

This amendment is a request for IRB review in order to contribute data from “A Trial of XX in Patients with Dermatomyositis and Polymyositis” to the International Myositis Assessment and Clinical Studies (IMACS) Outcomes Repository, which is housed under Protocol 94-E-0165, “Studies in the Natural History and Pathogenesis of Childhood-Onset and Adult-Onset Idiopathic Inflammatory Myopathies”. The IMACS Outcomes Repository project has a primary purpose of defining outcome measures for myositis therapeutic trials, based on combining data from core set measures from a number of clinical trials and natural history studies in order to measure clinically important improvement and worsening. The IMACS Outcomes Repository is also open for investigators with institutional review board-approved studies to apply for use of the data to address additional research questions related to the core outcome measures used in myositis trials, as well as treatment questions, such as meta-analyses across trials and studies. Although contribution of the trial data from the infliximab protocol to the IMACS Outcomes Repository was not previously specifically approved under this protocol, the use of the data in the IMACS Outcomes Repository has the same general purpose, which is to evaluate the response to treatment in patients with myositis. In fact, the subjects who consented to this clinical trial have given their permission for the evaluation of the treatment and the effects of that treatment in their previous informed consent for the protocol.

Request is made with this submission to waive the requirement for additional consent in order for the data from subjects in the Infliximab in Myositis trial to be included in the IMACS Outcomes Repository. The reasons for this waiver include: (1) The research involves no more than minimal risk to the subjects, and will not adversely affect the rights and welfare of the study subjects. The data contributed to IMACS will be de-identified data, without any personal identifiers being included, and only we as the investigators of the Infliximab trial will maintain a code to the specific patients. We will not share this code with the investigators of the IMACS Outcomes Repository; (2) The topic under investigation by the IMACS Outcomes Repository is consistent with the purposes of the clinical trial that the patients originally consented to; (3) The research cannot be carried out without the waiver of consent. Most of the patients enrolled in the XX trial have completed the trial and are no longer being followed in our protocols. It is important for the purposes of the IMACS Outcomes Repository to have a complete set of data; (4) Finally, there are no plans to communicate with the subjects about the research results of the IMACS Outcomes Repository, unless an important finding is discovered in the course of this research that has impact for the subjects who previously participated in this trial.