Study Application (Version 1.28)

1.0 General Information

***Please enter the full title of your study:**

Safety and Efficacy of Secukinumab in Adults with Chronic Plaque Type Psoriasis with a PASI score of 6 to 12

***Please enter the study short title:**

Secukinumab in Mild Psoriasis

Is this Study using Subject Management?

(•) Yes ( ) No

2.0 Add Lab/Dept(s)

2.1 List departments associated with this study:

Primary Dept?	Department Name
(•)	**RUH** - Laboratory of Investigative Dermatology (Krueger)
( )	**RUH** - Rockefeller University Hospital (RUH)

3.0 Assign key study personnel(KSP) access to the study

3.1 *Please add a Principal Investigator for the study:

Krueger, James, MD PhD

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Gilleaudeau, Patricia RN, MSN, FNP
Clinical- Co-Investigator
Kim, Jaehwan, MD, PhD
Clinical- Co-Investigator
Lee, Jongmi, MD PhD
Non-Clinical - Co-Investigator

B) Research Support Staff

Cueto, Inna, MS
Study Coordinator

Kunjravia, Norma, MD
Study Coordinator
Moreno, Ariana, BS
Study Coordinator

3.3 *Please add a Study Contact:

Cueto, Inna, MS
Gilleaudeau, Patricia RN, MSN, FNP
Kim, Jaehwan, MD, PhD
Krueger, James, MD PhD

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

4.0 Rockefeller University Conflict of Interest

4.1 Investigator Financial Conflict of Interest All KSP must complete an annual certification of their Significant Financial Interest ("SFI") disclosures in the University's online Research Administration System at https://RAS.rockefeller.edu. Disclosures also must be updated in connection with new human subjects research protocols ("Research Certification"), and within 30 days of discovering or acquiring a new SFI. To avoid delays in the IRB review process, when prompted by an email from rascoi@rockefeller.edu requesting an updated Research Certification, KSP should click on the Research Certification link contained in that email notification, or go to https://RAS.rockefeller.edu, to (a) review and update his or her SFI disclosures or certify that he/she has no updates, as appropriate, and (b) indicate whether any of his/her SFI disclosures are reasonably related to the design, conduct, or reporting of the research protocol. If a KSP discloses a SFI that might constitute a conflict of interest with respect to the proposed protocol, he or she must e-mail a copy of the Lay Summary of the draft protocol to Teresa Solomon, Esq. (solomot@rockefeller.edu). Doing so will facilitate addressing COI issues in step with the development of the study protocol. Non-compliance or tardiness in making or updating COI disclosures will result in a delay in IRB review. Institutional Conflict of Interest:

As early as possible the PI (or a designee) preparing a clinical research protocol must review a list of entities in which The Rockefeller University has an Institutional Financial Interest at https://icoi.rockefeller.edu/account/login.php. If the proposed study involves any entity on that list, the PI (or designee) must notify Teresa Solomon, staff to the FCOI Committee, by e-mail solomot@rockefeller.edu and Sarah Schlesinger, Chair of the IRB, by email: schless@rockefeller.edu, provide the name(s) of the entities and a copy of the Lay Summary. Doing so will facilitate addressing institutional COI issues in step with the development of the study protocol. Failure to take steps to review and address potential institutional conflicts of interest will delay the IRB review process.

5.0 External Personnel

5.1 List external personnel who will be working on the study:

Name	Institution	Telephone	E-mail	Role
No External Personnel has been added to this Study				

6.0 Delegation of Authority

6.1 Enter authorized activities for all Rockefeller University personnel named on the study.

Activity Codes:

1. Informed consent **
2. Inclusion / exclusion criteria
3. Medical/medication history *
4. Perform Physical Exam *

4a. Write / Sign LIP orders *

5. Skin assessments and photos
6. Study drug dispensing *
7. Study drug administration *
8. Study drug reconciliation
9. Study drug compliance
10. Administer study questionnaire(s)
11. Participant recruitment
12. Perform assays
13. Specimen / sample analysis
14. Lumbar puncture *
15. Femoral line placement *
16. Central line placement *
17. Insulin clamp procedure *
18. Leukapheresis *
19. Sigmoidoscopy *
20. Fat biopsy *
21. Skin biopsy *
22. Conduct sleep study
23. Diet design and preparation
24. Nutritional assessment and counseling
25. Addition of PABA to food
26. Data analysis
27. Data review
28. Data management
29. Maintain regulatory documents / files
30. Complete CRF's

Add up to three additional authorized activities specific to this study (do NOT add activities that have previously designated codes):

31:	
32:	
33:	

34. Behavioral Testing
35. Bod Pod
36. Bone Marrow Aspiration *
37. Neuropsychological Testing *
38. Conduct Focus Group
39. Conduct Smell Study
40. Genetic Counseling *
41. Apply EEG Electrodes **
42. Olfactometer Test
43. Study Participant Teaching
44. Resting Energy Expenditure
45. Source Document Review & Correction
46. Medical Photography
47. See 4a
48. Adverse Event Assessment
49. Clinical Trial Registration
50. Study Support Drug Dispensary
51. Internal Monitoring
52. Randomization

Enter delegation of authority for Rockefeller University Key Study Personnel:

NOTE:

* Indicates procedures requiring the individual complete specific credentialing **BEFORE** the activity may be added to their delegated activities.

** Indicates procedures requiring the individual complete specific training **BEFORE** the activity may be added to their delegated activities.

Name	Title	Authorized Activities	Start Date	End Date
Krueger, James, MD PhD	PI	1,2,3,4,5,7,9,10,11,12,13,21,26,27,28,29,30,43,45,46,47,48	11/22/2016	
Kim, Jaehwan, MD, PhD	Co-I	1,2,3,4,5,7,9,10,11,12,13,21,26,27,28,29,30,43,45,46,47,48	11/22/2016	
Lee, Jongmi, MD PhD	Co-I	12,13,26,27,28	11/22/2016	
Mrs. Gilleaudeau, Patricia RN, MSN, FNP	Co-I	1,2,3,4,5,7,9,10,11,21,29,30,43,45,46,47,48	11/22/2016	
Sullivan-Whalen, Mary M, RN, FNP	Co-I	1,2,3,4,5,7,9,10,11,21,29,30,43,45,46,47,48	11/22/2016	09/11/2020
Brassil, Donna, MA, RN, CCRC	Facilitator	29	11/22/2016	11/22/2019
Hutt, Richard, RN, BA, CCRC	Study Coord	29	11/22/2016	11/22/2019
Eylers, Ellen, MPH, MSN, RN, CCRC	Study Coord	29	12/06/2016	03/29/2018
Hawkes, Jason Ezra, MD	Co-I	1,2,3,4,5,7,9,10,11,21,29,30,43,45,46,47,48	03/29/2018	05/28/2019
Frew, John, MD	Co-I	1,2,3,4,5,7,9,10,11,21,29,30,43,45,46,47,48	11/26/2018	09/11/2020
Cueto, Inna, MS	study coord	27,28,29,30	02/18/2020	
Moreno, Ariana, BS	coordinator	28, 29	07/26/2021	
Kunjravia, Norma, MD	coordinator	1, 2, 28, 29	07/26/2021	

Enter delegation of authority for additional Rockefeller University Key Study Personnel:

Name	Title	Authorized Activities	Start Date	End Date
No records have been added				

Enter the authorized activities for External Personnel:

Name	Title	Authorized Activities	Start Date	End Date
No records have been added				

7.0 Study Description

7.1

Study Classification

Full Review

7.2

*** Submission Request Category**

Note: For each submission, please designate the level of review, or "Submission Request Category" you are requesting. When completing this field, please indicate the level of review you are requesting for the specific submission you are working on.
For example, if you are submitting an Expedited Amendment request to change the Key Study Personnel on your existing Full Board study, you should select "Expedited Review" in both the Amendment Submission Form and Study Application. The IRB will confirm an Expedited review of the Amendment submission is appropriate, and the overall study will remain classified as a full Board review. Please see the help bubble for guidance.

- ○ Exempt from Review
- ○ Exempt with Limited Review
- ◉ Expedited Review
- ○ Not Human Subjects
- ○ Full Review

7.3 *** Lay Summary**

Please provide a summary of your study in lay language. The summary should be no more than a half page (500 words or less) and should contain a clear statement of the rationale for the study.

Psoriasis is an immune-mediated disease of the skin that, even in mild disease, increases the risk of co-morbidities such as cardiovascular disease and metabolic derangements. Mild psoriasis tends to be treated with topical drugs, while moderate-to-severe disease is optimally treated with systemic immune modulators. However, the treatment of "mild" psoriasis needs to be re-thought because recent studies have revealed that mild psoriasis is characterized by stronger expression of pathogenic molecules, such as interleukin (IL)-17A, and higher numbers of T cells in the skin, compared to severe psoriasis. A key distinction between mild and severe psoriasis is now discovered to be the higher expression of negative immune regulatory genes in mild lesions. Therefore, targeted immune therapy with anti-IL-17A, which is highly effective in severe psoriasis, might be equally (or even more) effective in mild disease. Also, restoration of immune tolerance might be more easily achieved in mild disease. Thus, short-term anti-IL-17A treatment of mild psoriasis might prevent the recurrence and eventually cure the disease. The

aim of study is to test this hypothesis by exploring whether 3 months or 6 months of anti-IL17A treatment will prevent relapses after medication has been discontinued in mild psoriasis patients .

7.4

*** Public Health Impact Statement**

Provide a brief plain language statement (100 words or less) of the value of the research proposed and its potential impact on population health. Additional instructions located in Help.

Mild psoriasis not only progresses to moderate-to-severe psoriasis but also precedes systemic inflammation that leads to psoriatic arthritis and cardiovascular comorbidities. By curing mild psoriasis with a short-term anti-IL-17A treatment, we may reduce the costs of treating psoriasis and associated medical conditions, including psoriatic arthritis, cardiovascular disease, and diabetes.

