PARC-B

Psoriatic Arthritis Research Collaborative: Biologic Sub-Study

NCT03378336

Study Protocol and Statistical Analysis Plan

August 14, 2019

Modification

Basic Info

Confirmation Number:	**cjdfhgga**
Protocol Number:	**828357**
Created By:	**BUSH, KATHLEEN**
Principal Investigator:	**OGDIE-BEATTY, ALEXIS**
Protocol Title:	**Psoriatic Arthritis Research Collaborative: Biologic Sub-Study**
Short Title:	**PARC-B**
Protocol Description:	**Psoriatic arthritis (PsA) is an inflammatory arthritis with substantial variation in clinical features. We propose a multicenter collaborative approach to better understand the phenotypes and current management of PsA in the United States.The central goal of this proposal is to obtain the data necessary to design a pragmatic trial in PsA.**
Submission Type:	**Biomedical Research**
Application Type:	**PRIME**

PennERA Protocol Status

Approved

Resubmission*
No

Are you submitting a Modification to this protocol?*

Yes

Current Status of Study

Study Status

Currently in Progress

If study is currently in progress, please enter the following

Number of subjects enrolled at Penn since the study was initiated

0

Actual enrollment at participating centers

0

If study is closed to further enrollment, please enter the following

Number of subjects in therapy or intervention

0

Number of subjects in long-term follow-up only

0

IRB Determination
If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. For a modification to be considered more than minimal risk, the proposed change would increase the risk of discomfort or decrease benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant′s continued welfare. Examples: Convened Board Increase in target enrollment for investigator initiated research or potential Phase I research Expanding inclusion or removing exclusion criteria where the new population may be at increased risk Revised risk information with active participants Minor risk revisions that may affect a subject′s willingness to continue to participate Expedited Review Increase in target enrollment at Penn where overall enrollment target is not exceeded or potentially sponsored research Expanding inclusion or removing exclusion where the new population has the same expected risk as the previous, based on similarities of condition Revised risk information with subjects in long-term follow-up Minor risk revisions with no subjects enrolled to date
Expedited Review

Modification Summary
Please describe any required modification to the protocol. If you are using this form to submit an exception or report a deviation, enter 'N/A' in the box below.
Updating Personnel

Risk / Benefit
Does this amendment alter the Risk/Benefit profile of the study?
No

Change in Consent
Has there been a change in the consent documents?
No

If YES, please choose from the options below regarding re-consenting

Deviations

Are you reporting a deviation to this protocol?*

No

Exceptions

Are you reporting an exception to this protocol?*

No

Protocol Details

Resubmission*
Yes

Study Personnel

Principal Investigator

Name:	**OGDIE-BEATTY, ALEXIS**
Dept / School / Div:	**4261 - DM-Rheumatology**
Campus Address Mail Code	**4385**
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Pager:	
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HS Training Completed:	**Yes**
Training Expiration Date:	**11/15/2015**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**BUSH, KATHLEEN**
Dept / School / Div:	**4261 - DM-Rheumatology**
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Phone:	**-**
Fax:	**-**
Pager:	
Email:	**katbu@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/09/2017**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**HOPKINS, SARAH C**
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Campus Address Mail Code	**4283**
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Email:	**sarah.hopkins@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**07/08/2022**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**ALMONTE, MICHELE D**
Dept / School / Div:	**4261 - DM-Rheumatology**
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Pager:	
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HS Training Completed:	**Yes**
Training Expiration Date:	**02/12/2022**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Other Investigator

Name:	**GEORGE, MICHAEL**
Dept / School / Div:	**4261 - DM-Rheumatology**
Campus Address Mail Code	**4283**
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City State Zip:	**PHILADELPHIA PA 19104-4283**
Phone:	**-**
Fax:	**-**
Pager:	
Email:	**michael.george@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**08/04/2019**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Responsible Org (Department/School/Division):

4261 - DM-Rheumatology

Key Study Personnel

Name:	**CRAIG, ETHAN T**
Department/School/Division:	**DM-Rheumatology**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/12/2021**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**LUO, DEE**
Department/School/Division:	**Health System**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**DURKIN, CLAIRE**
Department/School/Division:	**Health System**
HS Training Completed:	**Yes**
Training Expiration Date:	**06/09/2022**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Biomedical Research

Clinical Trial*
Is this a clinical trial?
Yes

If Yes, please be aware that for each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available

Federal Web site that will be established as a repository for such informed consent forms.

Investigator Initiated Trial*
Is this an investigator initiated trial?
Yes

If Yes, please be aware that the investigator may be required to create and manage a record of this trial in https://clinicaltrials.gov.

