Grant #	Unfunded (part of large international cooperative project)	**Responsible Org.**	the American College of Rheumatology, EULAR
Project Title	International Myositis Classification Criteria Project (IMCCP)		
Principal Investigator	Name xxxxxx Title Address	Phone xxxxxx email Fax#: xxxxxxxxxx)	
Sponsor	**Regulatory Sponsor / IND or IDE holder:** Name American College of Rheumatology Address 1800 Century Place, Suite 250 City/State/Zip Atlanta, GA 30345-4300	**Funding Sponsor(s)/Agency** **(list all)** European League Against Rheumatism (EULAR), N/A The Myositis Association	

Please answer ALL of the following questions. Does this protocol contain or involve:

1. Administration of questionnaire, personality tests, quality of life assessment or other surveys or inventories? • **IF YES**, provide name and **two copies** if using an approved standard instrument/questionnaire OR **the number of copies indicated at the end of this form (full-board vs. expedited review)** of study or project specific proposed survey or questionnaire or other non-standardized test as part of the IRB submission packet.	**X** Yes ☐ No
2. Research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol? • **IF YES**, ☐ Protocol and Consent form submitted to RDRC/EHRS ☐ Copy of Approval Letter Attached If you have questions, call **215-898-7187.**	☐ Yes **X** No
3. Gene transfer (including all vectors) to human subjects? • **IF YES**, the protocol must be approved by the Institutional Biosafety Committee. Consult EHRS website: www.ehrs.upenn.edu/protocols/bio_humans.html for submission requirements. If you have questions, call **215-898-4453.**	☐ Yes **X** No
4. Drawing or use of human source material (i.e., human blood, blood products, tissues or body fluids)? • **IF YES**, consult the EHRS web site: www.ehrs.upenn.edu/programs/bio/bbpathogens.html for information on OSHA Blood borne Pathogens requirements (training, vaccination, work practices and Exposure Control Plan). If you have questions, call **215-898-4453.**	☐ Yes **X** No
5. Magnetic Resonance Imaging Center (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol? • **IF YES,** consult CAMRIS website: www.mmrrcc.upenn.edu/CAMRIS for application requirements	☐ Yes **X** No
6. Research project involves the use of an investigational agent or device within the Operating Room? • **IF YES,** contact Associate Executive Director, Surgical Services: **(215) 662-2089**	☐ Yes **X** No
7. Study will be conducted under an **IND** (Investigational New Drug Application) or an **IDE** (Investigational Device Exemption)? • **IF YES,** IND # or IDE # or 510k submission #: • **IF YES,** attach the appropriate number of **copies of the Drug or Device Brochure, or an FDA approved labeling** (these items will not be returned to you) as indicated at the end of this form (full-board vs. expedited review). **IF NO,** and the study involves use of FDA approved drug(s) or device(s) in any manner listed below, the IRB requires attached documentation of IND exemption from FDA or OHR (Upenn Office of Human Research). ☐ Drugs or products administered to subjects not indicated in the labeling. ☐ Drugs administered to subjects in combination with other drugs that is not considered standard of care. ☐ Drugs, products or devices prepared in a manner not in the labeling. Any questions, call OHR: **215-746-7400**	☐ Yes **X** No

8. Will Clinical Investigational materials involve any in-house manufacturing (including investigational cellular preparations), or processing (such as over encapsulating, or compounding), 8a. What is the source of the Investigational material? (check all that apply) ☐ Supplied by license holder or funding agency ☐ Purchased ☐ Manufactured for this study	☐ Yes **X** No
9. For research involving drugs, herbal products, or other chemical entities administered to human subjects, obtain a registration number if the test materials will be processed, distributed, blinded and accounted for through the Investigational Drug Service (IDS) by calling (215) 349-8817. **IDS Registration #:** **Note:** The study protocol must describe the storage, handling, administration and test material accountability tracking that will be maintained in the study.	☐ Yes **X** No
10. Has the Principal Investigator taken the on-line Patient Oriented Research training (questions call OHR: 215-746-7400) • **IF YES,** attach copy of certification. (required by School of Medicine for all SOM Faculty) 10a. List all study team members (Sub-investigators, Coordinators) and anyone involved with the conduct of the study. If more than 5 names, attach a separate sheet: **Name** **Role** **POR training?** Sub-Investigator	**X** Yes ☐ No
11. Does the research proposal involve the use and disclosure of research subject's medical information for research purposes? 11a**. IF YES**, please check the box next to one of the following that is provided with this submission: ☐ Separate authorization for use and disclosure of identifiable health information. **X** Modified research informed consent document that incorporates HIPAA requirements.	**X** Yes ☐ No
12. Do you or any member of your research group, spouses or any dependent children have any interest (i.e. any property of financial interest including stock in the sponsor company, patents, trademarks, copyrights or licensing, supplemental research grants or consulting arrangements) in the test drug/product, device, or research procedure that is the subject of this study? • **IF YES, please complete a Conflict of Interest Disclosure Form available through the Office of Research Services and submit one copy to the Office of Regulatory Affairs (ORA).** Please discuss how these conflicts will be managed during the period of the trial. Include language disclosing such interest in the consent form for the use by research subjects. 12a. In addition, for industry-sponsored trials, please attach the documentation submitted to the sponsor as required by 21CFR54.1, if applicable.	☐ Yes **X** No

