



THE OHIO STATE
UNIVERSITY

WEXNER MEDICAL CENTER

**Ohio State University Wexner Medical Center
Multiple Sclerosis and Neuroimmunology**

Clinical Fellowship Syllabus and Guide

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List of MS Center Faculty and Staff

Physicians

Tirisham Gyang M.D (Fellowship director)

Benjamin Segal, M.D

Emily Harrington, MD, PhD

Ninan Zhang, MD

Nurse Practitioners, Nurses and Medical Assistants

Kristi Epstein, CNP

Vicki Kascak, RN

Clinical Pharmacist

Margaret Hansen, RPh

Clinical Trial Coordinator/staff

Kasturi Ganesh Barki

Trittnee Robinson

Regular MS Center Meetings

Conference	Schedule	Description
Neuroimmunology Research Data/Journal Club	Monthly	MS Fellows and students present and discuss new research data and recent journal articles
Patient Rounds	Weekly	Patients are interviewed and examined in front of an audience of faculty, fellows, residents and students, followed by a discussion
Neurology Grand Rounds	Tuesday 7.30am	Internal and external speakers deliver lectures on topics in clinical neurology
MS Clinical and Neuroradiology Case Presentation Conference (Adult and Pediatrics)	Every 2 nd Thursday at 3pm	MS Center faculty and fellows and Neuroradiology faculty present and discuss patient cases and review imaging studies
MS Center Clinical Trial Meeting	Every 2 nd Thursday at 2.00pm	MS Center Faculty, staff and trainees discuss future and current clinical trials in MS therapeutics, and studies in biomarker discovery and epidemiology
MS Clinic Faculty and Staff Meeting	Every 2 nd Thursday at 4pm	MS Center faculty, staff and trainees discuss issues relevant to the Center's clinical practice, including protocols for drug administration and monitoring, the introduction of newly approved drugs, documentation practices and approaches for neuroimaging and laboratory testing
Neuroimmunology Lecture Series		Invited speakers with expertise in MS research deliver a lecture

Training in the Diagnosis and Management of Multiple Sclerosis and related disorders

Description of Training Experience

Fellows receive clinical training through case presentations and supervised patient management for the duration of their Fellowship. Training occurs in the outpatient setting in MS Clinics. Fellows are supervised by the Fellowship Director and other OSU staff physicians with appointments in the MS Center.

Educational Purpose

To gain subspecialty expertise in the diagnosis, evaluation and clinical management of MS. Specific goals include:

- To become expert in the evaluation and diagnosis of MS and related disorders (this includes the generation of a comprehensive differential diagnosis and familiarity with appropriate testing)
- To learn about the revised McDonald criteria
- To learn how to distinguish between the clinical subtypes of MS (such as CIS, relapsing-remitting, relapsing progressive, secondary progressive and primary progressive)
- To become adept in monitoring the disease course and to recognize the transition between relapsing and secondary progressive disease
- To become familiar with the radiological features of MS, particularly MRI characteristics that help to distinguish MS from alternative diagnoses
- To become knowledgeable about FDA approved disease modifying therapies (including their clinical indications, mechanisms of action and side effect profiles)
- To learn about novel disease modifying therapies that are currently under investigation
- To become skilled in the symptomatic management of MS (including the treatment of fatigue, depression, bladder and bowel dysfunction, sexual dysfunction, spasticity, pain and cognitive deficits).
- To provide comprehensive care as a member of the OSU multidisciplinary MS care team which, in addition to physicians, includes nurses, social workers, clinical and cognitive psychologists, physical therapists, and occupational therapists.
- To learn how to work with other subspecialists to optimize patient care (including urologists, physiatrists, pain specialists and neuroophthalmologists)

Assessment Tools

- Fellows will receive ongoing feedback from supervising faculty during case discussions in the clinic and at a weekly Multiple Sclerosis Clinical and Neuroradiology Case Presentation meeting. The fellows' clinical notes will also be reviewed and critiqued by clinical mentors on an ongoing basis.
- Fellows meet with the fellowship director every 6 months for a formal global verbal assessment and written assessment.
- Formal global verbal and written assessment every six months from the Fellowship Director.
- An annual 360° evaluation from clinical team members and patients will be performed as indicated.

