LCCC 2101: Geriatric-assessment-guided interventions to address functional deficits in older adults undergoing treatment for multiple myeloma

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations and ICH guidelines.

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1.0 BACKGROUND AND RATIONALE

1.1 Study Synopsis

We propose to pilot test a clinic-based intervention for prompt attention to Geriatric Assessment (GA)-identified deficits in patients 60 years or older undergoing treatment for multiple myeloma. Validated measures will be used to identify problematic geriatric syndromes / impairments. Impairments that are remediable will be matched with evidence-based interventions, primarily referrals to specialists. The Study Team will make referrals to specialists or services, and patient satisfaction with the intervention(s) will be assessed. Our hypothesis is that timely interventions that address deficits elucidated by GA can be planned during a clinic visit, and that older patients with multiple myeloma will be interested in and comply with intervention recommendations.

1.2 Background

Multiple myeloma (MM) is a clonal plasma cell malignancy associated with significant morbidity and mortality. In the United States, it is the second most common hematologic malignancy after non-Hodgkin lymphoma, accounting for approximately 19% of new diagnoses and 21% of deaths related to hematologic malignancies.[1] MM is disproportionately a disease of older adults, with a median age at diagnosis of 69 years and approximately 40% of new cases developing in adults over the age of 75 years.[2,3] Consequently, the care of patients with MM is often challenging due to the higher prevalence of vulnerabilities observed with advancing age.

However, chronologic age alone is not a comprehensive predictor of vulnerabilities as there is substantial heterogeneity in the process of aging, and consequently, more thorough assessment methodologies are required.[4,5] In both clinical practice and research settings, one approach to address this variation is the use of GA methodologies.[6]

A comprehensive geriatric assessment consists of a multidimensional evaluation of an older person's functional ability, physical performance, nutrition, comorbidities, cognitive function, and psychosocial support.[7] Traditional comprehensive geriatric assessment programs can take up to 2 hours to complete. This does not include the time taken to review the data and to formulate a plan for further management.[5] Although it provides useful information, the traditional multi-disciplinary geriatric assessment is consequently too time intensive and impractical to perform in a typical oncology practice.[8] For this reason, Hurria et al conducted a pilot study in order to develop a brief yet inclusive geriatric assessment that could be primarily self-administered, and to establish its feasibility in an oncology practice. The measures included in this abbreviated assessment cover all of the essential domains identified earlier and were chosen for their reliability, validity, brevity, and prognostic ability to determine risk for morbidity or mortality in an older patient.[4]

The mean time to complete the assessment in Hurria's pilot study was 27 minutes, and 78% completed the self-administered portion without assistance. There was no association between the ability to complete the assessment independently and age (p=0.56) or educational level (p=0.99). Eighty-three percent of patients stated that the assessment was easy to understand, and 100% stated that no items were upsetting. Ninety percent were satisfied with the length of the questionnaire.[5] The feasibility of using the geriatric assessment in an NCI-sponsored cooperative group setting was recently established by Hurria and colleagues for the Cancer and Leukemia Group B (CALGB) in a multi-center trial (CALGB 360401). In this trial of 88 patients, 88% were able to complete the assessment without help with a median time to completion of 22 minutes.[9] In a study of 1,088 seniors recruited from seven community clinics across North Carolina, UNC researchers reported mean time to complete the entire geriatric assessment was 19 minutes in the academic medical center and 22 minutes in community settings; study participants requiring assistance in completing the GA questionnaires was 14% in the academic medical center compared to 24% in the community setting.[10]

Similar abbreviated assessments have been previously deployed in studies of patients with MM. These assessments have been demonstrated to detect deficits among patients undergoing treatment for MM that may go missed in routine clinical evaluation.[11-14] Moreover, in patients with MM, scoring systems incorporating functional deficits have been found to predict treatment tolerance,[11,15-17] healthcare utilization,[18] candidacy for hematopoietic stem cell transplantation,[12,19] and survival.[11,15-17,20-22]

