

Q1. INFORMED CONSENT

Background and Purpose:

You are invited to participate in a research project on Inclusion Body Myositis (IBM). This research project is being conducted by Yale University in cooperation with The Myositis Association (TMA). The Principal Investigator is Dr. David Paltiel, professor in the Yale School of Public Health. The Senior Investigator and funder of the project is Dr. Martin Shubik, professor in the Yale School of Management and Economics Department.

Dr. Shubik has suffered from IBM for many years. His condition was originally diagnosed in 2003 as Polymyositis but in 2007, it was re-diagnosed as Inclusion Body Myositis. Like many with IBM, Dr. Shubik has watched the strength in his arms and legs disappear. The joys of long walks, golf, tennis, canoeing and other sports have been vanishing, the ability to travel and visit friends, go out to games or museums, to fairs, movies, concerts and many other events that require walking more than a few blocks or climbing a few stairs becomes more and more restricted.

IBM is an “orphan disease”, in that there are few drug companies, not-for-profit organizations or politicians interested in it. Unfortunately, doctors do not know what causes this disease and at this time, there is no known cure. Fortunately, however, TMA is highly supportive. Dr. Shubik has put in a considerable amount of his own time and money in order to start this project. With the collaboration of several neurologists and a rheumatologist, the following questionnaire survey has been put together.

From the survey that you and others complete and submit, we will develop a prospective patient registry. This systematic categorization of patient demographic, social, and clinical histories will be a valuable asset for patients and researchers and may inform the development of future treatments and a cure for IBM. It will also permit us to develop an online web site, which you, your families, your caregivers, and your doctors will be able to access to find answers to frequently asked questions, to compare your experience with IBM to that of other patients with the disease, and to obtain other up-to-date information on IBM.

Procedures:

The procedure involves completing this survey that should take approximately 45 minutes. Your responses will be confidential since we do not collect identifying information such as your name or address. The survey questions are about how Inclusion Body Myositis affects you and your day-to-day activities. Additional demographic questions are asked to help identify possible causal relationships.

Risks and Benefits:

The risks of the study are minimal and associated only with the time and inconvenience to you in filling out the questionnaire. While this study may not necessarily have any direct medical benefit for you, personally, we do anticipate that you, your caregivers, and your treating physicians may obtain some indirect benefits from the frequently asked questions (FAQs) page that will be made possible by your participation in this study. We anticipate that the information obtained from this research study will benefit future generations of patients with Inclusion Body Myositis.

Confidentiality:

All responses will remain anonymous. Your consent below will denote your authorization and agreement to participate. All data will be transferred and stored in a password protected electronic format. To help protect your confidentiality, all answers will be anonymous. The surveys will not contain information that can personally identify you and are designed such that answers cannot be linked to individuals. The results of this study will be used for information of those who have the disease and for research purposes only. The survey results will be shared with The Myositis Association.

Voluntary Participation:

Your participation in this research study is voluntary. You may choose not to participate. If you decide not to participate in this study or if you withdraw from participating at any time, you will not be penalized.

Questions:

If you have any questions about this study, you may contact the Principal Investigator, Dr. A. David Paltiel, P.O. Box 208034, New Haven, CT 06520-8034, david.paltiel@yale.edu, (203) 785-2854.

If you would like to talk with someone other than the researchers to discuss problems or concerns, to discuss situations in the event that a member of the research team is not available, or to discuss your rights as a research participant, you may contact the Yale University Human Subjects Committee, Box 208010, New Haven, CT 06520-8010, 203-785-4688, human.subjects@yale.edu. Additional information is available at <http://www.yale.edu/hrpp/participants/index.html>

CONSENT:

Please select your choice below. Checking the "I Agree" box below indicates that:

- You have read the above information
- You have had the opportunity to have any questions about this study answered
- You voluntarily agree to participate
- You are at least 18 years of age

I Agree

I Disagree

If you do not wish to participate in the research study or you checked "I Disagree" above, no further action is necessary.

Q2. Year and Place of Birth: (Please fill in each to the best of your knowledge)

Year Born: _____

City of Birth: _____

State of Birth: _____

Country of Birth: _____

Q3. Gender: (Check one)

Male

Female

Q4. Ethnicity – Please specify your ethnicity: (Check one box)

Hispanic or Latino

Not Hispanic or Latino

Q5. Race – Please specify your race: (Check all that apply)

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

Q6. Height: (Please fill in)

_____ feet _____ inches

Q7. Current weight: (Please fill in)

_____ pounds

Q8. Please check the highest educational level you finished: (Check one)

- 8th grade or less
- Some High School
- High School graduate or GED
- Some College or Junior College
- 2-year College Degree (Associates)
- 4-year College Degree (BA,BS)
- Masters Degree
- Doctoral Degree
- Professional Degree (MD, JD, etc.)