Expectations and Supervision

The duration and structure of the overall Fellowship is customized based on the goals and interests of the fellow. Fellows primarily interested in clinical training typically spend 60-80% of their time seeing patients and complete the Fellowship in one year. Fellows seeking more in-depth clinical research training require a two-three year Fellowship (particularly if they wish to complete the requirements for a Masters Degree) and spend 20-40% of their time seeing patients.

Fellows work with an assigned staff physician in half-day blocks, which include both new patient and follow-up visits. Fellows are responsible for the initial evaluation of the patient and development of an initial evaluation and treatment plan. The patient is presented to the supervising staff physician and feedback to the Fellow is provided immediately. Fellows then implement the plan and write the encounter note, which is reviewed and edited as needed by the supervising staff physician. Fellows also are responsible for reviewing laboratory and imaging results, composing letters to patients and referring physicians, and completing forms as needed.

Fellows maintain a log of all patients seen, which is reviewed periodically with the Fellowship Director to insure exposure to a broad range of MS-related diagnostic and therapeutic issues.

Inpatient consultations are conducted by Fellows under supervision of OSU staff physicians on a case by case basis.

Orientation

Clinical orientation occurs the first two weeks of the Fellowship. Fellows meet with the Fellowship Director to review the goals and expectations concerning clinical training. The Fellow shadows several physicians and the nurse practitioner to gain familiarity with the Center's general approaches to diagnosis and management, as well as standard patient care procedures at the MS Clinic. Fellows are provided with a reading list of seminal publications related to MS diagnosis and therapy.

Composition of patient population seen at the OSU MS Center

The patient population is composed of adults across all age ranges and a smaller number of pediatric patients, predominantly with MS but also other inflammatory disorders of the central nervous system (such as clinically isolated syndrome and neuromyelitis optica). A significant number of patients with neurologic symptoms for which MS is a diagnostic consideration are referred for evaluation.

List specific departmental conferences that the fellows are expected to attend

1. Neurology Grand Rounds (one hour per week). Members of the Neurology Department and outside speakers present updates on neurological topics.
2. Patient Rounds (one hour per week). A patient is examined and interviewed in front of the MS Center faculty and trainees. Aspects of the patient's history, exam findings and management are then discussed by the team.

3. MS Clinical and Neuroradiology Patient Case Conference (one hour per week). Patient cases are orally presented by MS fellows and faculty. MRI scans are reviewed. In addition to MS Center faculty, Neuroradiology faculty participate in this conference.
4. Neuroimmunology Journal and Data Club (1-2 hours per week). Every other week fellows and students training in the MS Center present recent publications or general reviews related to clinical issues, clinical research, and basic research in MS. On alternate weeks, trainees present the findings of their research projects.
5. Neuroimmunology Lecture Series (two hours each month). An expert in MS research delivers a lecture on a monthly basis. Fellows meet with each speaker one on one for advice about their research projects and career goals.

Self-Directed Learning

1. Reading List- Fellows are provided with a list of publications addressing MS pathogenesis, risk factors, clinical management and experimental therapeutics
2. Clinician's Primer on Multiple Sclerosis (Volumes 1-5), Consensus Medical Communications, 2011-2012.

Time distribution

Clinical fellows will be expected complete at 6 clinical half-days in the MS clinic, supervised by MS faculty. Fellows will have the option to participate in additional selective clinical learning experiences in allied disciplines depending on individual interest. These selective rotations can be arranged in tracts such as neuroimaging, neuro-ophthalmology, neuro-rheumatology, neuro-rehabilitation, neuropsychology and neuro-urology. Fellows will be expected to familiarize themselves with relevant selected readings suggested by the faculty in these disciplines.

Example of Weekly Schedule for Clinical MS Trainee

Adult MS/Neuroimmunology Clinic					
	Monday	Tuesday	Wednesday	Thursday	Friday
AM	MS clinic (Gyang)	Clinical pharmacy rotation	Neuro-rheum (Gyang) *2 nd Wednesdays only Self-directed learning/ Inpatient consults Week 1,3,4	Elective	MS clinic (*Segal/Gyang) *3 rd Fridays only Peds Neuroimm clinic -monthly (Hutchinson and Magana)
PM	MS clinic (Gyang)	MS clinic	MS clinic (Zhang)	Research meeting – 2pm* Case conf – 3pm* *2 nd Thursdays Self-directed learning/ Inpatient consults Week 1,3,4	Neurosarcoid clinic (Gyang)/ MS clinic (*Segal) *3 rd Fridays only

