Two example are presented below of institutional review board approved protocol language for the IMACS Outcomes Repository and sample consent form language for use of the repository.

Protocol language wording for IMACS Outcomes Repository in NIH Protocol, Studies in the Natural History and Pathogenesis of Myositis, 94-E-0165:

Objectives: The purpose of this investigation is:

An international group of specialists with interest in myosiits, known as the International Myositis Assessment and Clinical Studies Group (IMACS), has held interest in standardizing the assessment of adult and juvenile-onset patients with myositis using validated approaches and in performing collaborative clinical studies (http://www.niehs.nih.gov/research/resources/collab/imacs/main.cfm). Following the development of core sets of myositis activity and damage, IMACS has developed preliminary definitions of improvement as outcome measures for therapeutic trials, as well as a Myositis Damage Index. These assessment measures, particularly the preliminary definitions of improvement, require prospective validation in independent data sets. While a number of relatively small therapeutic trials and natural history studies are being initiated, none of these would individually contain sufficient power to prospectively validate these preliminary endpoints for therapeutic trials and clinical studies. A secure secure, internet accessible IMACS Outcomes Data Repository of core set disease activity, damage and quality of life measures has been established for adult and juvenile myositis patients as part of IMACS (see section: IMACS Outcomes Data Repository).

IMACS Outcomes Data Repository.

The IMACS Outcomes Data Repository is a secure oracle database that would be internet accessible only to participating IMACS members who have appropriate approvals in place. The data would contain no subject identifiable information, such as names, addresses, birth dates, social security numbers, etc. and as such is considered de-identified data. Dates are included for the month/year of diagnosis and illness onset, as well as for the date of assessment, but for investigators unable to contribute specific dates, these will be converted to time intervals. The data are all coded, and the data submitters would maintain a code key of the patients they contribute to the repository, but they have agreed to never share the coded identity of the subjects, and therefore, the data are one-way anonymized.

The repository will contain core set myositis activity and damage measures, as well as background demographic data at a baseline and last evaluation (usually 4 – 6 months) time points. This include physician and parent/patient global activity and damage assessments, manual muscle testing, physical function assessment by the (Childhood) Health Assessment Questionnaire and Childhood Myositis Assessment Scale (CMAS), muscle enzymes, extra-muscular assessment using the Myositis Activity Assessment Tool and the Disease Activity Score, Myositis Damage Index, Health-related Quality of Life measures (including SF-36 and Childhood Health Assessment Questionnaire), background demographic data, and a change in status at follow-up time points. All Outcomes Repository forms are found at the following IMACS websites:
http://www.niehs.nih.gov/research/resources/collab/imacs/diseaseactivity.cfm
http://www.niehs.nih.gov/research/resources/collab/imacs/diseasedamage.cfm
http://www.niehs.nih.gov/research/resources/collab/imacs/patientoutcome.cfm

http://www.niehs.nih.gov/research/resources/collab/imacs/imacsforms.cfm

The mechanism for data to be submitted to the IMACS Outcomes Data Repository are as follows: (a) Investigators of collaborating centers in protocol 94-E-0165 and their subjects would be collected under the protocol approved by the NIDDK and their IRB and the sign locally-approved consent forms; (b) Investigators involved in off-site therapeutic trials or natural history clinical studies can submit data collected under their protocol that has been approved by their local IRB. Local subjects would consent to the use of their data for the IMACS repository. In such instances, the collaborators at the NIH and the outside investigator enter into an agreement that no identifying information will be shared. (c) Investigators who want to submit existing data can submit their data based on their institutional policies and procedures, which may permit IRB exemption for submission to the Repository. In each of these cases, contributing investigators would be asked to sign an IMACS Outcomes Data Repository Data Transfer Agreement. Investigators who are full collaborators would be listed as collaborators, or where appropriate as associate investigators, on the protocol. The NIDDK IRB will be informed of data submissions to the repository, at minimum at the time of continuing review of this protocol. Information on the procedures for data submission to the repository, including the Repository Data Transfer Agreement, can be found at: http://www.niehs.nih.gov/research/resources/collab/imacs/outcomerepository.cfm. Data may be submitted using the investigator's own database, including a codebook of variables, or by using the secure IMACS Outcomes Repository Oracle web-based database, or a combination of both. Submitting investigators and their associated study personnel will only be given access to the IMACS database upon our receipt of their IRB approval and the fully-signed data transfer agreement for the IMACS Outcomes Repository.

