University of Pennsylvania
Office of Regulatory Affairs (ORA)
133 South 36th Street, Mezzanine Level
Philadelphia, PA 19104-3246

IRB Request for Waiver of HIPAA Authorization

to Use or Disclose Documents, Records or Data Sources Containing Identifiable, Protected Health Information (PHI) for Research Purposes

(Provide Original & 2 copies, unless full-board review is required)

Grant #	Unfunded	**Responsible Org.**	The American College of Rheumatology, EULAR
Project Title	International Myositis Classification Criteria Project (IMCCP)		
Principal Investigator	Name Title Address	Phone email 8 digit PennCard ID# 8	
Primary Contact (if not Principal Investigators)	Name Title Address	Phone email 8 digit PennCard ID#	
IRB USE ONLY	**This project meets the IRB criteria for waiver of authorization:** ☐ **Yes** ☐ **No** _____ Printed name: authorized IRB signatory _____ _____ Authorized IRB signature Date		

REQUIRED INFORMATION

The information **must** include a specific description of the procedure(s) and health information collected/used (e.g. surveys, record reviews, etc.), involving the human subjects in sufficient detail to demonstrate to the IRB reviewer that the research project/protocol meets the requirements for waiver of authorization and prospective informed consent. The information can be provided on this form or included as a separate addendum keeping the numbered heading scheme of this form.

If you are only collecting or using – *and <u>not</u> disclosing:*

- *<u>Indirect identifiers</u>* (listed in the right hand column of the table noted below), the risk is considered minimal risk to privacy. If you disclose information containing indirect identifiers under a data use agreement then the disclosure is also deemed minimal risk by the IRB.
- *<u>Direct identifiers</u>* (listed in the left hand column of the table noted below), then you must provide a rationale for the collection and use of these identifiers. The following issues must be addressed if applicable: How will the collected data be kept secure? Will the direct identifiers be kept separate from the collected health information and separately secured? These are addressed in the numbered items below.

If you are collecting or using – *and <u>will be</u>* disclosing:

- *<u>Direct identifiers</u>*, the risk to privacy may be greater than minimal and full IRB review is required. In this circumstance you will need to describe additional privacy protections in question # 8 below, in order to demonstrate to the IRB that the research will qualify as less than minimal risk.

Please provide the following information:

1. The objective (hypothesis) of the research project and a brief background for the study. If this is a new IRB submission please submit an **IRB cover sheet**, two copies of the protocol summary and full protocol. If this is a request to amend a protocol, provide a copy of the amended protocol and IRB number.

   The idiopathic inflammatory myopathies (IIM) or myositis syndromes are rare systemic disorders characterized by chronic progressive muscle weakness due to muscle inflammation of unknown etiology. A significant and fundamental problem in clinical studies is the classification criteria for inflammatory myopathies. Three different criteria have been proposed (Bohan & Peter 1975, Tanimoto 1995, Hoogendijk 2004) but the criteria of Bohan and Peter are the most often used in clinical studies. Several limitations of these criteria are recognized. Some criterion are not specified or operationally defined, for example, the biopsy criterion is considered too inclusive and may allow patients with some forms of muscle dystrophy to be

included in a group of inflammatory myopathies. These criteria also misclassify patients with inclusion body myositis (IBM). Because evolving concepts in pathogenesis have altered our thinking about myositis, and since new diagnostic tools including MRI and myositis-specific autoantibodies have been recently developed, it is now timely to develop and validate new myositis classification criteria.The aim of this project is to develop and validate classification criteria for polymyositis and dermatomyositis in adults and children for clinical research, especially clinical trials, and to document the reliability of these new criteria.

2. The rationale for the use of the selected subject population, record set, archives or material and sources of information.

   Data will be collected retrospectively. As there is no gold standard for definition of myositis, each case will be defined according to the expert submitting the case, who will list the variables that were used for the diagnostic decision for each case. We will ask that only cases with definitive diagnoses be submitted for this study. Cases will be assembled to cover the entire spectrum of disease and severity of disease. Cases and control conditions will have their clinical data recorded from patient records on standardized case forms and then entered directly into an elecronic template of the questionnaire in Survey Monkey.

   Comparator conditions which are commonly confused with idiopathic inflammatory myopathies and cause a differential diagnostic problem will be assembled. These conditions are:

   -Non-inflammatory inclusion body myopathies

   -Muscular dystrophies

   -Drug/toxin associated myopathies (particularly associated with statin use)

   -Metabolic myopathies

   -Mitochondrial myopathies

   -Endocrine myopathies

   -Rheumatic conditions; Systemic lupus erythematosus, Polymyalgia Rheumatica, and Scleroderma

   -Cutaneous manifestations mimicking dermatomyositis, including psoriasis, eczema, discoid lupus erythematosus and other skin conditions.

   De-identified data will be submitted to the IMCCP where it will be aggregated and statistical analyses will be performed. Through this multi-center international effort, it is hoped that a classification system will be proposed for myositis patients, as well as screening recommendations.

3. Describe the reasons why the research could not be practicably carried out without the waiver of authorization or consent to collect and/or use the protected health information.