The prevalence of geriatric impairment among patients with MM treated at UNC has been evaluated using one such abbreviated GA as part of an existing registry of greater than 150 patients with MM and other plasma cell disorders (LCCC 1728: Registry for Adults with Plasma Cell Disorders). Among participants in this registry, GA-identified impairments were common. Specific impairments were seen in a substantial minority of patients, including poor performance on the Timed Up and Go test (29.8%), dependence in one or more instrumental activities of daily living (35.6%), and one or more falls in the prior 6 months (13.5%).[14] Moreover, the presence of functional deficits was associated with inferior patient-reported quality of life among affected individuals.

1.3 Purpose and Rationale

While the presence of GA-identified deficits has clear prognostic significance for patients with MM, the feasibility and efficacy of clinic-based interventions targeting these deficits have been less thoroughly evaluated. In the general population, such targeted intervention has been shown to improve survival and functional outcomes in older adults.[23-26] There is recent data regarding the efficacy of GA-guided supportive interventions in improving clinically relevant outcomes for patients with solid tumors, both in the perioperative setting[27] and at new lines of systemic therapy,[28-31] though similar data for patients with hematologic malignancies (including MM) is lacking. Likewise, best practices for integration of geriatric assessments into oncology practice remain to be

determined. Further studies of the efficacy of GA-guided interventions among patients with hematologic malignancies are therefore needed.[32-35]

2.0 STUDY OBJECTIVES AND ENDPOINTS

2.1 Primary Objective

The primary objective of this pilot study is to evaluate the feasibility of an intervention program based on performing the GA in the outpatient oncology clinic in older adults undergoing treatment for MM.

This assessment will be quantified in terms of the percent of patients who accept referral to interventions for GA-identified impairments.

2.2 Exploratory Objectives

Secondary objectives include assessment of patient satisfaction with the intervention program, which will be assessed by a Likert scale response at 3-month follow up. [redacted]

3.0 PATIENT ELIGIBILITY

3.1 Inclusion Criteria

3.1.1 Patients age 60 years or older with a confirmed diagnosis of multiple myeloma currently undergoing or planned to begin treatment for multiple myeloma.

3.1.2 Enrollment in LCCC 1728 (patients already enrolled in LCCC 1728 prior to LCCC 2101 initiation and enrolling subsequent to LCCC 2101 initiation will be invited to co-enroll in LCCC 2101).

3.1.3 Presence of an intervenable deficit (as defined by metrics and dichotomization points in Table 1) on the participant's most recent LCCC 1728 assessment (Appendix I and II):

- Activities of daily living score < 14.
- Instrumental activities of living score < 14.
- Timed Up and Go test ≥ 14 seconds (or unable to complete the test).
- ≥ 1 fall in the prior 6 months.
- Eyesight poor or worse.
- Hearing poor or worse.
- Number of daily medications ≥ 10.
- MHI-13 Depression score ≥ 12.
- MHI-13 Anxiety score ≥ 6.

3.1.4 Willing and capable of providing written informed consent.

3.2 Exclusion Criteria

3.2.1 Dementia, altered mental status, or any psychiatric or co-morbid condition prohibiting the understanding or rending of informed consent.

4.0 STUDY PLAN

4.1 Schema

This is a one-arm observational pilot study of 40 patients. Patients with a confirmed diagnosis of multiple myeloma and undergoing treatment or planned to begin treatment are recruited per protocol for LCCC 1728. Week One and Two refers to the period after recruitment/consent.

Prior to enrollment		**Week One and Two**			**3 months after consent date**	**Following completion of participation**
As part of LCCC 1728, patients complete Geriatric Assessment and EORTC QLQ C30 and MY20 symptom surveys	Patients meeting inclusion criteria identified from existing registry. **Eligible patients contacted:** • **Recruit** • **Consent**	Intervention strategy based on GA-identified deficits (Table 1) developed by Study Team	Intervention strategy discussed and finalized with study participant	Participant-approved intervention referrals are completed and communicated to the study participant	Epic@UNC is reviewed for evidence of participant attendance at scheduled referrals. Study participants complete GA measures, EORTC surveys, and satisfaction survey.	No further dedicated assessments for current study. Further follow up as per LCCC 1728 protocol.

