



Immunology Study Enrollment Criteria (Adult)

General Instructions

The Immunology Study Enrollment Criteria form lists the inclusion and exclusion criteria for the Immunology Clinical Trial Study. This form is to be completed after the patient has completed the screening visit for the Immune Active study, eligibility for the Immune Active study is determined and the patient has provided written informed consent for study participation. This form should be completed when patient eligibility can be determined, most likely at the Immune Active baseline visit.

Specific Instructions

Patient ID: Record the Patient ID in the top right hand corner.

Date of Determination: Record the date (month/day/year) that patient eligibility is determined. Either the patient meets all inclusion criteria and none of the exclusion criteria (eligible) or the patient fails to meet at least one of the inclusion criteria or meets any of the exclusion criteria (ineligible).

Section I: Inclusion Criteria

Check "Yes" or "No" to indicate if the patient meets each of the inclusion criteria. The response to all inclusion criteria must be YES for a patient to be eligible for participation in this study.

Section II: Exclusion Criteria

Check "Yes" or "No" to indicate if the patient meets the following exclusion criteria. The response to all exclusion criteria must be NO for a patient to be eligible for participation in this study.

The following exclusion criteria require additional definitions:

Anemia: A hemoglobin result <10 or hematocrit result <30 based on the most recent hemoglobin and hematocrit tests performed. A hemoglobin or hematocrit does not have to be performed for the purpose of this ancillary study but should be performed if clinically indicated or if they are necessary to determine eligibility in the opinion of the investigator.

Active medical condition: The patient has an active medical condition which includes but is not limited to congestive heart failure, chronic lung disease requiring oxygen, coronary artery disease with unstable angina, sepsis, or renal failure that would make the patient unsuitable for the study.

Autoimmune or immunosuppression: The patient has a known autoimmune disease or is on immunosuppressive therapy.

The response to all inclusion criteria must be YES and all exclusion criteria must be NO for the patient to be eligible for participation in this study. If the patient is determined to be eligible, check "Yes" to the eligibility question at the bottom of the page. Samples are to be collected per the Immunology Clinical Trial Study protocol. If the patient is not eligible for participation then check "No" and no samples are to be collected for the Immunology study.