Drugs or Devices*
Does this research study involve Drugs or Devices?
No

IND Exemption

For studies that fall under an IND exemption, please provide the number below

For studies including IND or IDE's, please provide the number(s) below

IDE Review*
NOTE: For research involving investigational devices, you are required to review the guidance on Managing Research Device Inventory. Consult the Penn Manual for Clinical Research: https://www.med.upenn.edu/pennmanual/secure/investigational-product-management-at-sites-not-using-investigational-drug-services-(ids).html Please check the box Yes if you have reviewed the guidance.
Yes

Research Device Management*
Please indicate how research device(s) will be managed.
Not Applicable (no investigational devices)

Drug, Herbal Product or Other Chemical Element Management *
Please indicate how drugs, herbal products or other chemical entities will be managed.
Not Applicable (no drugs, herbal products or other chemical entities)

Radiation Exposure*
Are 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?
No

Gene Transfer*
Does this research involve gene transfer (including all vectors) to human subjects?
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
Yes

CACTIS and CT Studies*
Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?
No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Investigational Agent or Device within the Operating Room*
Does the research project involve the use of an investigational agent or device within the Operating Room?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Processing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

In-House Manufacturing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
Yes

If the answer is YES, indicate which items is is provided with this submission:

Modified research informed consent document that incorporates HIPAA requirements

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
Yes

Clinical Laboratory Services*
Will samples be collected by UPHS phlebotomy and/or analyzed by the hospital laboratory?
Yes

Anatomic Pathology Services*
Will tissue specimens (other than blood) be collected for clinical, diagnostic, or research purposes OR be processed through surgical pathology, cytopathology, neuropathology, or hematopathology?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?

N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
Yes

Primary Focus*
Epidemiological research

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
	Survey instrument
x	**None of the above**

The following documents are currently attached to this item:

There are no documents attached for this item.

Department budget code

None

Multi-Center Research

Penn as lead
1. Is this a multi-center study where Penn is serving as the Lead Site or the Penn PI is serving as the Lead Investigator?
No

Management of Information for Multi-Center Research

Penn irb of record
2. Is this a multi-center study where the Penn IRB will be asked to serve as the IRB of Record for other external study sites?
No

Other Sites

No other sites

Protocol

Abstract
Psoriatic arthritis (PsA) is a chronic inflammatory arthritis that can be associated with devastating outcomes including irreversible joint damage. The management of a patient with PsA is extremely challenging due to the high degree of phenotypic heterogeneity. The ultimate goal of this proposal is to prepare pragmatic trials in PsA trials that will encompass all relevant subgroups of patients. The aims of this study specifically focus on responses to biologic therapy among patients with PsA and determining the optimal set of outcome measures for PsA trials.

Objectives

Overall objectives
This is a multi-center cross-sectional study aiming to obtain the data necessary to design a pragmatic trial in PsA including responses to biologic therapy among patients and determine the optimal set of outcome measures for PsA trials.

Primary outcome variable(s)
Aim 1. Determine responses to biologic therapy with among patients with PsA in real world setting. Hypotheses: a) The magnitude of response to TNFi will be lower in a heterogeneous PsA population (ACR20 40%) than in the homogenous RCT populations reported in the literature (ACR20 ~60%). Additionally, the magnitude of response, as defined by multiple outcome measures including ACR20, will be lower in the subset of patients with active disease who would not be eligible for a typical RCT(3 swollen joints) compared to patients who would be eligible for an RCT (3 swollen joints). Rationale: The majority of patients with PsA are not represented in RCTs. To design high quality pragmatic trials with appropriate sample size estimates, response rates in real-life settings are needed.

Secondary outcome variable(s)
Aim 2. Define the optimal set of outcome measures for pragmatic trials with PsA. Hypothesis: A parsimonious set of instruments will be identified; these outcome measures will be responsive, non-overlapping, and feasible for pragmatic trials. Rationale: Optimal outcome measures for pragmatic trials will be feasible, valid, and responsive across the diverse spectrum of patients with PsA. We will examine the responsiveness, minimal clinically important improvement (MCII) and discrimination of multiple PsA outcome measures. These results will inform selection of the primary and secondary outcomes for pragmatic trials and will also be relevant for traditional RCTs. Because subgroups of patients may respond differently, we will also examine the performance of the outcome measures within subgroups, including subphenotypes (e.g., axial disease, polyarticular, oligoarticular), demographics (e.g., sex), and common comorbidities (e.g., obesity and depression). These analyses will a) identify outcome measures suitable for pragmatic trials, b) determine if outcome measure selection should differ according to PsA subgroups and c) inform stratification variables for pragmatic trials