   Given the number of patients in the department with this diagnosis, it will be unfeasible to obtain HIPAA authorization on all patients given the lack of funding associated with this international trial. If charts are greater than 70% complete for the variables of interest, subjects will not be contacted and HIPAA authorization will be waived.

4. Provide a rationale as to why the research described in the research protocol could not be practicably conducted without access to the health information.

   While a subset of subjects will not be contacted and thus HIPAA authorization will be waived, direct identifiers will need to be maintained during the initial aspects of this study to ensure that each patient is only enrolled once in this study. The coordinating center may also query the data entered in Survey Monkey and query outlying data.

5. The specific type of data to be collected and used and why this is considered the minimum necessary to conduct the analysis. (Must be specific and include a copy of a data collection sheet(s).) ***Please complete the attached table: "Identifiable Information."***

   Data collection sheets are attached in this IRB submission. Name, DOB, and MRN will be used to ensure that each patient is only enrolled once and to facilitate response to the data queries from the coordinating center. Identifying information (including name, date of birth or medical record number) will not be submitted to the coordinating center or the study database. Rather, only coded patient identification numbers will be used when submitting the data to the coordinating center.

6. Does the recorded data contain either a direct identifier or a link to allow the re-identification of the individual?[1]

☐ Yes ☒ No

If yes describe the procedures to protect the confidentiality and security of this linking data set and specific plans as to the time point at which the linking data set will be destroyed.

After entry of the data into Survey Monkey, each enrolled patient will be assigned a study identification number. We at the submitting center will temporarily maintain a link to the patient's name, date of birth and/or medical record number. Once the deidentified data are received via Survey Monkey at the coordinating center, the coordinating center will conduct periodic checks for completeness and query data out of range. Following the completion of the data query by the Coordinating Center, the link to the identifiable information at the contributing center will be destroyed.

If the linking set will not be destroyed provide written assurance that access to the identifiable data for future research will not be done without prior IRB approval.
While the link is maintained, access to the identifiable data will be stored securely with only the site Principal Investigator and participating staff having access to the link. THis will not be used for any other research and not without prior IRB approval.

7. During the conduct of the research what is your plan to protect the identifiers from improper use and disclosure?

No patient identifiers will be submitted to the IMCCP. During the data collection process at xxxxxxxxx University, all study related materials will be kept at the xxxxxxxxxxxx of Dr xxxxxxxxx. All identifiable data will be destroyed after data collection is complete and data aggregation has occurred, following addressing the queries regarding out of range data from the coordinating center.

8. If you intend to disclose information containing direct identifiers listed below in the “Identifiable Information” table (left column), the risk to privacy may be greater than minimal and full IRB review is required. Please provide the Committee a rationale as to why the disclosure of the protected health information with these direct identifiers, is thought to involve no more than minimal risk to the rights, welfare and/or privacy of the individuals. Fully describe any additional privacy protections that will be put in place in order to protect the privacy of the individuals. Please submit an original and 19 copies of this form.

No direct identifiers will be disclosed.

[1] The code or other means of record identification should not be derived from or related to information about the research subject and should not otherwise permit re-identification of the subject.

Please complete the following checklist related to specific identifiers of the research subject or of relatives, employers, or household members of the research subject to be collected, used or disclosed.

Direct Identifiers		**Identifiable Information**	**Indirect Identifiers** (Limited Data Set)	
Used/ Collected (check if yes)	**Disclosed** (check if yes)		**Used/ Collected** (check if yes)	**Disclosed** (check if yes)
☒	☐	Names		
☐	☐	Street Address, Apartment #, Precinct, or other geocode more geographically specific than zip code.		
		City/Town, State and Zip Code (*Note: for the records to be considered de-identified only the first three digits of the zip code can be used*[2])	☐	☐
		All elements of dates (except year) for dates directly related to an individual (e.g. date of birth/death, dates of admission/discharge etc.)	☒	☐
		Ages less than 90, and "90 and above" for those over 90.	☒	☐
☐	☐	Telephone numbers, including fax		
☐	☐	Electronic mail addresses		
☐	☐	Social security numbers		
☒	☐	Medical record numbers		
☐	☐	Health plan beneficiary numbers, or any other account numbers		
☐	☐	Certificate/license numbers, & vehicle identifiers and serial numbers, including license plate numbers,		
☐	☐	Implanted device identifiers and serial numbers		
☐	☐	Web Universal Resource Locators (URLs)		
☐	☐	Internet Protocol (IP) address numbers		
☐	☐	Biometric identifiers, including finger and voice prints or any audio recordings		
☐	☐	Full face photographic images and any comparable image, including video recordings		
☐ None of the Direct Identifiers noted above will be collected			☐ None of the Indirect Identifiers noted above will be collected	

[2] The first three digits of the zip code may be used as long as the population in that region is greater than 20,000. If the geographic unit is less than 20,000 only state may be used.

