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:

(1) To develop comprehensive and objective measures of disease activity for IIM which can be used as a standard to determine efficacy in future therapeutic trials or to validate novel laboratory measures of disease activity (Juvenile Myositis Collaborative Study of Disease Activity, a multi-center collaborative study of the Juvenile Myositis Collaborative Study Group and the International Myositis Assessment and Clinical Studies Group (IMACS)). The information collected in this protocol would be used to develop activity and chronicity (or damage) scores of the patient's status.

In the next phase, a secure, internet accessible database repository of core set disease activity, damage and quality of life measures will be established for adult and juvenile myositis patients as part of IMACS. Patients' names would not be used, but a code of patients would be developed and stored in locked files in the investigators office. An international group of myositis experts 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. We propose to create a database repository of core set activity and damage measures, as well as background demographic data at a baseline and last evaluation (usually 4 – 6 months) time points. This will 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.

The mechanism for enrollment of data into the IMACS repository would include three potential mechanisms: (a) Investigators would become collaborating centers in protocol 94-E-0165 and their subjects would sign locally-approved consent forms; (b) The off-site investigator's own therapeutic trial or natural history clinical study protocol is approved locally. Local subjects would consent to the use of their data for the IMACS repository. (c) Fully anonymized data would be received after data collection and would require approval for exemption by the Office of Human Subjects protection. In each of these cases, contributing investigators would be asked to sign an IMACS repository collaboration agreement that includes data transfer information. Copies of contributing investigators' local IRB approval or OHS exemption, along with collaborator agreements would be submitted to the NIDDK-NIAMS IRB for approval for inclusion in the IMACS

repository. Investigators who are full collaborators in protocol 94-E-0165 would be listed as associated investigators on the protocol.

The database is a secure oracle database that would be internet accessible only to participating IMACS members. Patient names would not be used. Once the data received from collaborating investigators is cleaned, the data would then undergo anonymization, where the original study identification numbers would be converted to random digit subject identification numbers and the source of the data would not be identified. The data would contain no subject identifiable information, such as birth dates, social security numbers, etc. The anonymized data would be housed in a separate database that could then be used to transfer data out of the repository.

For data transfers out of the repository, investigators are asked to submit their IRB-approved proposal and data distribution agreements for use of the IMACS database, which would also be submitted to the NIDDK-NIAMS IRB for their approval. The data distribution agreement also outlines the restrictions on use of the IMACS data and policies regarding publication. In addition, investigators who are approved for use of the IMACS database would be added to the consent form as recipients of data from the study.

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

Your DNA/blood/cell/urine/other samples/study records will remain stored indefinitely in order to allow for the studies to be completed and to allow for retesting of the samples as necessary. Your DNA/blood/cell/urine/and other samples will be stored at two sites: the National Institutes of Health and the repository of the National Institute of Environmental Health Sciences. The reason for duplication of long-term storage is to insure against accidental loss of frozen samples. All stored DNA/blood/cell/urine samples and information generated from this study will be identified by a code and not your name. This code will be kept secure in a locked area or in computer files that only Dr. Rider and

a few specific investigators or their designees in this study can access with a password. Your coded samples may be sent to other investigators involved in this protocol for research purposes, as defined in this protocol. These investigators will not know your name and will not know which samples are yours.

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.

Your samples will not be available for routine care or commercial diagnostic testing. 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.