For data transfers out of the repository, investigators are asked to submit their project outline to the IMACS Research Advisory Committee, composed of contributors to the IMACS Outcomes Data Repository. Investigators then seek local IRB approval, or in the case of full de-identified data, an IRB exemption, for their project pertaining to the use of the IMACS Outcomes Repository database, followed by completion of the Repository Data Use agreement. The data use agreement also outlines the restrictions on use of the IMACS Repository data and policies regarding publication. In addition, investigators who are approved for use of the IMACS database would be added to the protocol's consent form as recipients of data from this study. The PI will submit a list of investigators receiving data from the IMACS Outcomes Data Repository at the time of continuing review of this protocol.

Sample Consent Language for the IMACS Outcomes Repository in Studies in the Natural History and Pathogenesis of Myositis, 94-E-0165:

2. Clinical Evaluation

In addition to undergoing a history, physical examination, and blood and urine tests as outlined above, you may choose to come to the National Institutes of Health for additional clinical evaluation of your condition. This evaluation would last 3 to 7 days; follow-up evaluation may occur 1 or 2 times in a one year period. Whenever your health permits, this evaluation would be done as an outpatient, although you will need to be admitted to a ward in the hospital if you require an EMG study or muscle biopsy. This clinical evaluation, which would assess the extent and severity of your illness, is detailed

below. The main aspects of this clinical evaluation, including assessments of muscle strength, physical function, muscle enzymes, and other aspects of your myositis or longstanding changes related to the illness, will be stored in a database that will be accessible with permission to myositis researchers. The purpose of this database is to pool outcome measure, response to treatment and basic information about patient's illnesses from a number of clinical trials and natural history studies, in order to develop better outcome measures for myositis, to learn more about their illnesses, and to perform pooled analyses of treatment responses.

WHAT WILL HAPPEN TO THE SAMPLES OR INFORMATION THAT ARE COLLECTED FROM THIS STUDY

As part of this protocol, some of the data is stored coded in databases in which protocol investigators have access to the data; your child's information is coded and your child cannot be personally identified. In addition, a larger database is being created to pool outcome measures, responses to treatment and basic information about patients' illnesses from a number of clinical trials and natural history studies, in order to develop better outcome measures for myositis, to learn more about these illnesses, and to perform pooled analyses of treatment responses. In this database, known as the International Myositis Assessment and Clinical Studies (IMACS) Group, all subjects' information will also be de-identified and coded. When data is transferred to investigators with approved projects, all subjects' information will be anonymized in this database and no identifying information about your child will be provided to these investigators.

It is possible that your samples or study records may be shared anonymously with other investigators for other research use beyond the scope of this study. Such usage will be strictly anonymous, in that no identifying information about you, including your name, will be provided to the researcher, and there will be no way for the researchers to link these samples back to you.

Language in Chet Oddis' Protocol: Trial of Rituximab for DM, PM and JDM:

NIH Data Sharing Policy: At the conclusion of this clinical trial, de-identified data as noted above will be contributed to an IMACS international myositis trials registry so that data from different myositis research studies can be pooled to make meaningful conclusions regarding myositis and its treatment.

Consent form language in Rituximab trial pertaining to IMACS registry:

Who will know about my participation in this research study?

Any information about you obtained from or for this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in locked file cabinets. Your identity on these records will be indicated by a code number rather than by your name, and the information linking these code numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release). {*The University of Pittsburgh*} policy requires that all research records be kept for five years following the end of a research study.

At the end of this research study, data (information) will be contributed to an IMACS (international myositis trials registry), so that data from different myositis research studies can be pooled together to make stronger conclusions on how to measure the symptoms of this disease Your identity on this research data will be indicated by a code number as indicated above.