8.0 Screening for Expedited Review

Studies that may be reviewed by expedited review fall into 7 categories described in detail in 46CFR 8392. These include drawing of blood within prescribed limits, collection of samples such as saliva, mucosal and skin cells by scraping, and excreta or sweat. Data may be collected by physical sensors such as weighing, EKG, EEG, MRI, moderate exercise and strength testing, and body composition assessment. Collection of data from voice, video or image recordings obtained in research. Research on perception, cognition, social behavior employing surveys, interviews, focus groups and oral history.

Research may be conducted on data, documents, records or specimens that have or will be collected solely for non-research purposes in the course of medical treatment or diagnosis.

Note: Protocol studies that involve a drug that requires an IND, or that involve greater than minimal risk to participants, or that involve the use of X-rays or microwaves are not eligible for an expedited review.

* Based on the above information, does your research study qualify for an "expedited" review?

- (•) Yes
- ( ) No
- ( ) Not Sure

9.0 Clinical Trial Registration

9.1

Clinical Trial Registration

The types of studies listed below must be registered at **www.ClinicalTrials.gov**

- (•) Study involves testing of FDA regulated drugs or biologics (See HELP)

- ○ Study is funded by the NIH, and meets the definition of a "clinical trial" (see HELP)
- ○ Study meets the ICMJE definition of a "clinical trial" (See HELP)
- ○ None of the above

If you selected 1, 2, or 3, you must register your trial with ClinicalTrials.gov through the Rockefeller University institutional account. Please contact the Clinical Research Support Office x7408 for assistance.

10.0 Study Overview/Summary

10.1 * Who initiated this study?

Please specify one:

- ◉ Principal Investigator Initiated
- ○ Industry Initiated
- ○ Other

10.2 * This study in collaboration with:

- ○ Weill Cornell Medical College
- ○ Memorial Sloan-Kettering Cancer Center
- ○ Both Weill Cornell Medical College and Memorial Sloan-Kettering Cancer Center
- ◉ Neither Weill Cornell Medical College nor Memorial Sloan-Kettering Cancer Center

Please note: If any of the first three options is checked, you will be prompted to attach the **IRB of Record** forms later on in the submission. Links to these forms can be found in the Help link to the right.

10.3 *Are other institutions involved in the study?

- ◉ 1. No
- ○ 2. Yes, and a federal, industry or private organization is administratively coordinating the study.
- ○ 3. Yes, however, a federal, industry or private organization is not administratively coordinating the study.

10.4 * Is this a multi-center trial?

○ Yes ◉ No

10.5 * Who (What) is to be studied?

- ☑ Human Subjects - including coded samples and/or data with links to Identifiers
- ☐ Deidentified Samples - unable to be linked to identifiers by receiver
- ☐ Data Only - unable to be linked to identifiers
- ☐ Identifiable samples or data for exemptions (per 104 (s)(4))

10.6 *Study Type:

- (•) Interventional
- ( ) Observational

10.7 The initial date of IRB approval/determination was:

01/05/2017

10.8 * What is the expected duration of the study?

4 Years

10.9 * Are any of the following agents to be used in the study?

Check all that apply:

- [x] Drug FDA Approved
- [ ] Approved Drug for Off-Label Purpose (This might require an IND)
- [ ] Investigational New Drug
- [x] Biologic Agents
- [ ] Nutritional Supplements
- [x] Placebo
- [ ] Vaccines
- [ ] No Agents

10.10 * Are investigational devices to be used in the study?

( ) Yes (•) No

10.16 Special Research Procedures

Does the study propose to directly involve participants in the following special research procedures?

- [ ] Recombinant DNA
- [ ] Gene Therapy
- [ ] Fetal Tissue
- [ ] Embryonic Stem Cells
- [ ] Induced Pluripotent Stem Cells
- [ ] CRISPR-Cas9

If any item is checked, please see Help for details.

10.17 * Radioactive Isotopes Involved

Will participants be exposed to any radiation other than routine x-rays solely for clinical care purposes?

( ) Yes (•) No

11.0 Interventional

11.1 *Interventional, please specify:

- ○ Open Label
- ○ Single Blind
- ◉ Double Blind
- ○ Other

12.0 Objectives and Rationale

12.1 * Overview

Briefly state the ***purpose of this study***. Give enough background and rationale to provide both scientists and lay members of the IRB and ACCTS with the basis for exposing human participants to the risks involved.

Psoriasis is an immune-mediated disease of the skin that, even in mild cutaneous form, increases the risk of co-morbidities such as cardiovascular disease and metabolic derrangements that likely result from systemic inflammation. Treatments differ between "polar" forms of psoriasis, i.e., mild psoriasis tends to be treated with topical drugs, while moderate-to-severe psoriasis is optimally treated with systemic immune modulators. While it is recognized that topical agents are far less effective than most biologics that antagonize cytokines (anti-TNF, anti-IL-12/23, anti-IL-17), the decision not to treat "mild" patients (here mild psoriasis is defined by psoriasis affected Body Surface Area (BSA) less than 10% and Psoriasis Area and Severity Index (PASI) between 6 and 12) has been based on 1) significant toxicity associated with historical agents such as cyclosporine or methotrexate, so treatment was done only for patients for whom topical agents were not practical (>10% body surface) and 2) the perception that "mild" psoriasis involves less severe inflammation in the skin than in patients with more extensive psoriasis.

The treatment of "mild" psoriasis needs to be re-thought because 1) inflammation is not limited only to the skin as evidenced by the risk for co-morbid inflammatory conditions; 2) patients that develop psoriatic arthritis often come from the pool of "mild" patients, as the extent of psoriasis skin is often <10% in this group of patients that may be as much as 1/3 of all psoriatics; 3) current generation cytokine antagonists such as Ustekinumab and Secukinumab are not only highly effective in treating cutaneous psoriasis, but they are also extremely well tolerated drugs with minimal systemic toxicity profiles – this has changed the risk/benefit equation of treating mild patients with systemic drugs; 4) a new study we have conducted has directly compared IL-17-mediated inflammation and overall disease burden in skin lesions using global gene expression profiling of mild vs. moderate-to-severe lesions.

Surprisingly, mild psoriasis was characterized by significantly higher IL-17A expression, stronger expression of the core psoriasis transcriptome, and by higher numbers of T-cells in skin lesions. In contrast, severe psoriasis was characterized by stronger expression of some epidermal response genes (TGFA, CALM1, SMPD3 & IL1RL2). However, a key molecular distinction between mild and severe psoriasis was higher expression of negative immune regulatory genes (CTLA4, PD-L1 & CD69) in mild lesions compared to severe psoriasis lesions.

These data have relevant implications for therapy of psoriasis—first they suggest that anti-IL-17A approaches used in severe psoriasis might be equally (or even more) effective in mild psoriasis. Secondly, restoration of immune tolerance might be more easily achieved in mild psoriasis due to higher "regulatory" immune tone that effectively prevents unbounded T-cell expansion. Thus, short-term anti-IL-17A treatment of mild psoriasis might prevent the recurrence and eventually cure psoriasis. The aim of the study is to test this hypothesis by exploring whether 3 months or 6 months of Secukinumab treatment will prevent relapses after medication has been discontinued in mild psoriasis patients.

12.4 * Engaging Stakeholders: Describe any plans to engage other stakeholders (Scientists, practitioners, patients, advocacy groups, etc.) for hypothesis generation, or feasibility purposes.

We will engage stakeholders, including participants, their families, their health care providers, and the study sponsor, and to assure safe progression of the study and to address any concerns may arise.

12.5 * Hypothesis

Describe the ***research hypothesis*** in a single sentence.

COSENTYX (secukinumab) is efficacious in treating mild, chronic plaque type of psoriasis in adults.

12.6 * Aim(s)

Indicate how you will ***address the hypothesis*** (e.g., to compare groups, to estimate a parameter, to ascertain feasibility). Since the sample size determination is usually based on the primary aim only, the primary aim should be sufficient to justify the study.

1) To evaluate the efficacy of secukinumab for the complete resolution of mild plaque-type psoriasis after 3 months of secukinumab treatment by comparing the secukinumab-receiving mild psoriasis subjects (Group 1) and the placebo-receiving mild psoriasis subjects (Group 2).
*Mild psoriasis - psoriasis affected Body Surface Area (BSA) less than 10% and Psoriasis Area and Severity Index (PASI) between 6 and 12.
*Group 1 : 6 months secukinumab + 12 months observation
*Group 2 : 3 months placebo + 3 months secukinumab + 12 months observation
2) To explore whether secukinumab will prevent relapses after medication has been discontinued in subjects with mild plaque-type psoriasis.

3) To compare frequency of relapse between subjects who achieve a score of 0 (clear) on IGA (Investigator's Global Assessment) and subjects who do not achieve a score of 0 (clear) on IGA, within each group (Group 1 (6 months secukinumab) and Group 2 (3 months Placebo + 3 months secukinumab)).
4) To compare frequency of relapse between subjects who achieve a score of 0 (clear) on IGA between group 1 and group 2 (Group 1 (6 months secukinumab) and Group 2 (3 months Placebo + 3 months secukinumab)).
5) To evaluate the safety of secukinumab for the treatment of subjects with mild plaque-type psoriasis comparing the secukinumab-receiving mild psoriasis subjects (Group 1) and the placebo-receiving mild psoriasis subjects (Group 2) for 3 months.

12.7 * Primary Outcome(s)

Indicate which ***variable(s)*** will be assessed to judge the primary specific aim. Give measurement units, if applicable.

1) The proportion of subjects who have a reduction of 75% or more from baseline in the psoriasis area-and-severity index score (PASI 75) at week 12 (*primary endpoint*)[1]

2) The proportion of subjects who have a reduction of 90% or more from baseline in the psoriasis area-and-severity index score (PASI 90) at week 12[2]

3) The proportion of subjects who achieve a score of 0 (clear) on a 5-point modified investigator' s global assessment (IGA) at week 12[3]

[1,2,3]The 3 co-primary endpoints are subject to a step-down hierarchical closed testing procedure. (Primary objective is achived if any null hypothesis is rejected following the order: PASI75, PASI90, IGA0).

12.8 * Secondary Outcome(s)

Indicate which ***additional variable(s)*** will be assessed to judge the secondary outcome(s). Give measurement units, if applicable.

