCC for processing.

B.6 Verification of Patient Eligibility and Currency of Measures

A patient's eligibility will be verified as a collaborative effort between the CTC Coordinator, PI and UITN web-based DMS. Primary determination of eligibility is made by the CTC Coordinator and PI based on the results of study screening measures, including selected measures that may require manual scoring. In most studies, a second check will be performed prior to randomization by the UITN DMS. In these studies, all data must be entered and must "pass" programmed eligibility checks in order for the DMS to issue a valid Randomization Authorization Code. Without a Randomization Authorization Code, one cannot obtain a randomization assignment, regardless of mode of randomization (i.e. phone, internet, etc.). Less commonly, study design may be such that a patient can be consented, determined to be eligible and randomized on the same day (i.e. first visit). In such cases, a compromise between study logistics and staffing limitations may be such that randomization is permitted prior to any data entry (e.g. ValUE). If this latter method is employed, there is a greater responsibility on the PI and Coordinator for manual verification of eligibility prior to randomization. There will also be a higher level of data monitoring by the DCC at the beginning of such a protocol. For example,

in MIMOSA and ValUE, in which randomization is permitted prior to data entry, the DCC will review the first two randomized cases (Data Forms and source documents [with identifiers obscured and replaced with study ID]) for each Data Collector at every site. Sites will send this documentation via the DCC's secure fax server as soon as possible before or after randomization. Frequent monitoring of randomly selected cases study-wide will continue throughout the trial for each Data Collector, with later checks consisting of source documents directly checked against ADEPT data (i.e. most likely, the faxing of Data Forms will be discontinued).

In addition, for most studies, the DMS will verify that all measures are current, as defined per protocol (i.e., for each, the Steering Committee has categorized certain baseline measures as "expiring" within a specified timeframe). For example, in the SISTEr protocol, MESA results expire if more than 6 months transpires between completion of the measure and the expected date of surgery. Expired measures must be repeated prior to randomization to ensure eligibility for the trial as well as to obtain current baseline values for critical measures that would be subject to change over a 6-month period. Randomization Authorization numbers will be issued only for patients with complete and current baseline data. For the few studies that allow randomization prior to data entry, manual confirmation that all baseline data are current is key.

NOTE: For <u>all</u> UITN protocols, as a part of certification, Data Collectors are required to submit their first two sets of baseline Data Forms to the DCC for review <u>prior</u> to randomization. This requirement is particularly helpful at start-up to ensure a complete understanding of the protocol, baseline and pre-randomization procedures, and Data Form completion. Ideally, protocol design will allow for DCC confirmation of eligibility prior to data entry and randomization. Less common cases in which patients are randomized prior to data entry are discussed above. This Forms review requirement is also helpful in the event of CTC staff turn-over, as it provides another level of assurance that the new study team has a solid and accurate understanding of the protocol and procedures. In Phase II of the Network, for such latter cases, it was agreed that under the appropriate circumstances, if a veteran staff person (i.e., on the study for at least 1 year) was willing to conduct forms review for a new team member, that was another suitable option for this aspect of training.

B.7 Study Coordination and Communications

Each primary CTC will appoint a Study Coordinator who acts as a key staff person in assisting the PI to ensure proper implementation of all study protocols and adherence to QA procedures at the primary CTC and any subsites. Study Coordinator responsibilities include: communication with the DCC for all protocol issues; informing all CTC research staff of protocol updates; supervising the completion of all training and certification activities required for research staff; coordinating submission of all required certification materials and documents for all research staff; supervising recruitment, enrollment and study visit scheduling; supervising baseline and follow-up measurement activities; coordinating all intervention activities; completion of or supervision of local QA activities including observation and critique of all data collection activities and review of completed Data Forms and data edits; ensuring that source documentation is complete and in compliance with GCP and ICH guidelines; and supervising all data transfers to the DCC as required.

The DCC will organize and lead regular conference calls for UITN Study Coordinators and Data Managers. These conference calls will be used to discuss questions and issues regarding field

procedures. Discussion of problems early in the process of data collection can improve the quality of the data dramatically and accelerate the learning curve. Similarly, timely awareness and discussion of any issues that arise during study conduct ensure prompt resolutions.

