



Site Qualification Checklist

Date: (insert date)

Site: (insert site)

Location: (insert location)

PI contact information: (insert name, email, phone, other relevant contact info)

Study coordinator contact information: (insert name, email, phone, other relevant contact info)

Interest in study

Have you reviewed the protocol, informed consent and CRF?	
Do you understand that this is a longitudinal study that will require subject follow-up?	

Access to subject population

Total number of patients, 18 years and older, seen each year at your facility with:					
MS	CIS	TM	ON	ADEM	NMO
Number who are/will be recurring patients					
Average frequency of appointments (daily, monthly, yearly, etc) for each patient					
Number seen per year who are newly diagnosed/treatment naïve					
Your estimate of the number of MS patients, meeting the inclusion criteria, who will agree to participate in this study					
Your estimate of the number of CIS patients, meeting the inclusion criteria, who will agree to participate in this study					
Are you willing to perform this study on non-MS (control) subjects at your facility?					
Average distance travelled by patients to get to the site?					

Clinical data

What type of MRI do you perform?	
What % of clinically isolated syndrome patients are getting spinal taps?	

Staffing

Does the PI have sufficient time to perform the requirements of this study?	
Are other neurologists who see patients at the site interested/available for this study?	
How many study coordinators do you have on staff?	
Do you have a qualified study coordinator on staff with time to perform the requirements of this study?	
If not, will you be able to hire a qualified study coordinator to perform this study?	
Average time to hire study coordinators at your site?	
Do you have the ability/expertise on site to collect N tubes of blood?	
What backup staffing is available in the event of site turnover or leaves of absences?	
Will you require additional staff (beyond PI and study coordinator) to meet the requirements of this study?	
If yes, is that staff currently available?	

Facilities

Do you have the space to conduct lengthy (2 hour) subject interviews in a comfortable setting?	
Do you have a computer with high speed internet access in that setting?	
If not, could a laptop with internet access be utilized in that setting? (May be provided by ACP)	
What type of network connectivity is available in that area (ethernet, wireless, etc.)	
Does the study coordinator have experience with electronic data capture (EDC, eCRF)?	
Do you have a scanner for documents?	
Do you have the space to store study kits and shipping supplies?	
Do you have the space to store subject documentation and regulatory documents?	
Can the storage space for documents be locked?	
Do you have the facilities/refrigerator (4 degrees C) space to store blood samples for a short time prior to shipping?	
Do you have the facilities/freezer (minus 70 degrees C) space to store serum for up to a week prior to shipping?	
Do you have the means to use dry ice for packing and shipping samples?	
Do you have an on-site medical laboratory?	
Do you have a centrifuge (3,000 RPM)?	

Prior study experience

Number of studies conducted by PI at this site (at any time)?	
Number of studies <i>currently</i> being conducted by this PI at this site?	
Number of studies <i>currently</i> being conducted by the study coordinator at this site?	
Has the staff been trained in Good Clinical Practice methods?	
Has the staff been trained in regulatory requirements including HIPAA?	

IRB approval

Does the site have a local IRB?	
Has this PI received IRB approval for other studies at this site?	
Has the study coordinator received IRB approval for other studies at this site?	
Do you have someone who can prepare the IRB application?	
Can the IRB provide approval within 3 months of site engagement?	

Research

Is MS or MS related research conducted at this site?	
If yes, what research areas?	