4.2 Duration of Study

Contact will be maintained with study participants during the first week (5 working days) of enrollment in LCCC 2101 (Week One and Two). Two additional contacts with participants will be at 3 months from enrollment, either during a regularly scheduled clinic visit, through mailings, or electronically via the fully remote option.

4.3 Study Details

4.3.1 Patient Identification and Recruitment

Eligible patients will be identified from within the UNC Plasma Cell Disorders Registry (LCCC 1728). The principal investigators of this protocol (Jensen ,

Tuchman) are co-investigators on the LCCC 1728 protocol, and participants in LCCC 1728 have agreed to be contacted for potential future studies (as noted in section 5.4 of the LCCC 1728 protocol).

As part of the LCCC 1728 protocol, participants complete intermittent assessments consisting of a brief GA (Appendix I and II) and supplementary quality of life questionnaires: the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life of Cancer Patients Core 30 (QLQ-C30) and Myeloma Module (QLQ-MY20). These assessments are completed at patient enrollment, at 3 and 6 months after enrollment, every 6 months thereafter, and at additional time of points of clinical significance.

The registry's database will be queried by LCCC 1728 database administrator to identify patients meeting the inclusion criteria outlined in section 3.1.1 (diagnosis of MM, age 60 or greater, and presence of at least one of the specified geriatric impairments).

The research team will contact the patient's clinician for appropriateness for participation in LCCC 2101. The research team will then approach the patient during a regularly scheduled outpatient clinic appointment to describe the study and assess the patient's interest in participating. For patients being seen remotely, the research team will contact the patient by phone to discuss the study (see section 4.3.3). The research team will administer the Main Consent and HIPPA Consent to interested patients. HIPAA consent will be requested to allow the study team access to their medical records to describe the study sample and to document follow-up to intervention referrals.

4.3.2 Intervention

Patients will be matched to appropriate interventions based on the presence of geriatric impairments on their most recent Geriatric Assessment, completed as part of LCCC 1728 prior to enrollment on LCCC 2101. These interventions largely consist of referrals to relevant specialists and existing services (Table 1). In the event of complex or multiple symptoms/deficits, the study coordinator will consult with the Study Investigators to clarify and prioritize the interventions. All measures included in the assessment are summarized in section 4.3.3.

The Study Team will then communicate with the study participant about proposed interventions in order to reach an agreement on the patient's preference for specific intervention(s). The Study Investigators will order agreed-to referrals. All of these referrals will be completed within two weeks of the patient's recruitment into the study.

Table 1. Measures, dichotomization points, and interventions

GA Domain	Measures	Range	Cut point	Interventions
Function	ADLs (physical) IADLs Timed Up and Go Falls in past 6 months	0 - 14 0 - 14 N/A N/A	< 14 < 14 ≥ 14 seconds ≥ 1 fall	Physical and/or occupational therapy
Comorbidities	Eyesight Hearing	Excellent - blind Excellent - deaf	Poor or worse Poor or worse	Optometry Audiology
Polypharmacy	Number of daily medications	N/A	≥ 10	Clinical pharmacist
Psychological	MHI-13 depression MHI-13 anxiety	0 - 43 0 - 20	≥ 12 ≥ 6	Cancer center support program

4.3.3 Measures

Patients will complete follow up assessments at 3 months from enrollment. These follow up assessments are described below and are collected per protocol for LCCC 1728. All measures and assessment should take no more than 30-35 minutes.