13. Please indicate the applicable research committee(s) for this study, and status of any required approval(s):

Applicable?		Research Committee	Approval Status: Not sent	Pending	Approved	N/A
X Yes	☐ No	Clinical Trials Scientific Review and Monitoring Committee (UPCC)*	☐	☐	☐	☐
☐ Yes	**X** No	GCRC Scientific Advisory Committee	☐	☐	☐	☐
☐ Yes	**X** No	Radiation Safety Committee	☐	☐	☐	☐
☐ Yes	**X** No	CAMRIS	☐	☐	☐	☐
☐ Yes	**X** No	Biosafety Committee	☐	☐	☐	☐

*Clinical Trials Scientific Review and Monitoring Committee review and approval is required for all clinical studies involving cancer patients at the University of Pennsylvania that are not monitored under a cooperative group such as ECOG, GOG, RTOG and NABTT.

14. Human subjects or material involved in the proposed activity include any of the following special populations/categories:

☐ Minors **X** Pregnant Women ☐ Prisoners ☐ Fetuses

☐ Mentally disabled or cognitively impaired subjects **X** Employees or

X HIV-positive subjects

☐ **NONE of the above listed special populations/categories**

REQUIRED SIGNATURES: The department chair's signature for the individual department's with faculty participating in this study in addition to the principal investigator and principal investigator's department chair's signature, are required below. If additional signatures are required in excess of the number of spots below, please obtain and identify the appropriate signatures on another sheet and attach it to this form.

Principal Investigator (PI) Signature Date

Printed Name of PI

PI's Dept. Chair's Signature or Dean's Signature if PI is Dept. Chair Date

Printed Name of PI's Dept. Chair/Dean

Co-Investigator's Dept. Chair/Dean's Signature Date

Printed Name of Co-Investigator's Dept. Chair/Dean

Co-Investigator's Dept. Chair/Dean's Signature Date

Printed Name of Co-Investigator's Dept. Chair/Dean

Co-Investigator's Dept. Chair/Dean's Signature Date

Printed Name of Co-Investigator's Dept. Chair/Dean

Check all attachments that apply (see below for # of copies):

☐ Protocol

X Protocol Summary

X Informed Consent/Assent Form Document(s)

X Personality tests/inventories/questionnaires (Face Sheet Item #1)

☐ IND Exemption (Face Sheet Item # 7)

☐ Investigator's brochure/approved labeling (Face Sheet Item # 7)

X Patient Oriented Research Certificate Modules 1-4 (Face Sheet Item #10)

☐ Conflict of Interest Disclosure Form (Face Sheet Item # 12)

☐ Advertisement(s)

☐ Copy of grant application (minus appendices)

REQUIRED MATERIALS TO ACCOMPANY THIS FACE SHEET AND FACE SHEET ATTACHMENTS FOR IRB REVIEW

Full-Board Review:

1 each of the following: Original Signed Cover letter, Original Signed IRB Face Sheet and any Attachments, Protocol Summary, Informed Consent Document, Protocol, any Applicable Questionnaires, Diaries, etc., and applicable investigator drug(s)/device brochure(s) or package inserts clipped together in this respective order.

3 copies of the IRB Face Sheet and any Attachments, Cover Letter, Protocol, Protocol Summary, Informed Consent Document, Protocol, any Applicable Questionnaires, Diaries, etc., and applicable investigator drug(s)/device brochure(s) or package inserts clipped together in this respective order.

15 copies of the IRB Face Sheet, Cover Letter, Protocol Summary, Informed Consent Document, and any Applicable Questionnaires, Diaries, etc. clipped together in this respective order.

Expedited Review:

1 each of the following: Original Signed Cover letter, Original Signed IRB Face Sheet and any Attachments, Protocol Summary, Informed Consent Document, Protocol, any Applicable Questionnaires, Diaries, etc., and applicable brochure(s) clipped together in this respective order.