- Neuroimmunology monthly case conference – 2nd Thursdays at 3pm
- Neuro-rheumatology clinic – 2nd Wednesday of the month (East Outpatient Center)
- Neurosarcoidosis clinic – 3rd Friday of the month (Martha Moore House 2nd Floor)
- Pediatric neuroimmunology clinic – monthly on Friday morning with Drs Magana and Hutchinson

Clinical selective:

- Neuro-Urology
- Neuro-Rheumatology
- Neuro-Ophthalmology/OCT or ophthalmology
- Neurophysiology /Evoked Potentials
- Neuropsychology
- Physical Medicine and Rehabilitation

Clinical selective can be scheduled in blocks or be divided across the year depending on scheduling availability of faculty and fellows.

The fellow will also serve as the first line contact for inpatient neuroimmunology consultation and will staff patients seen with the designated MS faculty overseeing the service.

Core Competency Overview

1. Patient Care
2. Medical Knowledge
3. Practice-based learning and improvement
4. Interpersonal skills and communication
5. Professionalism
6. Systems-based Practice

PATIENT CARE: By the end of the Fellowship, Fellows will demonstrate the basic knowledge, attitudes, and skills necessary to provide compassionate, appropriate, and effective care of patients with MS and related disorders.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Obtain an accurate and comprehensive history including: the clinical course; neurologic, systemic, cognitive, and autonomic symptomatology; treatment history and current medications; degree of current disability/ activities of daily living; family and social history	-Direct patient care -Performance feedback from supervising faculty -Self-directed learning -MS Clinical and Neuroradiology Case Presentation conference	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology Patient Case Conference -Verbal and written assessment by fellowship director every 6 months -360° evaluation by clinical team when indicated -Patient satisfaction questionnaires administered annually

Determine the appropriate testing to confirm the diagnosis of MS and address other diagnostic considerations	<ul style="list-style-type: none"> -Direct patient care -Performance feedback from supervising faculty -Self-directed learning -MS Clinical and Neuroradiology Case Presentation conference 	<ul style="list-style-type: none"> Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology Patient Case Conference -Verbal and written assessment by fellowship director every 6 months -360° evaluation by clinical team when indicated
Summarize the history and physical exam, findings, and results of prior testing in cogent verbal and written presentations	<ul style="list-style-type: none"> -Direct patient care -Performance feedback from supervising faculty -Self-directed learning -MS Clinical and Neuroradiology Case Presentation conference 	<ul style="list-style-type: none"> Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology Patient Case Conference -Verbal and written assessment by fellowship director every 6 months -360° evaluation by clinical team when indicated
Develop and implement an appropriate management (treatment) plan	<ul style="list-style-type: none"> -Direct patient care -Performance feedback from supervising faculty -Self-directed learning -MS Clinical and Neuroradiology Case Presentation conference 	<ul style="list-style-type: none"> -Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology Patient Case Conference -Verbal and written assessment by fellowship director every 6 months -360° evaluation by clinical team when indicated
Gain proficiency in the neurologic exam relevant to MS and related disorders	<ul style="list-style-type: none"> -Direct patient care -Performance feedback from supervising faculty -Self-directed learning -MS Clinical and Neuroradiology Case Presentation conference Performance feedback from supervising faculty Self-directed learning 	<ul style="list-style-type: none"> -Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology Patient Case Conference -Verbal and written assessment by fellowship director every 6 months -360° evaluation by clinical team when indicated
Gain proficiency in performing lumbar puncture	<ul style="list-style-type: none"> -Direct patient care -Performance feedback from supervising faculty 	<ul style="list-style-type: none"> -Feedback from MS Center faculty in clinic
Gain proficiency in evaluating MRI studies relevant to MS	<ul style="list-style-type: none"> -Direct patient care 	<ul style="list-style-type: none"> -Feedback from MS Center faculty in clinic