1) The proportion of subjects who experience a psoriasis relapse at any time between week 24 and week 72. Psoriasis relapse is defined as loss of > 50% of the initial PASI improvement measured at week 24.
2) Severity of the relapses over the observation period.
3) Extent of relapse over the observation period.
4) Elapsed time from week 24 until relapse occurs before week 72, measured in weeks.
5) The proportion of subjects who achieve a PASI 100 or PASI 90 response at week 12
6) Frequency and severity of all AEs and SAEs that occur during the whole trial including the observational period (AEs and SAEs include but not limited to comorbidities, such as hypertension, diabetes, and cardiovascular diseases).

12.9 * Methods and Procedures

Please provide a description of the laboratory and clinical analyses and procedures that will be performed. Include the role of external collaborators and consultants when appropriate. Please refer to Help text for Guidance.

The trial will be conducted as a unicenter, randomized, double-blind, parallel-group, placebo-controlled exploratory study of Secukinumab in subjects with mild plaque-type psoriasis. The purpose of the study is to evaluate the efficacy and the safety of Secukinumab for 3 or 6 month treatment periods, and to explore whether relapse occurs after the medication has been discontinued, during the subsequent 12 month observation period.

Arms: (Group 1: 6 months of Secukinumab) vs. (Group 2: 3 months of Secukinumab). Patients will be randomly assigned in a 1:1 ratio to Group 1 or Group 2. Group 1 receives Secukinumab at a dose of 300 mg with injections administered once weekly at baseline and at weeks 1, 2, 3, and 4 and then every 4 weeks for 6 months of period until week 12.

Patients randomly assigned to Group 2 will receive placebo injections corresponding to the Group 1 regimen until week 8 in order to maintain a double-dummy design until week 12. However, Group 2 will receive Secukinumab at a dose of 300 mg with injections administered once weekly at week 12 and at weeks 13, 14, 15, and 16 and then every 4 weeks for 3 months of period. Both group 1 an 2 discontinue Secukinumab after week 24 being observed from week 25 to week 72 (48 weeks).

Both Group 1 and Group 2 patients will not receive topicals or any other therapies except Secukinumab during the study periods, including placebo and observation periods.

Secukinumab is dosed weekly for the first 4 weeks (ramp up) the monthly (maintenance). In order to maintain the blind for the 2 dose groups, group 1 will resume weekly injection weeks 12 through 16. The injections given at weeks 13, 14, and 15 will be placebo.

Visit			Group 1	Group 2	Skin biopsy & blood
1	Screening	Screening			
2	baseline	baseline	Secukinumab 300 mg	Placebo	Skin biopsy & blood

3		week 1	Secukinumab 300 mg	Placebo	
4		week 2	Secukinumab 300 mg	Placebo	
5		week 3	Secukinumab 300 mg	Placebo	
6	month 1	week 4	Secukinumab 300 mg	Placebo	
7	month 2	week 8	Secukinumab 300 mg	Placebo	
8	month 3	week 12	check primary endpoint (IGA 0,1 at week 12)		Skin biopsy & blood
			Secukinumab 300 mg	Secukinumab 300 mg	
9		week 13	Placebo	Secukinumab 300 mg	
10		week 14	Placebo	Secukinumab 300 mg	
11		week 15	Placebo	Secukinumab 300 mg	
12	month 4	week 16	Secukinumab 300 mg	Secukinumab 300 mg	
13	month 5	week 20	Secukinumab 300 mg	Secukinumab 300 mg	
14	month 6	week 24	Secukinumab 300 mg	Secukinumab 300 mg	Skin biopsy & blood
			observation	observation	
15	month 9	week 36			
16	month 12	week 48			
17	month 15	week 60			
18	month 18	week 72	check secondary endpoint (recurrence)		Skin biopsy & blood
	*Optional skin biopsy and blood : when recurrence occurs after week 24				

Study Visits

Visit 1--Screening Visit/Enrollment

- Vital signs (weight, height, blood pressure, temperature, heart rate, respiration)
- Physical exam and questions your general health
- Serum pregnancy if female of child-bearing potential
- POCT HIV
- Blood for Hepatitis B (antibody as well antigen) and C, Comprehensive metabolic panel, Lipid panel, Hgb A1c, CBC and optional QuantFERON-TB Gold (only if no PPD screen)
- Assessment of psoriasis status using several scales: Investigator Global Assessment (IGA), Psoriasis Area and Severity Index (PASI) with BSA, Dermatology Life Quality Index (DLQI), PASE
- PPD / TB skin test or QuantiFERON-TB Gold

Visit 1.1--PPD Reading Visit

- If PPD was placed at Screening Visit, PPD reading 48 hours later
- Chext X-Ray. (If PPD Positive)

Visit 2--Baseline visit (and first dose)

- Medications history
- Physical exam (symptom driven as indicated)
- Vital signs (weight, body temperature, heart rate and blood pressure)
- POCT Pregnancy
- Fasting Blood PAX DNA/RNA, CBC, SST (serum storage) sample, Comprehensive Metabolic Panel, Lipid panel, and Hgb A1c.
- Two 6mm skin biopsies, 1 lesional, 1 non-lesional.
- Medical photography
- Assessment of psoriasis, PGA, PASI with BSA, PASE, DLQI
- Adverse event assessment
- Dose of Secukinumab or placebo by subcutaneous injection.
- Observation period of 15 minutes (+/- 5 minutes) post study drug administration
- Subject will be offered a meal at end of visit.

Visit 3 to 7 and 9 to 13 --(Week 1 to 8 and 13 to 20)

- Physical exam (symptom driven as indicated)
- Vital signs (blood pressure, temperature and pulse).
- POCT Pregnancy
- Assessment of psoriasis, PGA, PASI with BSA, PASE, DLQI
- Adverse event assessment
- Dose of Secukinumab 300 mg or placebo by subcutaneous injections

Visit 8 and 14 –-(Week 12 and 24)

- Physical exam (symptom driven as indicated)
- Vital signs (blood pressure, temperature and pulse).
- POCTPregnancy
- Fasting Blood: Comprehensive metabolic profile, CBC, lipids and HgB A1c.
- Research blood
- Two 6mm skin biopsies, 1 lesional, 1 non-lesional. The lesional sample will be taken from the area the lesions were before.
- Medical photography
- Assessment of psoriasis, PGA, PASI with BSA, PASE, DLQI
- Adverse event assessment
- Dose of Secukinumab 300 mg or placebo by subcutaneous injection
- Observation period of 15 minutes (+/- 5 minutes) post study drug administration week 12 only
- Subject will be offered a meal at end of visit

Visit 15,16, and 17 —(Week 36, 48 and 60) Observation

- Physical exam (symptom driven as indicated)
- Vital signs (blood pressure, temperature and pulse)
- POCT Pregnancy
- Assessment of psoriasis, PGA, PASI, with BSA, PASE, DLQI
- Adverse event assessment

Visit 18 –(Week 72)

- Physical exam (symptom driven as indicated)
- Vital signs (blood pressure, temperature and pulse)
- POCT Pregnancy

- Fasting Blood: Comprehensive metabolic profile, CBC, lipids and Hgb A1c
- Reseach Blood
- Skin biopsy is optional when recurrence occurs after Week 24. Two 6mm skin biopsies, 1 lesional, 1 non-lesional. The lesional sample will be taken from the area the lesions were before.
- Medical photography
- Assessment of psoriasis, PGA, PASI with BSA, PASE, DLQI
- Adverse event assessment
- Observation period
- Subject will be offered a meal at end of visit.

*Visit window will be +/- 1 day for weekly visits (weeks 1, 2, 3, 4, 13, 14, 15,16) and +/- 2 days for all other visits (weeks 8, 12, 20, 24, 36, 48, 60, 72).

Unscheduled Visit--(as necessary)
Subjects will return to RUH for evaulation and/or additional blood work, as per the PI's discretion.

Relapse Visit

- Reseach Blood
- Skin biopsy is optional. Two 6mm skin biopsies, 1 lesional, 1 non-lesional.
- Medical photography
- Assessment of psoriasis, PGA, PASI with BSA, PASE, DLQI
- Adverse event assessment

Early Termination visit

- Reseach Blood
- Skin biopsy is optional. Two 6mm skin biopsies, 1 lesional, 1 non-lesional.
- Medical photography
- Assessment of psoriasis, PGA, PASI with BSA, PASE, DLQI
- Adverse event assessment

Translational research: 6-mm punch skin biopsies from lesional and non-lesional skin and blood samples will be obtained at baseline and weeks 12, 24, 72, at the time of psoriasis relapses, and at early termination. Genomic profiling of psoriasis skin will be conducted with the Affymetrix Human Genome U133 Plus 2.0 Array and RT-PCR. The phenotypes of activated T cells and regulatory T cells in psoriasis patients' blood will be studied by flow cytometry. Inflammatory and cardiovascular proteins in the blood will be investigated to develop a biomarker with Proximity Extension Assay technology (OLINK®).

Structure: Double Blind, Two-arm parallel group design, Randomized 1:1.

12.10 * Data Analysis

Describe method(s) of data analysis.

For the comparison between proportions a Fisher exact test will be performed in any case. The results will be presented as contingency tables and odd ratios will be calculated. 95% Confidences Intervals will be provided. To achieve the primary objective

The comparison between times of relapse must be done using a Wilcoxon-Mann-Whitney test. A Kaplan Meier analysis will be used to establish the relapse survival curve for each group and

the log-rank test will be made. A step-down hierarchical closed testing procedure will be done considering the order: PASI75, PASI90, IGA0.

12.11 * Explain the rationale for the choice of statistical measures and the number of participants proposed for the study, including the power calculations when applicable.