Geriatric Assessment (GA)
Our Study Team has extensive experience with conducting the GA I and II in older persons with cancer (LCCC 1728 and other studies in adults with cancer). (15 minutes required for completion)

Research Staff assessed (Appendix I):
- Karnofsky Performance Status[36]
- Timed Up and Go (TUG)[37]
- Montreal Cognitive Assessment (MoCA)[38]
- Blessed Orientation Memory Concentration (BOMC) Test[39]
- Data from the electronic medical record pertaining to the (1) patient's height, weight, weight approximately 6 weeks ago, calculated BMI, percent unintentional weight loss[40] and (2) patient's MM diagnosis and treatment.

Patient-Reported Functional Measures (Appendix II):
- Background – education, marital status, domestic living, current employment status, age, race, ethnicity
- Older Americans Resources and Services (OARS) Instrumental Activities of Daily Living (IADL)[41]
- Physical Activities of Daily Living (ADL)[41]
- Patient-assessed Karnofsky Performance Status[42]
- Nutritional status – unintentional weight loss in past 6 months,[40] current weight, weight 6 months ago
- Ability to walk one block

- Falls in the past 6 months
- Number of medications taken on a daily basis (prescribed, over-the-counter, herbs, vitamins)[43]
- Co-morbidities[44]
- Eyesight, hearing
- Social Activities[45]
- Mental Health Index-17[46-48]
- PROMIS Instrumental Support
- PROMIS Social Isolation
- Health Behaviors Questionnaire[49]
- Feedback on the questionnaire

Patient-Reported Symptom and Quality of Life Measures (Appendix III):
- European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ) Core questionnaire (C30)
- EORTC QLQ Multiple Myeloma supplement (MY20)

(25 minutes required for completion)

Additional measures:
Prior to 3 month follow up assessment, study investigators will review Epic@UNC for evidence of participant attendance at scheduled referrals. Patients will be asked about follow up and barriers to follow up at the time of the first follow up assessment (Appendix IV).

Patient satisfaction with the intervention(s) will also be evaluated at the 3-month assessment via a Likert scale (Appendix IV). (5 minutes required for completion)

4.3.4 Fully Remote Option

Due to the COVID-19 pandemic and efforts to maintain social distancing, a fully remote option is available for participants who are unable to come to clinic for all or a portion of the study. Participants will be contacted via phone to discuss the study and review the consent forms. The Main Consent and HIPAA consent forms will be provided to participants online and consent will be obtained through RedCap. For participants who choose the fully remote option, the MOCA and TUG will be administered via a video visit, and the BIA assessment will be omitted. If the participant does not have access to a smartphone or computer with video camera for a video visit, the TUG and MOCA will be omitted. The remainder of the self-report questionnaires will be completed either online through REDCap or will be mailed to the participant for completion. Upon receipt of the completed questionnaires, a study team member will contact the participant via telephone or email, per patient preference, to discuss the results and any recommended interventions. The study team member will order any accepted referrals and the patient will be notified via phone or email. At the time of 3-month follow up, the participant will be contacted via phone or email to discuss whether they would like to complete the assessment remotely or in-person. The

same procedure will be used for these follow up assessments as for the initial assessment.

4.4 Expected Risks

We anticipate that potential psychological or social risks (such as emotional distress or consequences of breaches of confidentiality) will happen rarely, if at all. There are no economic risks.

4.5 Removal of Patients from Protocol

If a study participant decides to discontinue the study, for any reason, they are free to do so at any time.

5.0 TIME AND EVENTS TABLE

	Baseline	Intervention	3 month follow-up (+/- 4 weeks)
Screening	X		
Informed Consent	X		
GA[1]			X
EORTC C30& MY20[2]			X
Patient Barriers questionnare[3]			X
Medical Records Abstraction		Continuously throughout study[4]	

[1] Geriatric assessment I and II
[2] European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Core Questionnaire (C30) and Myeloma supplement (MY20)
[3] Questionnaire regarding patient satisfaction with interventions and barriers to follow up.
[4] Data collected from medical records will include information on participation in referral interventions.