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this request for Waiver of HIPAA Authorization is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the privacy rights and welfare of human subjects and the ethical conduct of this research project/protocol. I agree to comply with all UPenn policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Permitting performance of the project only by qualified personnel according to the research project/protocol.
- Maintaining of a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects for at least three years following termination of the project unless otherwise necessary to protect subject confidentiality as described in the project/protocol.
- Acquiring the necessary review by the UPenn IRB if substantial changes are made in the research project/protocol or if any change is made which may result in the research no longer meeting the criteria for waiver.
- Maintaining as secure any protected health information collected for this research project/protocol, and not sharing access to such information with any individual without prior review and approval of the IRB and/or privacy officer unless such subset has been created to exclude all identifiable demographic information as defined in this document, or unless additional data use agreements have been obtained for distribution of limited data sets.
- Forbidding attempts to re-identify the subjects from the data collected under this waiver, and attempts to contact the subjects or their family members.

I have completed the required educational program on ethical principles and regulatory requirements in human subjects research and HIPAA as necessary prior to initiating the research.

_____ _____

Signature: Principal Investigator noted above Date

FACULTY SPONSOR'S ASSURANCE

(Only for projects where the Principal Investigator is a student, resident, fellow, or Collaborating Investigator outside of the Covered Entity, e.g. Wharton PI.)

By my signature as sponsor on this research application, I certify that the student or investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved project/protocol. In addition,

I agree to meet with the principal investigator on a regular basis to review study progress.

Should problems arise during the course of the study, I agree to be available, personally, to supervise the the student or fellow or provide assistance to the Collaborator.

I assure that the student, resident, fellow or Collaborating Investigator will complete all required educational programs on ethical principles and regulatory requirements in human subjects research as required.

If I will be unavailable, as when on sabbatical, leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the Office of Regulatory Affairs by letter of such arrangements.

N/A

_____

Printed Name: Faculty Sponsor

_____ _____

Signature: Faculty Sponsor Date

*The faculty sponsor must be a member of the standing UPenn faculty. The faculty sponsor is considered the responsible party for legal and ethical performance of the project.

DEPARTMENT HEAD SIGNATURE
(Only if the Principal Investigator is Faculty)

As department head, I acknowledge that this research is in keeping with the standards set by our department and I assure that the principal investigator will meet all departmental or school requirements for review and approval of this research prior to initiation.

_____
Printed Name: Department/Unit Head

_____ _____
Signature: Department/Unit Head Date

Definitions

"De-identified Data" Data that is "de-identified" under HIPAA is not regulated by HIPAA and may, accordingly, be used or disclosed for research and other purposes without patient authorization. Data is "de-identified" under HIPAA if the following identifiers of the individual or of relatives, employers, or household members of the individual are removed:

- ***Names***
- ***All geographic subdivisions smaller than a State***, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, (a) the geographical unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people: and(b) the initial three digits of a zip code for all such geographic units containing 20,000 of fewer people is changed to 000.
- ***All elements of dates (except year)*** for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or order.
- ***Telephone numbers***
- ***Fax numbers***
- ***Electronic mail addresses***
- ***Social security numbers***
- ***Medical record numbers***
- ***Health plan beneficiary numbers***
- ***Account numbers***
- ***Certificate/license numbers***
- ***Vehicle identifiers and serial numbers, including license plate numbers***
- ***Device identifiers and serial numbers***
- ***Web Universal Resources (URLs)***
- ***Internet Protocol (IP) address numbers***
- ***Biometric identifiers, including finger and voice prints***
- ***Full face photographic images and any comparable images***
- ***Any other unique identifying number, characteristic***, or code, except that a code may be assigned to allow information de-identified by removal of all above information to be re-identified provided that: (a) the code is not derived from or related to the information from and the individual and is not otherwise capable of being translated so as to identify the individual; and, (b) the code is not used for any other purpose nor disclosed to any outside entity

"**Disclosure"** means the release, transfer, provision of access to, or divulging of protected health information by any means to persons or entities outside of UPHS / SOM or other covered entity.

"Limited data set" Members of a covered entity may use or disclose data contained in a "limited data set" for research purposes, without obtaining individual authorization, provided that UPHS / SOM enters into a data use agreement with the recipient of the limited data set signed on behalf of the Trustees of the University of Pennsylvania by the UPenn Office of Research Services. A "limited data set" excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- ***Names***
- ***Postal address information, <u>other than town or city, State, and zip code</u>***
- ***Telephone numbers***
- ***Fax numbers***
- ***Electronic mail addresses***
- ***Social security numbers***
- ***Medical record numbers***
- ***Health* plan beneficiary numbers**
- ***Account numbers***
- ***Certificate/license numbers***
- ***Vehicle identifiers and serial numbers, including license plate numbers***
- ***Implanted device identifiers and serial numbers***
- ***Web Universal Resource Locators (URLs)***
- ***Internet Protocol (IP) address numbers***
- ***Biometric identifiers, including finger and voice prints***
- ***Full face photographic images and any comparable image***

"Protected Health Information (PHI)" Protected health information (PHI) is defined under the HIPAA regulations as information that is a subset of health information, including demographic information collected from an individual, and: (1) is created by a health care provider, health plan, employer, or health care clearinghouse: and (2) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

"Use" means to collect, share, employ, apply, utilize, examine, or analyze PHI within UPHS / SOM.