	-Performance feedback from supervising faculty -MS Clinical and Neuroradiology Case Presentation conference Performance feedback from supervising faculty Self-directed learning	-Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
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MEDICAL KNOWLEDGE: By the end of the Fellowship, Fellows will demonstrate specialized knowledge in the diagnostic criteria, clinical manifestations, laboratory findings, imaging features, diseases, disease therapies, and symptom therapies of MS and related disorders.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Demonstrate knowledge of the clinical manifestations of MS and related disorders	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of blood and cerebrospinal fluid test findings in MS, related disorders, and disorders in the differential diagnosis of MS	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of evoked potential findings in MS, related disorders, and disorders in the differential diagnosis of MS	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of the imaging features of MS, related disorders, and disorders in the differential diagnosis of MS	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of the diagnostic criteria for MS	Direct patient care Performance feedback	-Feedback from MS Center faculty in clinic

	Self-directed learning MS-related conferences	-Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of the differential diagnosis of MS and appropriate testing to address other diagnostic considerations	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of the prognosis of MS	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of the indications, benefits, adverse events, and monitoring of diseases therapies for MS	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of management of medical issues pertinent to MS e.g. reproductive issues and pregnancy, common infections in MS patients, vaccination, surgery, bone metabolism	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
Demonstrate knowledge of multidisciplinary care for clinical and psychosocial sequelae of MS	Direct patient care Performance feedback Self-directed learning MS-related conferences	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months

PRACTICE BASED LEARNING AND IMPROVEMENT: By the end of the Fellowship, Fellows will gain an understanding of the knowledge, attitudes, and skills necessary to initiate and maintain self-directed and independent learning.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Demonstrate an ability to locate, appraise, assimilate, and utilize evidence from the medical literature in patient care	Self-directed learning Performance feedback Attend weekly Neuroimmunology Journal/ Data Club	-Feedback from MS Center faculty -Feedback from MS Center team following presentations in Journal/ Data Club -Verbal and written assessment by fellowship director every 6 months

INTERPERSONAL SKILLS AND COMMUNICATION: Fellows will demonstrate interpersonal and communication skills that enable him/her to establish and maintain effective professional relationships with patients, their family members, physicians, and other healthcare providers.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Develop communication skills to address difficult clinical situations, e.g. delivering bad news (e.g. the diagnosis of MS, ongoing disease activity, progression), lack of diagnosis, demanding patients, patients with unrealistic expectations, suboptimal outcomes of therapy, recommendation not to drive, recommendation for nursing home placement, etc.	Direct patient care Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Develop skills in utilizing the electronic medical record.	Formal MyChart Training Direct patient care Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Gain skills in telemedicine	Direct patient care Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Gain skills in letter writing	Direct patient care Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Work collaboratively with other physicians and allied health professionals	Direct patient care Performance feedback Self-directed learning Modeling Participation in comprehensive care	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months

Develop presentation skills including preparation of slides and posters as appropriate. Types of presentations to include: 1. Scientific meetings 2. Grand Rounds and continuing medical education meetings 3. Educational conferences for residents and medical students 4. Patient groups	Giving presentations Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty in clinic -Feedback from MS Center team following presentations in Patient Rounds, the Neuroimmunology Journal/ Data Club and the MS Clinical and Neuroradiology MS Patient Case Conference -Verbal and written assessment by fellowship director every 6 months
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PROFESSIONALISM: Fellows should demonstrate behaviors that reflect commitment to continuous professional development and to the ethical practice of medicine in his/her interactions with patients, their families, physicians, and other healthcare providers.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Interact responsibly with patients and families, taking into consideration age, gender, culture, and disability issues	Direct patient care Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Demonstrate appropriate use of the electronic medical record in regards to patient respect and confidentiality	Direct patient care Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Interact responsibly with peers, supervising staff, other healthcare professionals, and outside physicians taking into consideration roles and responsibilities.	Direct patient care Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months

SYSTEMS BASED PRACTICE: By the end of the Fellowship, Fellows will gain an understanding of the context and systems in which MS healthcare is provided and gain an understanding of applying this knowledge to improve and optimize healthcare.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Appropriately carry out diagnostic evaluation and therapy in the outpatient or inpatient settings	Direct patient care Performance feedback Self-directed learning Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months

