

Default Question Block

INFORMED CONSENT

Background and Purpose:

You are invited to participate in a short set of follow-up questions to the research project on Inclusion Body Myositis (IBM). You may have been asked to complete an earlier, lengthier survey, that was available both online and as a paper hard copy, sometime between August 2012 and June 2013. You should only complete THIS short follow-up survey IF you completed the previous survey. This follow-up survey is only available online.

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 that can be answered online.

From the surveys 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 brief online survey that should take approximately one minute or less to complete. Your responses will be confidential since we do not collect identifying information such as your name, address or computer IP 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 of 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 (FAQ) 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 electronic consent below will denote your authorization and agreement to participate. This authorization will be required prior to your being able to advance to the on-line survey. All data is 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 to participate in this research survey, you may withdraw at any time. 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:

Dr. A. David Paltiel, P.O. Box 208034, New Haven, CT 06520-8034, (203) 785-2854, david.paltiel@yale.edu
-OR-

Dr. Martin S. Shubik, P.O. 208200, New Haven, CT 06520-8200, (203) 432-9186, martin.shubik@yale.edu

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>

ELECTRONIC CONSENT: Please select your choice below.

Clicking on the "agree" button 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**

If you do not wish to participate in the research study, please decline participation by clicking on the "disagree" button.

- Agree
- Disagree

Year and Place of Birth

Year Born (yyyy)

City of Birth

State of Birth

Country of Birth

What year did you first have symptoms that were likely related to IBM?

Year of first IBM symptoms (yyyy)

What year were you diagnosed with IBM?

Year of IBM diagnosis (yyyy)