6.0 UNANTICIPATED PROBLEMS

6.1 Definition

As defined by UNC's IRB, unanticipated problems involving risks to study subjects or others (UPIRSO) refers to any incident, experience, or outcome that:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

- Is related or possibly related to a subject's participation in the research; and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

6.2 Reporting

Any UPIRSO that occurs during the conduct of this study and that meets all three criteria listed in 6.1 must be reported to the UNC IRB using the IRB's web-based reporting system.

7.0 STATISTICAL CONSIDERATIONS

7.1 Study Design

This is a one-arm observational pilot study.

7.2 Sample Size and Accrual

Our one-year accrual goal is a minimum of 40 patients age 60 or older with multiple myeloma who are seen in the outpatient hematology/oncology clinic at UNC Cancer Hospital. Patients will be recruited from an existing registry of patients with plasma cell disorders treated at UNC (LCCC 1728).

7.3 Data Analysis Plans

7.3.1 Planned Analyses

We will estimate percentages and perform descriptive statistics of the patient population. Through electronic medical record chart abstraction and patient report, we will measure the rate of participants' attendance of at least one appointment following referrals. Additionally, all participants will complete a satisfaction survey that will be reviewed for qualitative analysis regarding the strengths and weakness of the study design and interventions.

PRO measures will be scored to provide a rating for each symptom with higher scores indicating higher severity and greater interference with daily activities. Paired *t* tests will be used to compare each symptom score before and after intervention. This will be considered an exploratory analysis given the small sample size.

7.3.2 Power / Precision Considerations

We anticipate an acceptance rate for intervention referral (as measured by attendance of at least one appointment) of at least 75%, thus the projected precision of a 95% exact binomial confidence interval is (58.8%, 87.3%). Additionally, all participants will complete a survey concerning the intervention study, including a 5-point Likert scale regarding their satisfaction. The percentage

of patients who report a 4 or 5 (indicating agree or strongly agree with the satisfaction statement) will be reported, with a 95% CI no larger than +/- 16.2%. The satisfaction surveys will additionally serve as the basis for an analysis regarding the strengths and weaknesses of the study design and interventions.

7.4 Data Management/Audit

All data will be collected and managed by Dr. Jensen and his designated staff. Data will include consent forms, contact and screening information, and responses to printed and electronic questionnaires. Dr. Jensen and his designated staff will be responsible for reviewing questionnaire responses for completeness and logical consistency. Designated staff will enter all questionnaire data into a REDCap™ database. They will be responsible for processing all stored data using well-developed procedures for pre-coded forms design, encoding, data entry, data editing, and file management. All procedures will be IRB and HIPAA compliant. Completed questionnaires, consent forms, contact information, and other documents will be kept by Dr. Jensen or his designees in a locked file cabinet until the basic reviews are completed, so that possible errors can be checked against the original forms.

As an investigator-initiated study, this trial will also be audited by the Lineberger Cancer Center audit committee every six or twelve months.

The Principal Investigator will provide continuous monitoring of patient safety in this trial with periodic reporting to the UNC Lineberger Data and Safety Monitoring Committee (DSMC) as required.

Meetings/teleconferences will be held at a frequency dependent on study accrual, and in consultation with the study Biostatistician. At these meetings, the research team will discuss all issues relevant to study progress, including enrollment, safety, regulatory, data collection, etc. and the team will produce summaries or minutes of these meetings. These summaries will be available for inspection when requested by any of the regulatory bodies charged with the safety of human subjects and the integrity of data including, but not limited to, the oversight (Office of Human Research Ethics (OHRE) Biomedical IRB, the Oncology Protocol Review Committee (PRC) or the North Carolina TraCS Institute Data and Safety Monitoring Board (DSMB).

8.0 STUDY MANAGEMENT

8.1 Institutional Review Board (IRB) Approval and Consent

It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations. The IRB should approve the consent form and protocol.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to Good Clinical

Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before recruitment and enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements currently required by the FDA Regulations and local or state regulations. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB-approved consent form.

Prior to a patient's participation in the trial, the written informed consent form should be signed and personally dated by the patient and by the person who conducted the informed consent discussion.

