

November 1, 2007

The Office of Regulatory Affairs  
Institutional Review Board

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**Re: International Myositis Classification Criteria Project (IMCCP)**

Dear Members of the Institutional Review Board:

Attached please find an IRB submission for expedited review for an unfunded large international cooperative project entitled the International Myositis Classification Criteria Project (IMCCP). We intend to perform a retrospective chart review of all patients diagnosed with myositis in the Departments of xxxxxx(Dermatology, Rheumatology or Neurology) at the Hospital of the xxxxx.

Enclosed are the following documents in this order: IRB face sheet, protocol summary, informed consent form, HIPAA authorization, IRB request for waiver of HIPAA authorization with an IRB cover sheet and two additional copies of the protocol summary, the IMCCP workshop meeting summary, and the IMCCP data collection form.

We have submitted informed consent, HIPAA authorization, and HIPAA waiver forms as a subset of our population will need to be contacted via telephone to obtain additional information not contained within their charts. Due to the quantity of subjects to be enrolled, as well as the unfunded nature of this study, we request that subjects with complete charts (>70% data variables captured) be waived of HIPAA authorization and informed consent.

Given the minimal risks associated with this observational study, we hope to obtain IRB expedited review with the plans of beginning data collection and review December 1, 2007.

Please do not hesitate to contact us with any questions.

Sincerely,