Communication between the DCC and the CTCs must be documented across all sites in a standardized manner. Official updates considered part of a study Manual will be issued as Operations Memos; Coordinators are responsible for internal distribution of such information to all appropriate staff at their CTC. Study-specific Operations Memos will be numbered sequentially; these documents should be kept in a Communications Log Book in a central location that is accessible to all study staff. Specified staff are obligated to read and initial all memos to document they have read them. In addition, these memos should be discussed at regularly scheduled local CTC staff meetings. The purpose of the Communications Log Book is to provide a single, reliable location for all updates and protocol changes that occur throughout the study. Operations Memos will be distributed to all centers simultaneously via an email alert of a posting to the UITN website. All other study correspondence must also be properly documented and filed (e.g. emails, phone logs, etc.).

Throughout the course of a study, research staff may have specific questions about protocols and procedures. Study Coordinators should review the Manuals, Data Forms and QxQs first for the answer to their question. If the answer is not contained in these reference materials in whole or in part, the Principal Investigator or Coordinator should not attempt to clarify the issue locally. Rather, all such questions regarding study protocols and procedures must be directed in writing to Kim Dandreo at the DCC (kdandreo@neriscience.com). The DCC is responsible for investigating such matters and communicating the appropriate response to the CTC and/or all CTCs if the inquiry has study-wide implications. In some instances, inquiry resolution will require consultation with a Work Group and/or the Steering Committee. A paper trail of all such inquiries and their resolutions will be kept on file at the DCC, both for the purposes of maintaining proper documentation of study communications and to ensure any similar, future questions are answered in a consistent fashion.

B.8 Ongoing Monitoring of Intervention and Evaluation Activities

B.8.1 CTC Certification at Start-up

Each CTC is required to attain "Site Certification" at the start-up of each study protocol and prior to the initiation of any associated research activities. NOTE: IRB approval alone, although a critical and required step prior to study initiation, is not sufficient for enrollment to begin in a UITN study. Each protocol has a study-specific list of criteria to be met in order to achieve site certification. The following list of criteria included on the Site Certification document for the TOMUS protocol is provided as an example.

1. Submitted IRB Approval Letter and Approved Informed Consent Form to the DCC
2. Have at least one UITN staff member certified in the TMUS Inside-Out or Outside-In procedure
3. Have at least one UITN staff member certified in the RMUS procedure
4. Have at least one UITN staff member certified as a UDS Tester
5. Have at least one UITN staff member certified as a UDS Reviewer
6. Have at least one UITN staff member certified as a Physical Examiner
7. Have at least one UITN staff member certified as a Stress Tester
8. Have at least one UITN staff member certified as an Interviewer/Data Collector*

9. Have at least one UITN staff member certified in Pad Test/Voiding Diary measure
10. Have at least one UITN staff member certified in Pain Diary measure
11. Have at least one UITN staff member certified as a Data Manager
12. Have all required study equipment and software

*If planning to certify an Interviewer in Spanish, this will require "passing" a mock interview conducted in Spanish in addition to the one done in English.

NOTE: The DCC completes this certification document and will send a copy to the CTC upon attainment of Site Certification. Until this document is received, a CTC is not Site Certified.

B.8.2 Local QA Activities

Local QA activities must be in place prior to any data collection. Beyond organization and oversight of CTC and staff certifications, Study Coordinators must supervise all local data collection activities. To that end, frequent review of protocol-specific data management reports is very important. CTCs must assure that all local research activities are in compliance with all the QA elements described herein. At a minimum, sites should implement a QA Plan that will ensure that their research team attains and maintains a minimum level of proficiency in the intervention, data collection, examination and testing skills as well as data entry and data management. Baseline certification and re-certification standards are described above. Also, prior to enrollment of any subjects, a comparison of the protocol and Data Forms to existing source documents should be completed. Any study-required elements not routinely documented in a clinic source need to be captured on an appropriate source document created for the study.

B.9 QA Site Visits

The DCC is obligated to conduct routine QA Site Visits (SVs) as frequently as each study budget allows; this would likely never be more frequently than on an annual basis. For the TOMUS study, each CTC will have one routine SV during the enrollment phase and one routine SV during the follow-up phase. NIH Project Officers and DSMB members may also attend SVs. Routine SVs will be coordinated in advance with each PI and Study Coordinator. However, Site Visits may be conducted without notice for cause. There are alternative options when routine, onsite monitoring is not feasible. For example, in MIMOSA and ValUE (as noted above), a random sampling of cases will be monitored for each Data Collector study-wide throughout the conduct of the trials. This will be accomplished by the site faxing requested source documents (with identifiers obscured and replaced with study IDs) and/or Data Forms via a secure fax server to the DCC upon request. As when onsite, source documents will be compared against Data Forms and/or the DMS and any discrepancies will be appropriately documented and resolved.