1.Sample Size Calculation for Primary Objective/First outcome (3 co-primary endpoints are subject to a step-down hierarchical closed testing procedure)

Langley et al. (2014) presented the results of two Phase 3 trials for Secukinumab: ERASURE and FIXTURE. Among others outcomes Langley reported the proportion of subjects with moderate or severe Psoriasis who achieve PASI75 (PASI score improvement over 75%) after 12 weeks of treatment in the 2 cohorts treated with Secukinumab 300 mg and the 2 Placebo cohorts with 245, 323, 246 and 324 subjects respectively. The worst scenario observed on Langley's results is: largest Placebo proportion=0.05 and smallest Secukinumab proportion=0.77. Assuming Langley's results as preliminary data, to find significant differences between groups by using a one-tail Fisher exact test with power equal to 0.95 and 99.9% of significance level, a sample size of 19 patients at each group (N=38) will be required. Considering the 5.6 % of dropout reported by Langley will be necessary to recruit 20 patients for each group (N=40). Power analysis for 3 co-primary endpoints and 19:19 patients is reported in the following table:

ENDPOINT	TREATMENT OBSERVED PROPORTION *	PLACEBO OBSERVED PROPORTION *	OBSERVED EFFECT SIZE*	SIGNIFICANCE LEVEL	POWER	DETECTABLE EFFECT SIZE
PASI 75	0.77	0.05	0.72	0.05	0.8	**0.49**
				0.05	0.9	**0.55**
				0.05	0.95	**0.60**
				0.01	0.8	**0.42**
				0.01	0.9	**0.48**
				0.01	0.95	**0.54**
PASI 90	0.54	0.02	0.52	0.05	0.8	**0.4**
				0.05	0.9	**0.47**
				0.05	0.95	**0.52**
				0.01	0.8	**0.52**
				0.01	0.9	**0.59**
				0.01	0.95	**0.63**
IGA0	0.24	0.01	0.23	0.05	0.8	**0.37**
				0.05	0.9	**0.44**
				0.05	0.95	**0.50**
				0.01	0.8	**0.50**
				0.01	0.9	**0.56**
				0.01	0.95	**0.61**

OR

ENDPOINT	TREATMENT OBSERVED PROPORTION *	PLACEBO OBSERVED PROPORTION *	OBSERVED EFFECT SIZE*	SIGNIFICANCE LEVEL	ESTIMATED POWER TO DETECT OBSERVED EFFECT SIZE
PASI 75	0.77	0.05	0.72	0.05	0.99
				0.01	0.99

PASI 90	0.54	0.02	0.52	0.05	0.99
				0.01	0.94
IGA 0	0.24	0.1	0.14	0.05	0.46
				0.01	0.25

* Langley et al. (2014)

2.Power Analysis for Exploratory Objectives/First outcome

Assuming the proportion of 300 mg secukinumab patients who achieve PASI 100 at week 24 as reported by Langley (0.4), the allocation ratio of subjects who achieve PASI 100 and subjects who not achieve PASI 100 for Group 1 (6 month of Secukinumab) will be 8:11. On that case a Fisher exact test to compare the proportion of patients who experience relapse with power equal to 0.80 and 95% of significance level will be able to detect significant differences only if the following relationship between proportions is observed:

Proportion of patients from Group 1, who achieve PASI 100 at week 24 and experience relapse	Proportion of patients from Group 1, who not achieve PASI 100 at week 24 and experience relapse
0.00	0.45
0.13	0.73
0.25	0.82
0.38	0.91
0.50	1.00

Assuming the proportion of 300 mg secukinumab patients who achieve PASI 100 at week 12 as reported by Langley (0.3), the allocation ratio of subjects who achieve PASI 100 and subjects who not achieve PASI 100 for Group 1 (6 month of Secukinumab) will be 6:13. On that case a Fisher exact test to compare the proportion of patients who experience relapse with power equal to 0.80 and 95% of significance level will be able to detect significant differences only if the following relationship between proportions is observed:

Proportion of patients from Group 2, who achieve PASI 100 at week 24 and experience relapse	Proportion of patients from Group 2, who not achieve PASI 100 at week 24 and experience relapse
0.00	0.54
0.17	0.77
0.33	0.85
0.50	1.00

With the previous assumptions, the allocation ratio of subjects who achieve PASI 100 in Groups 1 and 2 will be 8:6. On that case a Fisher exact test to compare the proportion of patients who experience relapse with power equal to 0.80 and 95% of significance level will be able to detect significant differences only if the following relationship between proportions is observed:

Proportion of patients from Group 1 who achieve PASI 100 at week 24 and experience relapse	Proportion of patients from Group 2 who achieve PASI 100 at week 24 and experience relapse
0.00	0.67
0.13	0.83
0.25	1.00

3.Power Analysis for Exploratory Objective/Second outcome

To compare the time to relapse between groups with a sample size of 19:19 a Wilcoxon-Mann-Whitney test for nonrelated samples with power equal to 0.8 and 95% of significance level will be able to detect differences only if the effect size observed is equal or larger than 0.96

12.12 * Will samples be coded?

(•) Yes ( ) No

If Yes, Please describe coding scheme consistent with GCP. If samples will not be coded, please provide justification for this proposed departure from GCP practice.

Samples will be coded using GCP with the following sequence

NSK__-001. NSK__-002, etc.

If available, upload the Data and Sample Sharing Management Plan approved by RU IT.

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.						

13.0 Participants of Study

13.1 Specify age range of participants:

* Minimum Age:

18

* Maximum Age:

99

Please note: If the age of participants indicated is less than 18 years old, you will be prompted to attach a Pediatric Assent form later on in the submission process. A link to the Pediatric Assent form can be found in the Help link to the right, or this form can be downloaded later on in the submission process.

13.2 * Indicate the gender(s) of the participants:

- [x] Female
- [x] Male
- [ ] Unknown
- [ ] Not Reported

13.3 * Indicate projected enrollment by race and ethnicity. See Help for disease/volunteer population demographics.

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	6	5	0	11
Not Hispanic or Latino	12	17	0	29
Unknown				

(individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	18	22	0	40
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	2	3	0	5
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	6	9	0	15
White	10	10	0	20
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	18	22	0	40

13.4 * Will participants of a specific racial/ethnic group be excluded from participation?

○ Yes ◉ No

13.5 Gender/Minority Exclusion Justification

All research involving human participants should be designed and conducted to include members of both genders and members of minority groups, unless a rationale and justification is provided. Please provide such justification below:

13.6 Vulnerable Populations

Indicate whether any of the following populations will be included in the study:

- ☐ Children
- ☐ Pregnant Women
- ☐ Cognitively Impaired Persons
- ☑ RU Employees
- ☑ RU Students
- ☐ Other:

If you checked any of the above, give a brief explanation of the need to use these particular individuals:

RU employees and students will be enrolled if they meet eligibility. Special precautions will be used in recruiting employees and students of the Rockefeller University to minimize the possibility of undue influence. Subjects will be reassured that refusal to participate in the study will not affect their studies or employment in any way and that all medical records will be kept in accordance with HIPAA guidelines to ensure privacy.

If the participant is a Rockefeller University employee, does she/he work within the Laboratory of the Principal Investigator or Co-Investigator(s)?

- (•) Yes
- ( ) No
- ( ) N/A

If the participant is a Rockefeller University student, does she/he work within the Laboratory of the Principal Investigator or Co-Investigator(s)?

- (•) Yes
- ( ) No
- ( ) N/A

13.7 *What is the total number of evaluable participants you plan to enroll at Rockefeller University Hospital over the course of the entire study?

40

13.8 * What is the total number of participants who will need to sign consent *at Rockefeller University Hospital over the course of the entire study* to result in the desired number of evaluable participants?

60

13.9 * What is the total number of participants you plan to sign consent *at Rockefeller University Hospital in the next year?*

0

13.10 * What will be the total number of evaluable participants *at all sites over the course of the entire study?*

40

13.11 Inclusion Criteria

Please list participant inclusion criteria:

Order Number	Criteria
1	Written informed consent must be obtained before any assessment is performed
2	18 years of age or older
3	Chronic plaque-type psoriasis for at least 6 months
4	Have a PASI between 6 and 12 and Body Surface Area (BSA) affected by plaque-type psoriasis less than 10% at screening
4	Negative PPD (negative chest w-ray if positive) or negative QuantiFERON-TB Gold.
5	Willing to wash off steroid creams and UVB therapy for 2 weeks prior to the basline visit

13.12 Exclusion Criteria

Please list participant exclusion criteria:

Order Number	Criteria
1	Has a nonplaque form of psoriasis (eg, eythrodermic, guttate, or pustular)
2	Has previously recieved Secukinumab or other biologics
3	History of Inflmmatory Bowel Disease (IBD)
4	History of Rheumatoid Arthritis
5	Use of topical treatments for psoriasis, including steroids, vitamin D derivatives, vitamin A derivatives, salicylic acid, tar (except moisturizures) and/or UVA/UVB phototherapy within the last 2 weeks (if these have used them, the participant needs to wash off of them for at least 2 weeks after signing consent prior to baseline)
6	Is pregnant, nursing, or planing a pregnancy (both men and women) within 5 months following the last administration of study drug
7	Has recently received or is planning to receive a vaccination while on the study
8	HIV positive
9	Chronic untreated hepatitis C, positive hepatitis B surface antigen
10	Known tuberculosis (TB) or evidence of TB infection. Subjects with a positive QuantiFERON® TB test or a positive purified protein derivate (PPD) skin test result may participate in the study if further work up (according to local practice /guidelines) establishes conclusively that the subject has no evidence of active TB.
11	Any severe, progressive or uncontrolled medical condition at screening that in the judgment of the investigator prevents the subject from participating in the study.

14.0 Study Plan

14.1 * Describe the study plan:

*** What is the total number of outpatient visits for all participants projected for the next year?**

50

*** What is the average length of each outpatient visit (in hours)?**

2

*** What is the total number of Day Patient visits for all participants projected for the next year?**

0

*** What is the average length of each Day Patient visit (in hours)?**

0

*** What is the total number of inpatient days for all participants projected for the next year?**

0

14.2 *Number of Patients per arm

Study Arm	Number of Patients
Group 1	20
Group 2	20

15.0 Investigational and Support Medications

15.1 List all the investigational medications

See Help for link to Rockefeller University Research Pharmacy web page for additional information.