Appropriately implement diagnostic evaluation or therapy at the MS clinic or coordinate through referring local neurologist or primary care physician	Direct patient care Performance feedback Self-directed learning Modeling	Global rating (METS) -Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Identification of psychosocial factors and their impact on disease manifestations	Direct patient care Performance feedback Self-directed learning Modeling Participation in comprehensive care	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Appropriately carry out patient education or refer to OSU Nursing, the OSU Learning Center, support organizations such as the National MS Society, or pharmaceutical patient support programs	Direct patient care Performance feedback Self-directed learning Modeling Participation in comprehensive care	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Appropriately document patient encounters to meet JCAHO requirements	Direct patient care Performance feedback from clinical supervisors Modeling	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months
Appropriately prepare for future professional opportunities, e.g. including deciding on research vs. clinical practice, deciding on type of practice or institution, preparing a cover letter and CV, identifying and evaluating potential opportunities, interviewing, negotiating salary and contract terms	Self-directing learning Modeling Guidance from Fellowship Director and other OSU staff Guidance from OPSA Office of Physician Recruitment	-Feedback from MS Center faculty -Verbal and written assessment by fellowship director every 6 months

Training in Clinical Research: Goals and Objectives

Description of Training Experience

Fellows receive training in experimental therapeutics by participation in ongoing trials conducted by the OSU Multiple Sclerosis Center. Training occurs in the outpatient setting in the Multiple Sclerosis clinic. Fellows are supervised by the Fellowship Director and other OSU Clinical Faculty.

Goals

- To become familiar with the basic principles and practical aspects of MS clinical trials (including trial design, budget negotiation, randomization, regulatory processes, safety monitoring procedures, and standard outcome measures)
- To become adept in administering disability scoring tools used in MS clinical trials (EDSS, MSFC)

Approach

- *Orientation.* Fellows will initially be introduced to clinical trials by shadowing the clinical trial coordinator for one day each week during the first two months of the fellowship. During the same time period he or she will observe the examining neurologist perform standardized neurological examinations and assess study participants for degree of disability using clinical rating scales (such as the Expanded Disability Status Scale, or EDSS) and quantitative functional assessment tools (such as the Multiple Sclerosis Functional Composite, or MSFC). Fellows will be expected to obtain certification as an EDSS examiner via the Neurostatus e-test. Fellows will also become familiar with quality of life measurement tools (including Multiple Sclerosis Impact Scale, MS Symptom Check list score, Fatigue impact scale and Patient Determined Disease Step Score).
- *Active participation in clinical studies.* Following orientation, fellows will serve as a co-investigator in ongoing industry and grant funded trials. At the minimum, each fellow is expected to participate in one or more trials as an examining neurologist to gain expertise in performing a standardized neurologic examination, calculating clinical rating scales such as the EDSS, performing quantitative functional assessments such as the MSFC, and administering QOL surveys, such as the Multiple Sclerosis Impact Scale. Based on their interests, fellows may act as the treating neurologist (to become familiar with issues involved in patient management in the context of a study protocol) or as the *de facto* site Principal Investigator under the supervision of MS Center faculty for a multicenter trial. As a *de facto* site principal investigator, fellows are given the responsibility for composing the consent form, preparing Institutional Review Board forms and correspondences, coordinating budget and contract negotiation, managing regulatory documents, developing the subject recruitment strategy and monitoring subject accrual, assessing personnel needs, planning study visits, developing source documents, and working with study coordinators and study monitors to address queries. Study activities will be discussed as a team at a monthly Clinical Trial Coordination Meeting, which is attended by the entire MS Center faculty, trainees and trial coordinators. Fellows are expected to discuss their progress and plans in clinical research at each meeting.

Evaluation

- Ongoing feedback from supervising staff during pre-study preparation and trial performance.
- Feedback from study monitors and the sponsor regarding study conduct.
- Informal verbal assessment every month from the site principal investigator of the relevant trial.
- Feedback based on presentations at the monthly Clinical Trial Coordination Meeting.
- Formal verbal and written assessment every six months by the Fellowship Director

Range of clinical studies at OSU

The OSU MS Center will be involved in a large number of clinical trials that include:

- Multicenter phase 3 and 4 trials of disease-modifying and symptomatic therapies.
- Phase 2-4 clinical trials in clinically isolated syndromes, relapsing-remitting MS, and primary and secondary progressive MS.
- Single site biomarker and MRI studies in relapsing-remitting and progressive MS
- Clinical surveys of sleep disturbances and fatigue in MS
- Epidemiological studies of the contribution of environmental factors to MS relapse and progression
- Industry and grant sponsored trials.