Background
Psoriatic arthritis (PsA) is a chronic inflammatory arthritis associated with psoriasis, one of the most common autoimmune skin diseases affecting 2-3% of the population. Despite many advances in disease pathogenesis and therapeutics, approximately half of PsA patients continue to have active disease despite treatment. Therefore, it is imperative to test new treatment modalities including non-pharmacologic therapies and novel management strategies. While randomized controlled trials (RCTs) can address efficacy, or whether a drug can work, the homogenous population selected for inclusion in RCTs is not generalizable to the broader population of patients with PsA (a highly heterogeneous disease). By contrast, pragmatic trials test the effectiveness of management strategies in "real-world" clinical practice as opposed to the highly controlled settings in RCTs. Many important questions facing patients with PsA (e.g., comparative effectiveness) can be addressed with pragmatic trials. However, before this approach can be launched effectively, there is a fundamental need to identify appropriate outcome measures for PsA pragmatic trials. Currently the primary outcome in PsA RCTs, is the American College of Rheumatology 20% Response Criteria (ACR20), an outcome designed for rheumatoid arthritis, a substantially different inflammatory arthritis. Furthermore, the ACR criteria have intrinsic weaknesses that ultimately limit feasibility for a pragmatic trial, including the need for a blood test at two time points and underperformance in the most common PsA subpopulation (the half of patients with less than three swollen and tender joints at therapy initiation). The ultimate goal of this proposal is to prepare pragmatic trials in PsA trials that will encompass all relevant subgroups of

patients. Three objectives are envisioned: 1) Examine response in the heterogeneous population of patients that can be enrolled in pragmatic trials and compare those to the subset of patients who would be eligible for a traditional RCT; 2) Define the optimal set of outcomes for use in a pragmatic trial; and 3) Examine how subgroups (e.g., sex, phenotypes, comorbidities) affect outcome measurement. We will address the aims in a prospective observational cohort study conducted within the multicenter Psoriatic Arthritis Research Collaborative (PARC). The four centers will also be the sites for the proposed pragmatic trial. At completion of the Aims, we will have all of the necessary components to initiate a pragmatic trial for PsA: outcomes will be selected, stratification variables identified, sample size calculated, and data collection methods solidified. Additionally, we will identify expectations for treatment response in clinical practice, calculate minimal clinically important improvement, and examine how subgroups affect measurement of response. The results from the proposed studies will additionally inform outcome measures for traditional RCTs and clinical practice.

Study Design

Phase*
Not applicable

Design
a) prospective multicenter observational cohort study: phenotypes and patient characteristics will be compared among 4 psoriatic arthritis clinics in the United states

Study duration
The length of subject participation in the trial will be approximately 3 months. Estimated 2 years to enroll all subjects and complete study.

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
The study team is composed of 5 investigators with diverse and complementary talents and experiences that are in line with the study goals. All investigators are members of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and all collaborate extensively with local psoriasis experts. Furthermore, all four centers have already been collecting data from patients in their PsA clinics, have published on many topics in PsA, and hold grants from a variety of sources. All four centers have outstanding scientific environments with supportive of division directors and track records for successful competition for NIH funding. The scientific environments at all four institutions are outstanding. All institutions have unmatched resources for clinical and translational research and all investigators have access to institutional Clinical and Translational Science Award (CTSA) resources. Additionally, all of the investigators have published studies in psoriatic arthritis and are active members within GRAPPA. Given that each center sees approximately 40-60 new patients with PsA each year, obtaining 55 new or return patients within the study period is feasible. Aligning data capture among our centers through completion of this study will allow for continued uniform data capture and collaboration. Furthermore, this model is sustainable and low cost as primary data is collected and stored within each institution primarily and data will be transferred into the PARC database as needed. Thus, the model could be modified by each institution to serve other ongoing studies and could be extended to other sites in the future.

Characteristics of the Study Population

Target population
Rheumatology clinic patients with active PsA switching to or adding a TNFi.

Subjects enrolled by Penn Researchers
55

Subjects enrolled by Collaborating Researchers
220

Accrual
Patients seen by any rheumatology provider will be recruited at their new patient visit or return visit. Flyers about the study will be posted in examination rooms and rheumatology practitioners within the division will be educated about the study. The Penn Psoriatic Arthritis Clinic sees approximately 65-75 patients with psoriatic arthritis per year.