View Details	Drug Name	FDA Approved	IND Number
⊟	**Trade Drug Name:** Cosentyx **Generic Drug Name:** Secukinumab **Investigational Drug Name:**	Yes	

Trade Drug Name:	Cosentyx
Generic Drug Name:	Secukinumab
Investigational Drug Name:	
Identify the name of the manufacturer or source of investigational drug/biologic:	Novartis
Is the Drug FDA Approved:	Yes
Is an IND necessary	No
IND Number	
Who holds the IND:	N/A
IND details:	The PI will file an IND exemption and will not initiate the study until the FDA determination has been submitted and acknowledged by the IRB.
Are you currently using this IND in another research project?	No
If yes, list the IRB Number(s):	
Dose(s):	
Dosing Frequency:	

15.2 * Will the study involve the use of a placebo?

(•) Yes ( ) No

If yes, complete A and B.

A. Is there a proven effective therapy for the condition under study?

(•) Yes ( ) No

If Yes, please specify:

Corticosteroid cream/ointment, vitamin D derivative cream/ointment, vitamin A derivative cream /ointment, salicylic acid, tar, topical Ulatraviolet-A phototherapy, and Narrow Band Ultraviolet-B (NB-UVB) phototherapy.

B. Please give a justification for the use of the placebo.

From baseline to week 8, the use of the placebo is necessary to determine whether any improvements on histological skin reversal are directly due to Secukinumab or simply reflect spontaneous healing. Of note, in a subset of patients placebo treatment per se improves psoriasis (estimated placebo response rate 5-10%). Patients randomized to the placebo group will be receiving Secukinumab treatment from week 12 onwards in order to minimize the amount of time spent without active treatment. From week 13 to week 15, the use of the placebo is necessary to maintain double-blind, parallel-group design.

15.3 Study support medications are medications that will support the conduct of the study. Please list all support medications to be used in the study (include all prescription drugs, over the counter drugs herbs, and supplements).

16.0 Consent Procedure

16.1 * This study will use the following types of informed consent:

- [x] Informed Consent Form Standard - a standard consent form with instructions for adapting it to your study
- [ ] Consent Form Genetic- a consent form designed for a study where genetic testing (as defined by NYS law) is to be done in the CURRENT study
- [ ] Consent for studies including genome wide sequencing
- [ ] Pediatric Assent Form (To be used in addition to Consent) for Pediatric patients
- [ ] Other (e.g., waivers)

Links to the **Standard Consent, Genetic Testing Consent** and the **Pediatric Assent** forms can be found in the Help link to the right, or these forms can be downloaded later on in the submission process.

16.2 * Indicate the consent process to be used. (See Help for CCTS SOP)

Describe how the required information is being presented to participants (consent form, orally, information sheet, etc.). Attach a copy of what is being presented to participants (usually the ICF and Assent forms).

Prior to the initiation of any study related procedures, the potential subjects will be given a copy of the most recent IRB stamped and approved informed consent form to read. Additionally, the

PI or study staff member who has been designated and is proficient in the consent form process will discuss the specifics of the study including but not limited to the purpose of the research, procedures, time commitment, required tasks, test article or device, alternative treatments, benefits, risks, confidentiality etc. in a comprehensible (non-scientific) manner, using language readily understandable by the subject. Subjects will be told that participation is voluntary and that, if they do not give informed consent, they will not be penalized. The person obtaining informed consent will assure the voluntariness of the subject.

Describe the circumstances under which consent will be obtained, where the process will take place and any waiting period between informing the prospective participant and obtaining consent.

A private, confidential setting will be provided for the potential subject to read and discuss the informed consent form free from coercion, undue influence or constraints of time. All subjects will be given a chance to ask questions and express concerns. They will be given the option to take the consent form home and discuss it with family, friends, and /or health care providers. After a subject and the person conducting the informed consenting process, signs and dates the consent form, the subject will be given a copy of the signed informed consent form for their records. An enrollment note will be written in the source document as to who obtained consent, how, when, where, questions asked and answered, and that a copy of the informed consent was given to the subject.

Describe the experience of the investigators designated for this task in the DOA in obtaining consent from participants.

The following staff all have experience enrolling participants in clinical trials, Jaehwan Kim, Patricia Gilleaudeau. Norma Kunjravia has completed her Consent training.

How will it be determined that the participants or the participants' authorized representatives understand the information presented?

The "Teach Back" method will be used in the clinical research setting to ask research participants to repeat or “teach back” the information, concepts and directions that the staff member has attempted to convey to the participant. This method is used to assess comprehension and retention of protocol requirements, adverse event information, risks and benefits, and the participant's rights described in the Informed Consent process.

If English is not the participants' native language, how will written and/or verbal translation be provided?

Under rare circumstances where English is not the native language a short form consent will be used together with the use of a certified translation service (Pacific Interpreters)

Will any participants be cognitively impaired so that they may not have the capacity to give consent?

○ Yes ◉ No

For participants where it has been determined that they lack the capacity to give consent, describe the provisions for obtaining consent from the participants' legally authorized representative.

16.3 * Based on the demographics, will this study's participant population require foreign language consent form?

○ Yes ◉ No

16.4 * This study's consent procedure will require the following waivers: (See Help for additional information.)

- ○ Waiver of one or more elements of informed consent, 45CFR46.116(d)
- ○ Waiver of documentation of informed consent, 45CFR46.117(c)
- ◉ No waiver is requested

16.5 * Does this study include video/audio recording, photography or other electronic recording of human participants?

◉ Yes ○ No

16.6 Please select from following:

- ☑ Photography
- ☐ Video Recording
- ☐ Audio Recording
- ☐ Other Electronic Recording

16.7 Describe what will be done:

This protocol involves medical photography of areas of the body involved by psoriasis lesions. Photographs will be taken prior to biopsies to capture the extent of involvement, and in some cases after biopsy to document the biopsy locations. A designated member of the research team will take the medical photographs and make every effort to maximize privacy by the use of drapes or clothing to minimize exposure of uninvolved body parts. If photographs of sensitive areas of the body are planned, a chaperone should be present for the photography. The participant may ask for a chaperone for photography of any body area. Names are not attached to the photographs; the photographs will be coded using the study participant ID, and stored securely on an encrypted digital device. Photography of identifying marks, such as birthmarks or tattoos will be avoided. When facial photographs are planned, participants may be offered goggles to make identification harder. Images that are not personally identifiable may be used in research presentations and publications pertaining to the research. Digitally stored images may be preserved for research purposes. When images are of no additional research value, they will be destroyed and the destruction of the photographs logged. The research team follows the Rockefeller Hospital policy relevant to medical photography of research participants.

17.0 Recruitment and Advertising

For assistance consult CRSO to create a robust Recruitment Plan see Help.

17.1 * What is the plan for recruitment?

Recruitment is now closed.

17.2 *From the date of final IRB approval, how long will it take to complete enrollment of the study?

- ○ 6 Months
- ◉ 12 Months
- ○ 18 Months
- ○ 24 Months
- ○ More than 2 years (specify in years)

17.3 This Study

- (•) Involves an intervention or comparison and a defined enrollment target
- ( ) Is a natural history study with expected annual enrollment over many years
- ( ) Is an exploratory mechanistic study
- ( ) Other

17.4 This Study will enroll:

- ( ) Healthy volunteers
- (•) Individuals affected with a specific disease/disorder
- ( ) Both

17.5 * Do you plan on using the Research Participant Repository (RKO-0648) ?

(•) Yes ( ) No

17.6 * Are you screening or recruiting from or through a record review of an existing patient database of a healthcare provider?

( ) Yes (•) No

17.7 * Please describe how the Recruitment Plan addresses recruitment of the volunteers consistent with the demographics of the condition under study:

Recruitment is now closed.

17.8 * Do you plan to advertise directly to potential volunteers? (As opposed to relying on practitioner referrals or flyers to practitioners)

( ) Yes (•) No

17.9 * Do you plan to use the free, web-based volunteer registry, ResearchMatch.org, as a recruitment tool?

( ) Yes (•) No

18.0 Research Participant Repository (RKO-0648)

18.1 This protocol, will be linked with the Research Volunteer Screening/Recruitment Data Repository run by the Recruitment staff and the Clinical Research Support Office (protocol RKO-0648-1008). In order to participate in the generation of the Repository the PI will enter into a Collector/Collaborator agreement regarding the Repository. The role of Collector/Collaborator is to contribute to the Repository the name, contact and demographic information, recruitment referral information, and screening outcome information, as well as appropriate protocol specific screening information, of volunteers who are screened by telephone or in person for entry into the protocol regardless of the screening outcome. In addition to screening volunteers for the PI's current study, verbal consent will be obtained from the volunteers regarding their willingness to be contacted in the future about possible additional research studies. This permission may be obtained by the Recruitment office staff through the central Call Center. If the PI receives calls directly from participants for initial prescreening, then the PI is responsible for collecting the required information and conveying it to the Recruitment staff for data entry. The consent or withholding of permission will be recorded in

the Repository as will the name of the person who obtained the permission. A volunteer's permission or declination will not affect their eligibility for my current protocol, or future protocols. The Recruitment staff of the Clinical Research Support Office may gather the Repository information and request the verbal consent of the volunteer for re-contacting on my behalf as part of our recruitment plan. In order to benefit from the Repository, the PI will enter into a Recipient/Collaborator agreement with the Repository. The Recipient/Collaborator may receive from the Repository pre-screened lists of potentially eligible participants for his/her study as a means to facilitate recruitment. The Recruitment staff will prepare the Repository queries according to the protocol eligibility requirements and available Repository information, and may re-affirm permission to re-contact volunteers as necessary. The PI may use the information and names in the list from the Repository only for the current study and may not save the list to use for a future study of his/her own, nor may he/she share the list with colleagues for other studies."

19.0 Potential Benefits to Participants

19.1 * Will participation in this study provide direct benefits to the participant?

(•) Yes ( ) No

19.2 If Yes, describe the potential direct benefits:

Participants will receive secukinumab, which is a biologic drug approved by FDA for moderate-to-severe psoriasis, for 3 months or 6 months of period.