8.2 Required Documentation

Before the study can be initiated at any site, the following documentation must be provided to the Clinical Protocol Office (CPO) at the University of North Carolina.

- A copy of the official IRB approval letter for the protocol and informed consent
- CVs and medical licensure for the principal investigator and any associate investigators who will be involved in the study
- A copy of the IRB-approved consent form

8.3 Registration Procedures

All participants will be registered and entered into the web-based clinical research platform Oncore®.

8.4 Adherence to the Protocol

Except for an emergency situation in which proper care for the protection, safety, and well-being of the study patient requires alternative treatment, the study shall be conducted exactly as described in the approved protocol.

8.4.1 Emergency Modifications

UNC investigators may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior UNC IRB approval.

For any such emergency modification implemented, a UNC IRB modification form must be completed by UNC Research Personnel within five (5) business days of making the change.

8.4.2 Single Patient/Subject Exceptions

Eligibility single subject exceptions are not permitted for Lineberger Comprehensive Cancer Center Investigator Initiated Trials under any circumstances. Other types of single subject exceptions may be allowed if proper regulatory review has been completed in accordance with Lineberger Comprehensive Cancer Center's Single Subject Exceptions Policy.

8.4.3 Other Protocol Deviations/Violations

According to UNC's IRB, a protocol deviation is any unplanned variance from an IRB approved protocol that:

- Is generally noted or recognized after it occurs
- Has no substantive effect on the risks to research participants
- Has no substantive effect on the scientific integrity of the research plan or the value of the data collected
- Did not result from willful or knowing misconduct on the part of the investigator(s).

An unplanned protocol variance is considered a violation if the variance meets any of the following criteria:

- Has harmed or increased the risk of harm to one or more research participants.
- Has damaged the scientific integrity of the data collected for the study.
- Results from willful or knowing misconduct on the part of the investigator(s).
- Demonstrates serious or continuing noncompliance with federal regulations, State laws, or University policies.

If a deviation or violation occurs please follow the guidelines below:

Protocol Deviations: UNC personnel will record the deviation in OnCore® (or other appropriate database set up for the study), and report to any sponsor or data and safety monitoring committee in accordance with their policies. Deviations should be summarized and reported to the IRB at the time of continuing review.

Protocol Violations: Violations should be reported by UNC personnel within one (1) week of the investigator becoming aware of the event using the same IRB online mechanism used to report UPIRSO.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO: Any events that meet the criteria for "Unanticipated Problems" as defined by UNC's IRB (see section 6.1) must be reported by the Study Coordinator using the IRB's web-based reporting system.

8.5 Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Principal Investigator at UNC. It should also be noted that when an amendment to the protocol substantially alters the study design or the potential risk to the patient, a revised consent form might be required.

The written amendment, and if required the amended consent form, must be sent to UNC's IRB for approval prior to implementation.

8.6 Record Retention

Study documentation includes all Case Report Forms, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed patient consent forms).

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study.

Government agency regulations and directives require that all study documentation pertaining to the conduct of a clinical trial must be retained by the study investigator. In the case of a study with a drug seeking regulatory approval and marketing, these documents shall be retained for at least two years after the last approval of marketing application in an International Conference on Harmonization (ICH) region. In all other cases, study documents should be kept on file until three years after the completion and final study report of this investigational study.

8.7 Obligations of Investigators

The Principal Investigator is responsible for the conduct of the clinical trial at the site in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki. The Principal Investigator is responsible for personally overseeing the treatment of all study patients. The Principal Investigator must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and all FDA/GCP/NCI regulations and guidelines regarding clinical trials both during and after study completion.

The Principal Investigator at each institution or site will be responsible for assuring that all the required data will be collected and entered onto the Case Report Forms. Periodically, monitoring visits will be conducted and the Principal Investigator will provide access to his/her original records to permit verification of proper entry of data. At the completion of the study, all case report forms will be reviewed by the Principal Investigator and will require his/her final signature to verify the accuracy of the data.

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10.0 APPENDICES

See separate documents.