Key inclusion criteria
-Age 18-89 -Active PsA (at least one swollen joint or enthesitis) -Meet CASPAR criteria (Table 2) (103) -Initiation of TNFi (etanercept, adalimumab, infliximab, certolizumab, golimumab) (At the time of the submission of this grant, TNFi biosimilars have been approved by the FDA but are not available on the US market. Once available, patients starting TNFi biosimilars will similarly be eligible for participation. Patients may have been on the medication in the past but must have had greater than 2 months off the medication.Patients may be taking other traditional DMARDs. A washout period is not required.)

Key exclusion criteria
-Unable to give informed consent -Out of the age range -Switching therapies for skin psoriasis in the setting of well controlled joint and enthesis symptoms. -Patients with only active PsA

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
Although not directly targeted, mentally disabled persons, economically or educationally disadvantaged persons, and/or employees or students of the University of Pennsylvania will not be denied enrollment and any special protections and/or additional safeguards will be undertaken in order to protect the rights and welfare of these subjects from coercion or undue influence as appropriate.

Subject recruitment
Patients seen by any rheumatology provider may be recruited by the study team (as listed in HS-ERA) at their new patient visit or return visit. Flyers about the study will be posted in examination rooms and rheumatology practitioners within the division will be educated about the study.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

Participants will receive $30 at the completion of the second visit for their participation in the study. Participants will be compensated by Clincard. Greenphire/Clincard have agreed to waive Social Security number collection for this study.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
Patients may be recruited before or after a new patient visit or return visit. In the case that the visit encounter is completed before enrollment, only the additional information not collected for clinical purposes will be collected. In other words, most of this information is collected in a routine clinic encounter. The information collected during that encounter will be used to complete as much of the CRF as possible and then the additional elements from the CRF will be completed by the research coordinator or site PI following that visit using information from the visit notes. After informed consent is obtained by a member of the study team listed on HS-ERA, a detailed history about the patient's arthritis will be taken and a complete examination will be performed by the rheumatologist. Patients will complete a set of Patient Reported Outcome (PRO) surveys electronically or on paper. Participants may also choose to have the survey link emailed and complete the PRO's within the 2 weeks following the baseline enrollment visit. Results of laboratory tests and radiography obtained for clinical purposes will be recorded. We will record the therapeutic regimen planned at the end of the clinical encounter. This data will be collected by the rheumatologist and the research coordinator at each site. Patients will also undergo a blood draw by venipuncture at the outpatient lab. Approximately 40 mL (4 tubes) of blood will be drawn at each visit. No more than 50 mL will be drawn at each visit. Clinical labs may also be drawn at this time. The study team will pick up the blood, process it, and store it onsite at UPenn/UPHS. The research blood draw will be ordered in EPIC and charged to the study but all other items in this study are considered clinical care and will be charged to insurers/subjects as usual. At a follow up visit approximately 3 months from the initial study visit, a thinned version of the CRF will be used to update the information collected from the participant and record any changes and response to therapy. . The participant will also fill out a different version of patient outcome measurements, have a complete examination performed by a rheumatologist, and undergo a blood draw again. A link to the PRO surveys will be emailed out 2 weeks prior to the scheduled follow-up visit and will be available until 2 weeks after the visit. Participants can also choose to complete the PROs at the visit on paper or electronically. The blood and information collected throughout this study will be used to build a repository for future research projects. The de-identified information stored in the redcap will available to the study teams at each of the sites involved in this study and to those PIs for future research. Researchers not involved in this study will not be permitted to request or use data or samples from this study. Blood samples will be processed and stored at individual sites. Blood samples may be shipped to a central location for further testing but will not be made available to outside researchers. Further testing will be focused on bio-markers of treatment response and disease progression. Participants may retract permission and ask that their samples be destroyed.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
We will report demographics and disease characteristics of the patients by center. Similarly, we will describe the PsA phenotypes of patients enrolled at each site, patients previous therapies, and new therapy prescribed stratified by PsA phenotype. The chi-squared test will be used to test the difference in prevalence of each disease phenotype by center. A one-way ANOVA test (or Kruskal Wallis, the non-parametric equivalent) will be used to determine whether there is a significant difference between centers in mean disease severity (DAS66/68 score, HAQ score, RAPID3 score) and duration of psoriasis. With 20 patients in each group and an effect size 1.1 (assuming difference in min and max mean scores of 5.5 and standard deviation of 5), we will have 82% power to detect a significant difference (=0.05). While this is a modest estimation of standard deviation for some of the measures listed, we believe the sample size will be adequate to provide important initial observations in this proof-of-concept study. Furthermore, understanding of the basic epidemiology of psoriatic arthritis phenotypes within the four clinics will provide important observations for future study planning.