20.0 Potential Risks to Participants

20.1 * Describe any potential risks: physical, psychological, social, legal or other and assess their likelihood and seriousness. Indicate risks both to the participants and to the embryo or fetus if the participant is or may become pregnant. Please provide the potential risks below:

Potential side effects associated with study drug (Secukinumab) includes but is not limited to infection, inflammatory bowel disease, and allergic reactions.

Infections
Because Secukinumab suppresses the immune system, it may increase the risk of infections. In clinical trials with patients who had moderate to severe psoriasis, a higher rate of infections was observed in Secukinumab treated subjects compared to placebo-treated subjects. A higher rate of common infections, such as nose and throat (11.4% vs 8.6%), upper respiratory infection (2.5% vs 0.7%) and skin and mucous membrane candida (1.2% vs 0.3%) were observed with Secukinumab compared with placebo. A similar increase in risk of infection was seen in placebo-controlled trials in patients with psoriatic arthritis and ankylosing spondylitis.

Inflammatory Bowel Disease
In clinical trials of patients with plaque psoriasis, psoriatic arthritis and ankylosing spondylitis, there has been worsening of known inflammatory bowel disease, in some cases serious. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with Secukinumab. In an exploratory study in 59 patients with active Crohn's disease, there were trends toward greater disease activity and increased adverse events in the Secukinumab group as compared to the placebo group. Patients who are treated with Secukinumab should be monitored for signs and symptoms of inflammatory bowel disease.

Allergic Reactions
Sometimes peole have allergic reactions to drugs. Anaphylaxis and cases of hives occurred in Secukinumab treated patients in clinical trials. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction are:

- A rash
- Difficulty breathing
- Wheezing
- A sudden drop in blood pressure

- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Cancer
Drugs similar to Secukinumab have been known on rare occasions to be associated with certain cancers. This has not been observed with Secukinumab.

Risks Related to Skin Biopsy
During the injection of the local anesthetic to numb subject for the skin biopsy, there may be a burning sensation that will last only seconds. There may be a feeling of pressure or tugging while the biopsy is being performed. Occasionally people faint or feel faint during the biopsy procedure. There is a small chance that the skin biopsy site could become infected.

These skin biopsy sites heal in a variety of ways. The final appearance will depend in part on the area of the body biopsied, the reason for the biopsy, and the underlying skin appearance before the biopsy. Scars may continue to change for many years after the sutures are removed. In addition, everyone heals differently, and it is possible that the scars may be red for some time, or become raised, darker or lighter than the surrounding skin. Subject will most likely have a permanent scar of some kind.

Risks Related to a Blood Draw
Potential risks associated with having blood drawn include discomfort, pain, bleeding, bruising, infection at the needle site, and fainting or feeling lightheaded.

Risks Related to Completing Questionnaires
Subject may feel anxious while completing the questionnaires.

Privacy Risks
There is the risk that there could be computer security breaches which could reveal subject's identity. There may be the risk that data about the subject may become public, and could be used by employers or law enforcement agencies.

Contraception and Pregnancy
Animal studies so far have not shown that Secukinumab harms an unborn or nursing baby. The risks to humans are not known.

21.0 Procedures to Minimize Risks

21.1 * Describe the procedures for protecting against or minimizing any potential risks, and include an assessment of their likely effectiveness. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing medical treatment, if needed.

The increased risks of infections are minimized by screening for latent tuberculosis infection. The risks of infection are also minimized by reporting any infections to the Study Team or the Study Staff, as well as any fever, chills, loss of appetite, throat pain, cough or colds. In some cases of infection, the Study Team may decide that the study drug should be discontinued.

The risks of exacerbating autoimmune disorders is minimized by screening for and excluding individuals with known inflammatory bowel diseases. Any change in bowel habits, including diarrhea, cramps, and blood in the stool, will be reported to the Study Team during the study.

If an allergic reaction occurs, administration of Secukinumab will be discontinued immediately and appropriate medical therapy will be given. Subject will be asked to remain at the Study Site for two hours following administration of the Study injections. Subject will be observed during this time for any sensitivity reactions. Subject should get medical help and contact the Study Team if subject have any of these or any other side effects during the study.

Women who are pregnant or nursing must not participate in this trial. The risks of teratogenicity are minimized by screening for pregnancy at each visit. If subject is a woman who is able to become pregnant, subject should use an effective form of birth control (contraception) during the study and for 20 weeks after the last dose of study drug. Subject may choose to use an occlusive cap (diaphragm or cervical/vault cap) with spermicide or subject's male partner can use a condom combined with a spermicidal foam/gel/film/cream/vaginal suppository. The following methods are more effective and are also acceptable: 1) total abstinence from male/female intercourse, or 2) male/female sterilization or 3) use of oral, injected of implanted hormonal methods of contraception (in case of oral contraception subject should have been using the same pill on a stable dose for a minimum of 3 months before taking study drug), or 4) placement of an intrauterine device (IUD) or intrauterine system (IUS). If subject

becomes pregnant or suspect being pregnant during the study, subject must inform the Study Team immediately. Subject will not be allowed to continue study drug if subject is pregnant. Study Team will medically follow subject's pregnancy and collect information about the pregnancy until delivery to monitor the subject and subject's child's safety.

Skin biopsies will be performed using sterile technique. Treatment of the area post-procedure will include the use of an antibiotic ointment and the application of dry, sterile dressing. The subject will be taught how to care for the biopsy site and will be given the supplies to do so. All procedures will be performed by trained qualified staff.

Samples of skin are to be identified by number and not by patient name in an effort to protect confidentiality. A confidential master codebook will be kept by the PI. The study coordinator, or investigator, manages protocol-specific data on paper forms organized by patient number and/or study. These are kept in a secure, double-locked area of the lab. All lab personnel that work with patient data or samples have passed human subject protection courses and will keep data confidential in designated laboratory files. Data are not recorded in computerized spreadsheets, except for final analysis of data. Since Microsoft Excel is often used for data analysis, only the primary "sheet" is used and data cannot be copied to another sheet. Data entries are certified against primary source documents in the lab.

22.0 Alternative Methods or Treatments

22.1 * Describe alternative methods or treatments for the disease(s) under study, if any, that were considered and why they will not be used:

Alternative methods for treating mild, chronic plaque-type psoriasis include Corticosteroid cream /ointment, vitamin D derivative cream/ointment, vitamin A derivative cream/ointment, salicylic acid, tar, topical Ulatraviolet-A phototherapy, and Narrow Band Ultraviolet-B (NB-UVB) phototherapy.

23.0 Data and Safety Monitoring

This section describes the Data and Safety Monitoring Plan (DSMP) required of each protocol undertaken at the CCTS according to HRPP and NIH policies Notice 98 -084 and Notice 00-038, as cited in Help Sections below. Depending on the level or risk and trial phase, some protocols will need Data and Safety Monitoring Boards.

23.1 * Overall Risk Classification

An estimate of risk is necessary to evaluate the adequacy of the planned monitoring. The HELP section provides guidance in making the risk assessment.

Read the risk definitions and examples of risk in the HELP section and select the risk category that best describes the current study.

If your assessment differs from the definitions the HELP section, describe any factors that modify your judgment of the overall risk in the text box after the risk designation.

- ○ MINIMAL RISK
- ○ LOW RISK
- ◉ MODERATE RISK
- ○ SIGNIFICANT RISK

Please provide any optional description(s):

23.2 Protocols Involving Minors

The chance of direct benefit to the child, or to understanding a disorder not otherwise understood, may be major factors in justifying more than minimal risk in research involving children.

Based on the above definitions, please specify your study's risk classification below:

- ○ NOT GREATER THAN MINIMAL RISK (the risk of daily life to a healthy child living in a safe environment) 45 CFR 46.404
- ○ GREATER THAN MINIMAL RISK WITH DIRECT BENEFIT TO PARTICIPANT; 45 CFR 46.405
- ○ GREATER THAN MINIMAL RISK, NO DIRECT BENEFIT, BUT BENEFIT TO UNDERSTANDING OF PARTICPANT'S DISORDER; 45 CFR 46.406
- ○ RESEARCH NOT OTHERWISE APPROVED PRESENTING OPPORTUNITY TO UNDERSTAND, PREVENT OR ALLEVIATE SERIOUS PROBLEM AFFECTING CHILDREN 45 CFR 46.407 (cannot be approved by IRB; requires public comment)

23.3 DSMB

1. The NIH requires that all SIGNIFICANT RISK protocols have a **Data and Safety Monitoring Board** and provide information about the expertise and independence of that Board
2. Phase III trials require a Data and Safety Monitoring Board,
3. A DSMB may be appropriate for some Phase I and II protocols. (See Help for examples.)
4. It is the investigator's responsibility to report to the IRB, the findings and recommendations of the DSMB as they become available.

Please specify:

- ○ A DSMB is required for this study
- ◉ A DSMB is not required for this study
- ○ Unsure

If a DSMB is not required, but is being constituted for other reasons, please explain:

23.4 * Safety Review

Select one:

- ◉ Safety Review is conducted as follows: Laboratory results for research volunteers will be reviewed in a timely manner, usually within 24 hours of receipt by a licensed practitioner. The potential clinical significance of any abnormal finding will be documented in the medical and research record(s), and an appropriate plan or referral developed. The PI's review of safety issues at research team rounds will be documented in the meeting minutes.
- ○ Protocol Specific

23.5 Monitoring

Monitoring Personnel: See Help Bubble to the right.

Internal Monitoring

The PI or his/her designee shall conduct internal monitoring to assure the safe and proper conduct of the protocol and all the elements list above in monitoring, following the general principles of quality management. The intensity and frequency of internal monitoring will depend on the protocol risk to participants, the experience of the PI and research team, rate of enrollment, and specific details of the protocol.

Internal monitoring of informed consent and eligibility documentation will be conducted by the research team shortly after enrollment begins. Internal monitoring activities will be documented by logs, meeting minutes or other systematic means.

Specify the research team members who will conduct the internal monitoring of the study (see Help for who may monitor):

Internal monitoring will be performed by Pat Gilleaudeau

For new investigators: Internal monitoring should be conducted at least monthly by new investigators until there are essentially no findings to correct at each review.