B.9.1 Site Visit Activities, Preparation & Attendance

At minimum, fundamental activities of a SV include a review of site staffing and administrative procedures (including inspection of study files and storage procedures), review of all consented patients' informed consent forms, and thorough monitoring of the data for a randomly selected number of study IDs (this sample will always be ≥10% of the total number of patients enrolled at the time of the SV; a similar overall approach will be employed for studies monitored remotely). For the IDs selected for monitoring, all Data Forms and <u>all</u> source documents must be available for review; source documents include all shadow files, clinic charts and medical records. Data Forms will be reviewed against source documents and the Data Management System. Planning

and collaborative organization between CTC and DCC staff is critical to a successful SV. DCC staff need to know the CTCs current policies regarding monitor access to original clinic charts and medical records (MRs). For example, with the shift to electronic MRs, some hospitals require monitors to complete training before they can view MRs; this task needs to be considered when planning time onsite. Another example is the situation in which a hospital will not allow medical records to leave the MR Department (i.e. they cannot be viewed in the room designated for the audit); again, in such cases, proper time needs to be allotted for reviewing these critical items. Other documents that may be reviewed prior to or during a SV are as follows:

1. A list of all study staff, their responsibilities, percent effort allocated to the UITN protocol(s), and currency of certification status.
2. Site organizational chart delineating lines of authority and communications.
3. Record(s) of staff meetings and attendance.
4. A written description of local recruitment procedures.
5. Copies of IRB approval letters for protocols and current approved informed consent documents.
6. Copies of all recruitment materials and standard patient correspondence in use.
7. A list of any satellite sites used for patient recruitment, screening, testing, intervention and/or study follow-up visits.
8. All standard study materials including all copies of all Manuals of Operations, Procedures Manuals, Communications Log Books, study-wide minutes of meetings and conference calls, Data Forms, etc.

Other possible SV activities include a tour of research facilities (especially on a first SV and/or if any part of the research space is significantly altered or relocated) and observation of study measures, including consent procedures, interviewing, data collection, testing and intervention activities. Observations are especially important when there are new staff members. When appropriate, observations provide another important method by which monitors can evaluate the quality of the data being collected as well as proficiency in the administration of standardized study measures in a realistic setting.

All possible SV activities are outlined in the UITN QA Site Visit Guide posted on the study website. It is strongly recommended that CTCs use this document to ensure adequate preparation for a SV.

PIs, Study Coordinators, Data Managers and all other certified study staff should be available, in person, during a routine SV. Due to scheduling challenges, it is conceivable that a SV could be conducted at a site that has not had critical staff turnover in the absence of the PI and/or Data Manager and/or other select, certified staff.

B.9.2 Post-Site Visit Documentation

Upon completion of an onsite SV, the DCC will provide the CTC PI and NIDDK Project Officers with copies of a narrative report and a completed QA Site Visit Guide. If any corrective actions or recommendations are warranted, they will be noted in the report. Corrective actions require a response from the CTC PI in the form of a plan of correction; the deadline for returning a plan of correction to the DCC will be specified in the cover letter that accompanies the report. There is also a signature page at the end of the report which the PI must sign to document that s/he has reviewed the report and discussed it with his/her team, as required; the original signature

page must also be returned to the DCC by the specified deadline. The report contents, a copy of the plan of correction and a copy of the signature page should remain in the master file at the CTC. In the case of remote monitoring, an alternative report summarizing findings will be sent to the site.

Any specific data discrepancies noted during monitoring will be documented on Data Monitoring Reports (DMRs); originals will be left onsite at the completion of the visit. DMRs are specific to patient ID and Data Form, much like Edit Reports, such that when they are complete, they must be filed with the corresponding Data Form in the patient's research binder. The Study Coordinator is responsible for making sure the original Data Collector resolves each discrepancy noted and for ensuring that all edits are completed on the DMRs and in the DMS and that copies of all completed DMRs are returned via a trackable mailing method to the DCC by the deadline noted in the cover letter accompanying the SV report. (NOTE: Original DMRs stay onsite for filing.) DCC staff review all returned DMRs to ensure that all edits are addressed appropriately and thoroughly and to ensure that all corrections are made successfully in the DMS. In most cases, DMRs will be used to document findings of cases monitored remotely as well.