Core Competency Overview

1. Patient Care
2. Medical Knowledge
3. Practice-based Learning and improvement
4. Interpersonal skills and communication
5. Professionalism
6. Systems-based Practice

PATIENT CARE: By the end of the Fellowship, Fellows will demonstrate the basic knowledge, attitudes, and skills necessary to carry out scientifically valid clinical trials and protect subjects' safety and rights, and meet regulatory requirements. Fellows also will demonstrate the ability to provide compassionate, appropriate, and effective care of patients with MS within the context of clinical trials.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Demonstrate ability to review the goals, conduct, requirements, and potential risks of a clinical trial with study subjects and obtain informed consent as required by study protocols	- Shadowing site principal investigator and study coordinator during orientation - Participation as Treating Neurologist in selected trials - Attendance of Investigators' meetings	- Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor - Reports from study monitoring visits
Demonstrate ability to gather essential and accurate information concerning demographics, MS history, and medical history as required at each study visit by study protocols	- Shadowing site principal investigator and study coordinator during orientation - Participation as Treating Neurologist in selected trials - Attendance of Investigators' meetings	- Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor - Reports from study monitoring visits

Demonstrate ability to perform standardized neurological exams as required at each study visit by study protocols	<ul style="list-style-type: none"> - Shadowing examining neurologists during orientation - Performance of standardized neurological examinations under the observation of MS Center faculty on at least four occasions - Participation as Treating Neurologist in selected trials 	-Critique and feedback from MS faculty observing the fellow's neurological examinations
Demonstrate ability to summarize the demographic, history, and physical exam at each study visit using source documents required by study protocols	<ul style="list-style-type: none"> - Shadowing examining neurologists during orientation - Obtaining history, performing physical exam and documenting findings under the supervision of MS Center faculty on at least four occasions -Participation as de facto site investigator in selected trials 	-Critique and feedback from MS faculty supervising these activities
Demonstrate ability to develop and implement an appropriate management plan for neurologic or medical issues arising during a study	<ul style="list-style-type: none"> - Shadowing site principal investigator and study coordinator during orientation - Participation as Treating Neurologist in selected trials - Attendance of Investigators' meetings 	<ul style="list-style-type: none"> - Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor - Reports from study monitoring visits
Demonstrate proficiency in performing a standardized neurologic exam and calculating clinical rating scales based on it such as the EDSS	<ul style="list-style-type: none"> -Participation as Treating Neurologist in trials -Investigators' meeting attendance -Certification via Neurostatus e-test 	Certification as EDSS examiner by Neurostatus
Demonstrate proficiency in performing quantitative functional assessments such as MS Functional Composite	<ul style="list-style-type: none"> -Shadowing examining neurologists during orientation -Performing MSFC under observation of trained study coordinator or neurologist -Participation as co-investigator in trials 	<ul style="list-style-type: none"> -MSFC certification -Critique and feedback from clinical trial staff and MS faculty supervising these activities
Demonstrate proficiency in determining MS relapses as defined by a study protocol	<ul style="list-style-type: none"> -Participation as Treating Neurologist in trials Investigators' meeting attendance -Modeling -Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor 	<ul style="list-style-type: none"> - Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, sponsor

Gain proficiency in administering patient self-report health status and quality of life tools such as the MS Quality of Life Inventory	Participation as a co-investigator in trials Investigators' meeting attendance Modeling Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor	- Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor - Reports from study monitoring visits
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MEDICAL KNOWLEDGE: By the end of the Fellowship, Fellows will demonstrate specialized knowledge in clinical trial design, planning, conduct, and regulatory requirements.

OBJECTS	EDUCATIONAL METHOD	ASSESSMENT METHOD
Gain familiarity with: 1. Principal Investigator regulatory responsibilities 2. Managing regulatory documents 3. Composing a consent form 4. Preparing Institutional Review Board forms and correspondence 5. Coordinating budget and contract negotiation 6. Developing the subject recruitment strategy and monitoring subject accrual 7. Assessing personnel needs 8. Planning study visits 9. Developing source documents 10. Working with study coordinators and study monitors to address queries	-Participation as <i>de facto</i> site Principal Investigator for selected trial -Investigators' meeting attendance	- Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, sponsor
Demonstrate knowledge and understanding of ethical issues and human subject protection in clinical trials	-On-line PEERS or CITI course -Clinical Research Grand Rounds	- Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, sponsor - Reports from study monitoring visits
Demonstrate knowledge of the practical issues, reliability, and interpretation of clinical trial outcomes assessments	-Participation as Treating Neurologist, Examining Neurologist, and <i>de facto</i> site Principal Investigator in selected trials -Investigators' meeting attendance Modeling -Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor	- Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, sponsor - Reports from study monitoring visits