External Monitoring

* Is external monitoring planned for this protocol?

- ○ Yes
- ◉ No
- ○ Unsure

If external monitoring is planned, please specify (see Help for who may monitor):

- ○ (Significant Risk) External monitoring will occur at least every six weeks unless there is no enrollment
- ○ (Moderate Risk) External monitoring will occur at least quarterly
- ○ (Low or Minimal Risk) External monitoring will occur at least annually

If external monitoring is planned, please specify the name of the monitor:

- ☑ Note that copies of external monitoring reports must be supplied to the IRB and the CRSO as soon as they are made available

Additionally, audits of the research records of minimal, moderate or significant-risk protocols may be performed by the CRSO staff on a random basis or as part of a prospectively identified auditing plan.

23.6 Adverse Event Classification

Adverse events are classified by definition, severity, and association with the investigational trial.

Definition of an Adverse Event
Any unfavorable or unintended sign (including abnormal lab findings), symptom or disease temporally associated with the use of a medical treatment or procedure, or protocol, regardless of whether it is considered related to the medical treatment or procedure or protocol.

Definition of a Serious Adverse Event
Any unanticipated event that involves the following:
- o results in death
- o is life-threatening
- o requires hospitalization or prolongs existing hospitalization
- o results in persistent or significant disability/incapacity
- o is any medical event which requires treatment to prevent one of the outcomes listed above

Other events can be classified as "serious adverse events" at the discretion of the PI.

Definition of Anticipated/Expected Adverse Event

Any adverse event, which has been reported in the Investigator's Brochure, package insert, safety reports, clinical protocol, consent form or listed in the NCI agent-specific Expected Adverse Event List[3], is classified as an expected adverse event. The investigator must provide the available data of known adverse events and toxicities that have been associated with the study drug, device, intervention, or procedures. This information helps to define the level of risk of the trial and enables safety monitoring. A minimal risk trial may not have any defined risks and a statement to that effect is sufficient to meet the DSMP requirements.

Definition of an Unanticipated/Unexpected Adverse Event
Any adverse event that is not consistent with the known, predicted possible effects of the research protocol. An unexpected adverse event varies in nature, intensity or frequency from information on the investigational product provided in the Investigator's Brochure, package insert, safety reports, clinical protocol, or listed in the consent form.

Definition of an Unanticipated Problem (UaP)
A UaP is an event or circumstance that meets all the following three criteria: [1] the nature, severity, frequency of the event (s) or information was not expected in the descriptions in the study documents or the characteristics of the participant population being studied; [2] there is a reasonable possibility that the procedures involved in the research caused or are linked in a significant way to the problem; [3]the event or information suggests that the research places particpants or others at a greater risk of harm than was previously known or recognized (including physical, psychological, economic, or social harm.

Grade and Relatedness of Adverse Events:

Adverse Events are graded for severity and scored for relatedness to the protocol, according to a published scale. Several standardized AE Reporting scales are available. (See Help for links to these scales.)

* Please indicate the scale you intend to use:

- ○ CTC v2.0 (http://ctep.info.nih.gov/reporting/ctc.html)
- ○ CTCAE v3.0 (http://ctep.info.nih.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf)
- ◉ CTCAE v4.0 (http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf)
- ○ CTCAE v5.0 (https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf)
- ○ AIDS Clinical Trials Group (http://aactg.s-3.com/)
- ○ Other

23.7 Reporting Adverse Events

All AEs will be reported to the IRB at least annually.

Reporting Serious AEs

☑ Serious Adverse Events, (SAEs) will be reported to the IRB according to policy, within two working days of identification of the SAE.

Select all that apply:

☐ SAEs will be reported to the Sponsor and or ESCROW

SAEs will be reported to the sponsor within how many days of the event?

☐ SAEs will be reported directly to the FDA, per 21 CFR 312

SAEs must be reported directly to the FDA within 7 days of the event by the investigator/sponsor.

☐ SAEs will be reported to another entity

Describe:

Reporting Unanticipated AEs:

Select all that apply:

☑ UAEs will be reported to the IRB

UAEs that are related and greater than moderate severity must be reported to the IRB according to policy, within two working days of identification of the UAE.

☐ UAEs will be reported to the Sponsor

UAE will be reported to the sponsor within how many days of the event?

☐ UAEs will be reported to the FDA, per 21 CRF 312

UAEs will be reported to the FDA, per 21 CRF 312, within 15 days.

☐ UAEs will be reported to another entity

Describe:

23.8 Reporting Unanticipated Problems

☑ Unanticipated problems involving risks to participants or others will be reported to the IRB and the CRSO within five working days.

23.9 CLIA/CLEP

Only laboratory and research tests that are CLIA/CLEP certified or waived may be used to determine eligibility, shared with research volunteers, and used in clinical decision making.

Select if applicable:

☑ This study includes tests that are not CLIA/CLEP certified; the results of such tests will not be used in clinical decision making, or to determine eligibility, or shared with participants or their health care providers.

23.10 Tissue Repository

Human Tissue and Data Repositories collect, store, and distribute human tissue materials and or data for research purposes. Repository activities involve three components: (i) the collectors of tissue samples\data; (ii) the repository storage and data management center; and (iii) the recipient investigators.

* Select one:

◉ I DO NOT intend to collect, store, and distribute human tissue materials for research purposes

○ I DO intend to collect, store, and distribute human tissue materials for research purposes, therefore this protocol entails the Operation of a Tissue Repository. The IRB requires that the protocol specify the conditions under which data and specimens may be accepted and shared, and ensuring adequate provisions to protect the privacy of participants and maintain the confidentiality of data.

If you do intend to collect, store, and distribute human tissue materials, you will be asked to upload the following documents later on in the submission:

- A Sample collection protocol (for tissue collector collaborators to follow) and informed consent document for distribution to tissue collectors and their local IRBs.
- A Certificate of Confidentiality (to protect confidentiality of repository specimens and data).
- A Recipients Agreement describing the commitment of the recipient to preserve the anonymity of the samples shared.

24.0 Toxicity Management and Stopping Rules

24.1 * Describe any drug toxicity or other conditions under which the participation of a participant or the conduct of the study would be stopped in order to maximize safety (e.g., toxicity management and stopping rules):

Suspend Secukinumab or study drug placebo administration if the participant develops an infection or other AE that the investigator judges to be significant. If the infection or AE resolves, Secukinumab or study drug placebo may be restarted at the next scheduled dose.

*** Indicate withdrawal criteria and procedures below:**

1) A grade 3 or greater AE that the protocol chair and/or the medical monitor, in consultation with the site investigator, judge to be possibly, probably, or definitely related to Secukinumab.

2) Two sequential doses of Secukinumab are withheld.

25.0 Compensation/Costs

25.1 *Will any compensation be offered to participants in return for their participation, e.g., direct payment, medical care, tests, etc.?

- ○ No
- ◉ Yes

Please Describe

Participants will be offered $50 per skin biopsy and $50 per study visit. They will be paid in 3 bulk payments after the following visits are completed-week 1, week 24, and last day of study.

25.2 * Will there be any costs to participants associated with their participation in research?

- ○ Yes
- ◉ No

26.0 Bibliography

26.1 Enter your bibliography below:

1. Kim J, Bissonnette R, Lee J, Correa da Rosa J, Suarez-Farinas M, Lowes MA, et al. The spectrum of mild-to-severe psoriasis vulgaris is defined by a common activation of IL-17 pathway genes, but with key differences in immune regulatory genes. The Journal of investigative dermatology. 2016.

2. Kim J, Oh CH, Jeon J, Baek Y, Ahn J, Kim DJ, et al. Molecular Phenotyping Small (Asian) versus Large (Western) Plaque Psoriasis Shows Common Activation of IL-17 Pathway Genes but Different Regulatory Gene Sets. The Journal of investigative dermatology. 2016;136(1):161-72.

3. Kim J, Nadella P, Kim DJ, Brodmerkel C, Correa da Rosa J, Krueger JG, et al. Histological Stratification of Thick and Thin Plaque Psoriasis Explores Molecular Phenotypes with Clinical Implications. PloS one. 2015;10(7):e0132454.

4. Kim J, Krueger JG. The immunopathogenesis of psoriasis. Dermatologic clinics. 2015;33 (1):13-23.

27.0 Appendices

27.1 Enter your appendices below:

28.0 Funding

28.1 * Do you have sufficient financial resources to support your study?

(•) Yes ( ) No

28.2 If this study is/was pilot funded, please specify dates of funding:

From date:

To date:

28.3 Specify funding by Rockefeller University, industry sponsor and/or grant:

	Sponsor	Funding
Rockefeller University		
Industry	Norvartis	■
Grant		
Pilot Award		

28.4 List grants in which this study is named:

PHS or Non-PHS	Program	Grant Number	Grant Name	From Date	To Date
No records have been added					

29.0 Clinical Services

29.1

- [x] Well/Minimally Ill
- [ ] Moderately Ill
- [ ] Severely Ill
- [ ] Other

☐ Not Applicable

If other than Well/Minimally Ill, please describe:

29.2 * Does your study group have special care needs?

○ Yes ◉ No

29.3 * Does your study have special equipment needs?

○ Yes ◉ No

29.4 * Will you require storage space on the clinical units for supplies to conduct this study?

○ Yes ◉ No

29.5 * Is special training of hospital staff required?

○ Yes ◉ No

30.0 Pharmacy Services

30.1 * Does the study require Pharmacy Services?

◉ Yes ○ No

If Yes, please proceed to the next set of questions.

30.2 Types of pharmacy services required:

☑ Dispensing
☑ Randomization
☐ Compounding
☐ Other

30.3 Dispensing:

☑ Sponsor supplied drugs
☐ Pharmacy supplied drugs
☐ Other

30.4 Type of medication(s):

☑ Injectable
☐ Ophthalmic
☐ Inhalational
☐ Topical
☐ Suppository
☐ Other

If Injectable, please specify:

☑ Monday-Friday 8:30AM-5PM
☐ Off-hours [all other days/times]

31.0 Bionutrition

31.1 * Will study require patient meals?