The following documents are currently attached to this item:

There are no documents attached for this item.

Data confidentiality

x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**

x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**

Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

x **Wherever feasible, identifiers will be removed from study-related information.**

A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.

Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality
All four institutions use the Epic electronic medical record system and have existing REDCap databases (see Computer Resources for more information on REDCap). For the purpose of this study and use in future studies, we will build a PARC Core REDCap Database. All four institutions will have access to this Core REDCap Database with designated data use agreements. The PARC Core REDCap Database will then be populated from each of our existing institutional RedCap databases. Personal identifiers (name, medical record number) will not be stored as a part of this dataset. Instead, personal identifiers will remain within each individual institution and only de-identified data placed in the Core REDCap database. To ensure the protection of the subjects and data integrity, we will maintain the highest security settings for the Core REDCap Database. Each user will have a specific user-ID and password and will access only de-identified data. Personal identifiers from each site will only be visible to providers and study team at that site.For our site, any data involving personal identifiers or contact

information will be kept on a UPHS maintained server and accessed via password protected computers. This REDCap Database will include elements of dates. A data use agreement was executed between the institutions involved in this study for the PARC study (819801) and an appendix has been added to that agreement in order to include the specifics of this study.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Subject Privacy
Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
Patients will be seen in private clinic rooms with only the physician and possibly the coordinators, both of which are HIPAA trained and will not discuss the patient outside of clinic areas. Patients will be recruited through word of mouth, by other rheumatologists mentioning the study, and also by patients themselves seeing the flyers. All participation is voluntary. All questionnaires being presented to the patients are well-accepted methods of data collection, and the answers to the questionnaires will be discussed with the patient in the private clinic room should any questions arise. Participants will be asked to provide their phone numbers and/or email addresses for study follow-up. This contact information will not be shared outside of the study team or used for purposes outside this study.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
Yes, data will included in a RedCap database and shared with study teams at NYU, Cleveland Clinic and University of Utah. Personal identifiers and contact information will not be included in this database. A data use agreement has been set up between these institutions.

*Data Protection**

- x **Name**
- **Street address, city, county, precinct, zip code, and equivalent geocodes**
- x **All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- x **Telephone and fax number**
- x **Electronic mail addresses**
- **Social security numbers**
- x **Medical record numbers**
- **Health plan ID numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Device identifiers/serial numbers**
- **Web addresses (URLs)**
- **Internet IP addresses**
- **Biometric identifiers, incl. finger and voice prints**
- **Full face photographic images and any comparable images**
- **Any other unique identifying number, characteristic, or code**
- **None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
Yes

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
Yes

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
Yes

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
Yes

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
Yes

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
This study may include testing of bio-markers to better understand the phenotypes of psoriatic arthritis as well as treatment response and disease progression. This testing is exploratory and the results will not be returned to participants or recorded in medical records.

Consent

1. Consent Process

Overview
Patients seen by any rheumatology provider may be recruited at their new patient visit or return visit. Flyers about the study will be posted in examination rooms and rheumatology practitioners within the division will be educated about the study. Informed consent may be obtained by the PI or study personnel listed in HS-ERA. Study personnel will discuss the goals of the study and the information that will be collected from the medical record and clinical notes. They will also discuss the kinds of questionnaires/surveys that the participant will be asked to complete and any risks involved in the study including loss of confidentiality. Since this study involves de-identified data being shared with study teams and stored for future research, this will also be discussed with participants. This consent process will also cover how and why blood will be collected, tested, and stored and the risks of this procedure.

Children and Adolescents
N/A

Adult Subjects Not Competent to Give Consent
Adult subjects not competent to give consent will not be consented.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
No Waiver Requested

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
No

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks
There is a minimal risk of loss of confidentiality. There are also risks involved in collecting blood via venipunture including local pain, bruising, bleeding, fainting, blood clot formation, and in rare instances, an infection at the blood draw site. This study does include blood that may be used in bio-marker studies but these tests are exploratory and the results will not be returned to participants. Because this study is framed around clinical procedures, incidental findings are not considered a risk as their discovery would be considered part of clinical care.

Potential Study Benefits
There are no individual benefits to be obtained through participating in the study. However, the benefit to our understanding of psoriatic arthritis and how to better treat psoriatic arthritis will be significant.

Alternatives to Participation (optional)
The alternative is to not participate.

Data and Safety Monitoring
Principal Investigators will monitor the study at each individual site.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
Minimal Risk

General Attachments

The following documents are currently attached to this item:

Cover Letter (pb_irbcoverletter_8_14_2019.doc)

Additional forms (citi_deeluo.pdf)