Q9. Please check the box with your total household annual income before taxes: (Check one)

- \$25,000 or less
- Above \$25,000 but below \$75,000
- Above \$75,000 but below \$150,000
- Above \$150,000
- Prefer not to answer

Q10. Please check your current marital status: (Check one)

- Married
- Separated
- Divorced
- Widowed
- Never married

Q11. Do you currently live in (check one)...

- A house or apartment
- A relative's residence
- An assisted living residence
- Other – Please specify: _____

Q12. Do you live (check one)...

- Alone
- With spouse
- With other relative
- With a friend
- With unmarried partner
- With other person – Please specify: _____

Q13. Employment Status: Are you currently working? (Check one)

- Working Full-time
- Working Part-time
- Unemployed (skip the next question)
- Retired (skip the next question)

Q13a. If you answered working full or part-time in the previous question, are you (check one)...

- Self-employed
- Employed by someone other than yourself

Q14. What symptom(s) of IBM brought you to the doctor? (Check all that apply)

- Trouble Swallowing
- Impaired use of arms and legs
- Weakness
- Fatigue
- Falls
- Difficulty climbing stairs
- Other – Please specify: _____

Q15. How long was the time between your first observed symptoms and your first doctor's diagnosis? (Check one)

- 1-3 Months
- 3-6 Months
- 6-12 Months
- 1-2 Years
- 2 or more Years
- Not applicable

Q16. What was your first diagnosis? (Check one)

- IBM
- Polymyositis
- Arthritis
- Do not know
- Other – Please specify: _____

Q17. Which Physician gave you this diagnosis? (Check one)

- Primary Care
- Neurologist
- Rheumatologist
- Other – Please specify: _____

Q18. If the first diagnosis was incorrect, how much time was there between it and the correct diagnosis? (Please fill in)

Months – Specify: _____
Years – Specify: _____

Q19. Which Physician was the first to diagnose your disease as IBM? (Check one)

- Primary Care
- Neurologist
- Rheumatologist
- Other – Please specify: _____

Q20. Did you have a biopsy at that time? (Check one)

- Yes
- No
- Don't know

Q21. Within three years before your first diagnosis of IBM, did you have any other major medical problem(s)? (Check all that apply)

- Cancer
- Heart
- Arthritis
- Do not know
- Other – Please specify: _____

Q22. Aside from IBM, how would you describe your health? (Check one)

- Excellent
- Very Good
- Good
- Fair
- Poor
- Very Poor
- Bad

Q23. How many times a year do you see a physician specifically concerning IBM? (Check one)

- Zero
- One
- Two
- More – Please specify number: _____

Q24. What Physician(s) do you see specifically concerning IBM? (Check all that apply)

- Neurologist
- Rheumatologist
- Other – Please specify: _____

Q25. Has your doctor recommended any medications, vitamins or food supplements as potentially relevant to your IBM treatment? (Check one)

- Yes
- No

If you answered “Yes”, please answer Question 25a below. If you answered “No”, please skip to Question 26.

Q25a. If you answered yes above, please check the box corresponding with any recommended medications and vitamins you currently use and please record the your daily dosage in the space provided. (Check and fill in all that apply)

- Prednisone _____
- Vitamin B _____
- Vitamin C _____
- Vitamin D _____
- Vitamin E _____
- Multivitamins _____
- Other _____
- None

Q26. Do you actively exercise, including physical therapy and all other exercises?

- Yes
- No

If you answered "Yes" above, please answer Questions 26a and 26b below. If you answered "No" above, please skip to Question 27.

Q26a. How many hours per week do you generally exercise, including physical therapy and all other exercises? (Please check one)

- More than 0 but less than 5 hours per week
- At least 5 hours but less than 10 hours per week
- More than 10 hours per week

Q26b. What exercises do you do? (Check all that apply)

- Physical Therapy
- Swimming
- Other – Please specify: _____

Questions 27-36 are based primarily on the IBM functional rating scale with some extra considerations. Please select one answer for each question.