PRACTICE BASED LEARNING AND IMPROVEMENT: By the end of the Fellowship, the Fellow will gain an understanding of the knowledge, attitudes, and skills necessary to initiate and maintain self-directed and independent learning.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Demonstrate an ability to locate, appraise, assimilate, and utilize evidence from the medical literature into clinical trial design and conduct	-Monthly Clinical Trial Coordination meeting attendance -Weekly journal club attendance -Performance feedback	-Presentation evaluations by fellowship director and MS Center faculty

INTERPERSONAL SKILLS AND COMMUNICATION: Fellows will demonstrate interpersonal and communication skills that enable him/her to establish and maintain effective professional relationships with study subjects, their family members, other clinical trial personnel, study monitors, and sponsors.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Develop communication skills to address issues with subjects that arise during clinical trials, e.g. recruitment of potential subjects, obtaining informed consent, on-study treatment failure, subject retention	-Participation as a co-investigator in trials -Investigators' meeting attendance -Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor	- Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, sponsor
Develop presentation skills including preparation of slides and posters for scientific meetings, internal meetings (weekly data/ journal club, monthly clinical trial coordination meeting, weekly MS Clinical and Neuroradiology case conference), and patient oriented conferences (Annual MS Patient and Caregiver Conference, patient talks for NMSS)	-Preparing and giving presentations -Performance feedback	-Formal verbal and written assessments from fellowship director -Feedback on presentations from MS faculty and patient evaluations (The latter are solicited from audience members of the Annual MS Patient and Caregiver Conference and biannual patient talks sponsored by NMSS chapters)

PROFESSIONALISM: Fellows should demonstrate behaviors that reflect commitment to continuous professional development and to the ethical practice of clinical research in his/her interactions with study subjects, their families, other clinical trial personnel, study monitors, and sponsors.

OBJECTS	EDUCATIONAL METHODS	ASSESSMENT METHOD
Interact responsibly with study subjects, families, and co-workers taking into consideration age, gender, culture, and disability issues	-Participation as a co-investigator in trials -Investigators' meeting attendance -Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor	--Formal verbal and written assessments from fellowship director - Feedback from site Principal investigator and research staff -Reports from study monitoring visits
Interact responsibly with study personnel, including performing study-related tasks accurately and in a timely fashion	-Participation as a co-investigator in trials -Investigators' meeting attendance	-Formal verbal and written assessments from fellowship director -360° evaluation by research staff as indicated

	-Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor	
Demonstrate appropriate use of the electronic medical record, source documents, and case report forms in regards to study subject respect, safety, and confidentiality	-Participation as a co-investigator in trials -Investigators' meeting attendance -Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor	-Formal verbal and written assessments from fellowship director -360° evaluation by research staff as indicated

SYSTEMS BASED PRACTICE: By the end of the Fellowship, Fellows will gain an understanding of the context and systems in which MS clinical trials are performed and gain an understanding of applying this knowledge to improve and optimize planning and conducting clinical trials.

OBJECTIVES	EDUCATIONAL METHOD	ASSESSMENT METHOD
Gain familiarity with appropriate interactions with study subjects and their family members, the study team, IRB study governance, study management, and sponsor to balance subject protection, scientific goals, and regulatory requirements	-Participation as a co-investigator in trials -Investigators' meeting attendance -Monthly Clinical Trial Coordination meeting attendance -Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor	-Formal verbal and written assessments from fellowship director -360° evaluation by research staff as indicated -Reports from study monitoring visits
Gain familiarity with the various roles and responsibilities of the study team, monitor, study governance, and study management	-Participation as a co-investigator in trials -Investigators' meeting attendance -Monthly Clinical Trial Coordination meeting attendance -Performance feedback from Fellowship Director, site Principal Investigator, study nurse and coordinator, study monitor, sponsor	-Formal verbal and written assessments from fellowship director -360° evaluation by research staff as indicated -Reports from study monitoring visits