◉ Yes ○ No

If Yes, please specify:

Type of Diet	In/Outpatient	Pack Meal
Standard	☐ Inpatient ☑ Outpatient	○ Pack Meal
Therapeutic	☐ Inpatient ☐ Outpatient	○ Pack Meal
Research Diet	☐ Inpatient ☐ Outpatient	○ Pack Meal
Formula Diet	☐ Inpatient ☐ Outpatient	○ Pack Meal

Nutrient(s) to be controlled (specify):

31.2 Will meal times be altered?

○ Yes ◉ No

31.3 Does the protocol require any of the following activities?

☐ Food Frequency Questionnaire
☐ Bod Pod/ Anthropometric Measurements
☐ Diet History/ Food Records
☐ Diet/ Nutrition Education

31.4 Will food be provided to caregiver, parent or significant other?

○ Yes ◉ No

31.5 For metabolic diets, is diet homogenization required for nutrient analysis by independent lab?

○ Yes
○ No
◉ N/A

32.0 Clinical and Translational Research Facilitation Office

32.1 Indicate navigation assistance requested and/or received in the development of the study:

	Requested	Received
Protocol Development	☐	☐
Protocol Implementation	☐	☐
Protocol Conduct	☐	☐
ACCTS/IRB Submission	☐	☐

32.2 Indicate additional education assistance requested and/or received in the development of the study:

	Requested	Received
IND	☐	☐
IDE	☐	☐
Team Science Education	☐	☐
Study Progress Meeting	☐	☐
Investigator Responsibilities	☐	☐
Regulatory Binder/Folder	☐	☐
Source Documentation	☐	☐
Participant Involvement in Research	☐	☐

33.0 Clinical Research Support Office Resources (CRSO)

33.1 Indicate regulatory input assistance requested and/or received in the development of the study:

Regulatory Support/Design	Requested	Received
General, Vulnerable Populations, Minors, Group Harms	☐	☐
IND/IDE advice, assistance, and referral	☐	☐
Informed Consent/Assent		

	☐	☐
Data Safety Monitoring Plan	☐	☐
Clinical Trial Registration	☐	☐
Plan For Return of Research Results	☐	☐
Audit/Monitoring Service, Referrals, SOPs	☐	☐

33.2 Indicate recruitment assistance requested and/or received in the development of the study:

Recruitment of Participants	Requested	Received
Recruitment Planning and/or written Plan	☐	☐
Advertising Strategy, Content, Placement	☐	☐
Repository/Research Match Queries	☐	☐
Call Center/Prescreening /Scheduling	☐	☐
Cost Sharing for Advertising	☐	☐

33.3 Indicate community engaging assistance requested and/or received in the development of the study:

Community Engagement	Requested	Received
PHI Statement/Engaging Stakeholders Section	☐	☐
CEnR Navigation – fostering pt /community partnership	☐	☐
Outreach to community/partner /advocacy group/CE Studio	☐	☐

33.4 Indicate other assistance requested and/or received in the development of the study:

Other	Requested	Received
Survey design, fielding, validation	☐	☐

Data transfer and security planning	☐	☐

34.0 BERD: Biostatistics, Epidemiology and Research Design Resource

34.1 Indicate Biostatistic assistance requested and/or received in the development of this study:

	Requested	Received
Development of experimental design	☐	☐
Power analysis/Sample size determination (# of subjects)	☐	☐
Navigation (Did Statistician participate in a navigation meeting)	☐	☐
Randomization schedule	☐	☐
Data analysis	☐	☐
Development of new statistical techniques for data analysis (Statistical research)	☐	☐
Protocol implementation	☐	☐
Other	☐	☐

34.2 If you are/will be using data analysis specify:

- ☐ Exploratory
- ☐ Descriptive
- ☐ Hypothesis testing
- ☐ Statistical modeling
- ☐ Other

34.3 If you are/will be assisted with protocol implementation, specify:

- ☐ Publication
- ☐ Conference
- ☐ Other (type of dissemination)
- ☐ Grant(s)

34.4 Please select the Biostatistician on this Protocol:

- [ ] Roger Vaughan, DrPH
- [ ] Caroline Jiang, MS
- [x] Sandra Garcet, PhD
- [ ] Neha Singh, MS
- [ ] Other

35.0 Biomedical Informatics Resources

35.1 Indicate Bioinformatics assistance requested and/or received in the development of this study:

	Requested	Received
Microarray analysis	☐	☐
Pathway analysis	☐	☐
RNA-seq analysis	☐	☐
Bioinformatics training and consultation	☐	☐
Bioinformatics experimental design	☐	☐
HPC computing	☐	☐
Other	☐	☐

35.2 If you are/will be using pathway analysis software, specify:

- [x] Ingenuity IPA
- [ ] David
- [ ] GSEA
- [ ] Other

35.3 If you are/will be using RNAseq analysis software, specify:

- [ ] Tophat
- [ ] Cufflinks
- [ ] Cuffdiff
- [ ] CummRbund
- [ ] STAR
- [ ] featureCounts
- [ ] DESeq2
- [ ] VOOM
- [ ] RNA-SeQC

If other, specify:

35.4 Indicate Medical Informatics assistance requested and/or received in the development of this study:

	Requested	Received
Data storage inside of iRIS	☐	☐
Redcap Database	☐	☐
Custom or Ad Hoc reports	☐	☐
Study plan creation	☐	☐
Specialize database or custom software	☐	☐
Other	☐	☐

36.0 HIPAA Form

36.1 A study's specific HIPAA form signed by the volunteer is required for institutions that are HIPAA covered entities so that they may communicate Private Health Information (PHI) to the Investigator.

Below, Memorial Sloan Kettering Cancer Center, New York-Presbyterian Hospital and Weill Medical College of Cornell University are listed so that that they may report laboratory results and X-ray readings respectively. If you foresee that any other entity may need to provide PHI then add them to the field highlighted in green.

36.2 Name of Study:

Safety and Efficacy of Secukinumab in Adults with Chronic Plaque Type Psoriasis with a PASI score of 6 to 12

36.3 Principal Investigator:

James Krueger, MD PhD

36.4 Industry Sponsor:

If the funding source is industry please type in the sponsor here

Who may obtain, use, and/or disclose your health information?

The following persons and organizations may obtain, use, or disclose health information about you.

- The Principal Investigator(s) listed at the top of this form, and persons who assist the Investigator(s) in carrying out the research

- Each research site for this study, including The Rockefeller University, and the research management and support staff and the medical staff at each site
- Health care providers who have provided in the past, or currently provide, health care services to you
- Laboratories and other persons and organizations that will analyze your health information and/or biological samples as part of this study, including Memorial Sloan Kettering Cancer Center, New York-Presbyterian Hospital and Weill Medical College of Cornell University

Other entities that may need to provide PHI:

Novartis and its agents.

- Members and staff of the Institutional Review Board and other boards and committees that watch over research at The Rockefeller University
- Members and staff of The Rockefeller University's Office of Sponsored Research
- The sponsor(s) of the research, named above, and persons who watch over the research for the sponsor(s)
- The United States Food and Drug Administration, other government agencies, regulatory entities and Rockefeller University consultants that watch over the safety, effectiveness, and quality of research and/or fund The Rockefeller University Hospital
- Others (as described here):

What information will be obtained, used, or disclosed?

The persons and organizations listed above may obtain, use, and disclose:

- Information about you that is created or collected during the research study (but not including any HIV-related information)
- Health information in your medical records that is relevant to the research study (but not including any HIV-related information)
- **And**, if checked below:

___ HIV-related information (this includes any information indicating that you have had an HIV-related test or have HIV infection, HIV-related illness, or AIDS, as well as information that could indicate you may have been exposed to HIV)

___ Other information (as described here):

_____
_____
_____
_____

By signing this form, you give permission to the persons and organizations listed above to obtain, use and disclose your health information noted above.

How will your health information be used?

The health information noted above, as well as information shown by the boxes checked above (if any), may be obtained, used, and disclosed:

- to conduct the research study explained to you during the informed consent process; and
- to assure the quality, safety, and effectiveness of the research study

Please note that the persons and organizations listed above may re-use or further disclose your information if they are permitted by law to do so.

What are your rights?

It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in the research study. Your health care outside the study will not be affected. The payment for your health care and your health care benefits will not be affected.
If you sign this authorization form, you will have the right to withdraw it at any time except to the extent that the persons and organizations listed above:

- have already taken action based upon your authorization;
- need the previously collected information to complete analysis and reports of data for this research; or

- will continue to use and disclose previously collected information as permitted by the informed consent form signed by you (except as to HIV-related information, for which disclosure to new persons or organizations will not occur unless permitted by federal or state law).

If you withdraw the authorization, you will not be permitted to continue taking part in the research study. This authorization form will not expire unless you withdraw it. If you want to withdraw this authorization, please write to the above named investigators.
You have a right to see and copy your health information described in this authorization form in accordance with The Rockefeller University's policies; in certain circumstances where the integrity of the study will be affected, you will not be able to obtain your health records in this study until the study has been completed.
You will receive a copy of this form after you have signed it.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that such information may not be shared without your approval unless permitted by federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.

Your signature

I have read this form, and all of my questions have been answered. By signing below, I acknowledge that I have read and accept all of the information above.

_____
Signature of participant or participant's legal representative

_____
Date

_____
Printed name of participant

_____
Printed name of legal representative (if applicable)

_____
Representative's relationship to participant

THE STUDY PARTICIPANT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.

37.0 End of Application Form

37.1 The study application form is complete.

The next step in the submission process is to gather attachments before proceeding to the submission form.

The following submission reports are generated in the Lab/Dept Reports menu, Submission Reports section:

- **Delegation of Authority** (if applicable, and if not previously generated)
- **HIPAA form** (if applicable)
- **CCTS Utilization Report** (required for all submissions)
- **Study Progress Report** (if the study has been managed in iRIS for a minimum of one year, generate the Progress Report from the report menu in iRIS. if the study has not been managed in iRIS for one year, complete the Progress Report located on the IRB website.)

All other required forms can be downloaded from the corresponding sections' help links above or from the IRB website.