Q27. SWALLOWING: (Check one)

- Normal
- Early eating problems--occasional choking
- Dietary consistency changes
- Frequent choking
- Needs tube feeding
- Not applicable

Q28. HANDWRITING (with dominant hand prior to IBM onset): (Check one)

- Normal
- Slow or sloppy; all words are legible
- Not all words are legible
- Able to grip pen but unable to write
- Unable to grip pen
- Not applicable

Q29. CUTTING FOOD AND HANDLING UTENSILS

- Normal
- Somewhat slow and clumsy, but no help needed
- Can cut most foods, although clumsy and slow; some help needed
- Food must be cut by someone, but can still feed slowly
- Needs to be fed
- Not applicable

Q30. FINE MOTOR TASKS (opening doors, using keys, picking up small objects)

- Independent
- Slow or clumsy in completing task
- Independent but requires modified techniques or assistive devices
- Frequently requires assistance from caregiver
- Unable
- Not applicable

Q31. DRESSING

- Normal
- Independent but with increased effort or decreased efficiency
- Independent but requires assistive devices or modified techniques (Velcro snaps, shirts without buttons, etc.)
- Requires assistance from caregiver for some clothing items
- Total dependence
- Not applicable

Q32. HYGIENE (Bathing and Toileting): (Check one)

- Normal
- Independent but with increased effort or decreased activity
- Independent but requires use of assistive devices (Shower chair, raised toilet seat, etc.)
- Requires occasional assistance from caregiver
- Complete dependence
- Not applicable

Q33. TURNING IN BED AND ADJUSTING COVERS

- Normal
- Somewhat slow and clumsy but no help needed
- Can turn alone or adjust sheets, but with great difficulty
- Can initiate, but not turn or adjust sheets alone
- Unable or requires total assistance
- Not applicable

Q34. SIT TO STAND

- Independent (without use of arms)
- Performs with substitute motions (leaning forward, rocking) but without use of arms
- Requires use of arms
- Requires assistance from a device or person
- Unable to stand
- Not applicable

Q35. WALKING

- Normal
- Slow or mild unsteadiness
- Intermittent use of an assistive device (ankle-foot orthotic device or AFO, cane, crutches, walker, etc.)
- Dependent on assistive device
- Wheelchair dependent
- Not applicable

Q36. CLIMBING STAIRS

- Normal
- Slow with hesitation or increased effort; uses hand rail intermittently
- Dependent on hand rail
- Dependent on hand rail and additional support (cane or person)
- Cannot climb stairs
- Not applicable

ASSISTANCE WITH DAILY LIVING QUESTIONS

Q37. Approximately what percentage of your usual living routine is _____? (Please fill in the percentage for each answer below)

still done by you? _____%

done by your spouse, other family or friends? _____%

done by paid household help? _____%

done by paid healthcare help? _____%

TOTAL OF ALL ANSWERS SHOULD EQUAL **100%**

Q38. What is your walking ability? (Check one)

- More than a mile
- 1/2 to 1 mile
- 1/4 to 1/2 mile
- A city block or two
- Less than a city block

Q39. Within the last month, which mode(s) of transportation have you used? (Check all that apply)

- Self driven auto
- Auto driven by other
- Train
- Airplane
- Public Bus or Subway
- Other – Please specify: _____
- Not applicable

Q40. In the last year how many days have you been away from home? (Check one)

- Less than 7 days
- At least 7 days but less than 30 days
- At least 30 days but less than 90 days
- 90 days or more

Q41. During the past year, how much did your IBM interfere with your normal work (including both work outside the home and housework)? (Check one)

- Not at all
- Slightly
- Somewhat
- Considerably
- Extremely
- Not applicable

Q42. Do you feel that IBM has influenced your energy levels? (Check one)

- Not at all
- Scarcely
- Some of the time
- Most of the time
- All of the time
- Not applicable

Q43. Do you feel that IBM has influenced your mood towards depression?

- Not at all
- Scarcely
- Some of the time
- Most of the time
- All of the time
- Not applicable

Q44. Have you or do you know anyone who has had a remission from IBM?

- Yes
- No

Q45. Is there a question that you feel to be important that has been left out?

- Yes
- No

If you answered "Yes", please answer Question 45a below. If you answered "No", please skip to Questions 46.

Q45a. If yes, please specify which additional question(s) should be asked:

Q46. Additional feedback is welcome. If you have any additional feedback, please provide it in the space below:

End of Survey Questions

Dear Participant,

Thank you for your time and participation; your input is valued and respected, should you have any questions regarding this study, please contact the Principal Investigator, Dr. A. David Paltiel, P.O. Box 208034, New Haven, CT 06520-8034, david.paltiel@yale.edu, (203) 785-2854. For additional information regarding research participation, please visit:

<http://www.yale.edu/hrpp/participants/index.html>