Protocol No.	Investigator No.	Screening No.	Participant Initials	Visit
ITN019AD	**001**	**S** ___ ___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

RESEARCH SPECIMEN CONSENT

Date of Informed Consent: _____/_____/_____
dd mmm yyyy

Please refer to the section "Specific Indications of Consent" of the Consent Addendum.

If the consent is checked "Yes" in Section A, mark:

1 ☐ My blood and tissue may be used for this research study (as described in the main consent).

If any box is checked in Section B, mark all that apply:

2 ☐ My further consent is required prior to the use of my blood and tissue in any subsequent research project.

3 ☐ My further consent is not required, only if my blood and tissue sample is stripped of (separated from) all information that could link it to me. By checking this box, I allow researchers my consent to use my blood and tissue sample in future research as long as the sample is stripped of (separated from) all identifiers that can in any way link the tissue to me.

4 ☐ My further consent is not required for any testing. By checking this box, I allow researchers my consent to use my blood and tissue sample(s) in future research.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

INCLUSION CRITERIA

Visit Date: ____/_____/_____
dd mmm yyyy

	No	Yes
1. Able to comprehend and grant a witnessed, written informed consent prior to any study procedures.	0 ☐	1 ☐
2. Male or female 18 to 50 years of age.	0 ☐	1 ☐
3. Female participant of childbearing age must have a negative urine pregnancy test at Visit -01 and a negative urine pregnancy test at subsequent visits. In addition, female participant must be using a medically acceptable form of birth control.	0 ☐	1 ☐
4. History of seasonal allergic rhinitis for at least 2 years with symptoms during the ragweed pollen season requiring pharmacotherapy.	0 ☐	1 ☐
5. A positive skin test by prick method to ragweed pollen at Visit 00. A positive skin prick will be defined as a ragweed pollen-induced wheal ≥ 3 mm larger in diameter than diluent control (measurements will be made 15-20 minutes after application).	0 ☐	1 ☐
6. Must be capable of faithfully completing the diary and of attending regularly scheduled study visits.	0 ☐	1 ☐
7. Should intend to remain in the ragweed pollen area from August 15 through September 30. Any travel outside of the pollen area should be noted in the source documents. Participants who travel outside of the ragweed pollen area for prolonged periods of time should be evaluated by the investigator as to their suitability to continue in this study.	0 ☐	1 ☐
8. Willing to avoid prohibited medications for the periods indicated in the protocol.	0 ☐	1 ☐
9. Participant must meet pretrial eligibility requirements for trial enrollment (acceptable medical history, physical examination results, normal electrocardiogram and acceptable laboratory test results).	0 ☐	1 ☐
10. Participant must have a baseline serum IgE level ≥ 10 and ≤ 700 IU/mL.	0 ☐	1 ☐

If any items are marked 'No', the participant is NOT ELIGIBLE to participate in the study.

Please provide participant's Screening number: **S** ___ ___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

EXCLUSION CRITERIA

		No	Yes
1.	Participant < 30 kg or > 120 kg.	0 ☐	1 ☐
2.	Participant who is pregnant or lactating.	0 ☐	1 ☐
3.	Participant with a history of severe anaphylactoid or anaphylactic reaction(s).	0 ☐	1 ☐
4.	Participant with a history of immunotherapy within the past 10 years, if received one full year of immunotherapy, or within the past 5 years if received less than one year of immunotherapy.	0 ☐	1 ☐
5.	Participant with a history of allergy injections to treat ragweed SAR (desensitization immunotherapy).	0 ☐	1 ☐
6.	Participant with known hypersensitivity to trial rescue medication (fexofenadine HCl).	0 ☐	1 ☐
7.	Participant taking beta-adrenergic antagonists in any form.	0 ☐	1 ☐
8.	Participant taking ophthalmologic medication for allergic symptoms.	0 ☐	1 ☐
9.	Participant with clinically significant perennial rhinitis that would interfere in assessment of ragweed-induced seasonal allergic rhinitis symptoms.	0 ☐	1 ☐
10.	Presence of a severely deviated nasal septum, septal perforation, structural nasal defect or large nasal polyps causing obstruction.	0 ☐	1 ☐
11.	History of an upper respiratory or sinus infection requiring treatment with an antibiotic within 2 weeks prior to Screening Visits.	0 ☐	1 ☐
12.	Documented evidence of acute or significant chronic sinusitis, as determined by the Investigator.	0 ☐	1 ☐
13.	Asthma (either history of, abnormal spirometry, [FEV_1 < 80% predicted], or use of asthma medications as specified in Section 5.10).	0 ☐	1 ☐
14.	Chronic or intermittent use of inhaled, oral, intramuscular, or intravenous corticosteroids; or chronic or intermittent use of topical corticosteroids within 4 weeks of Screening Visits.	0 ☐	1 ☐
15.	Chronic use of medications (e.g., tricyclic antidepressants) that would affect assessment of the effectiveness of the study medication.	0 ☐	1 ☐
16.	Rhinitis medicamentosa.	0 ☐	1 ☐
17.	History or presence of significant renal, hepatic, neurologic, cardiovascular, hematologic, metabolic, cerebrovascular, respiratory, gastrointestinal, or other significant medical condition, including autoimmune or collagen vascular disorders, aside from organ-specific autoimmune disease limited to the thyroid that in the Investigator's opinion could interfere with the study or require medical treatment that would interfere with the study.	0 ☐	1 ☐
18.	History of cancer other than basal cell carcinoma of the skin.	0 ☐	1 ☐
19.	History within the past year of excessive alcohol intake or drug addiction.	0 ☐	1 ☐
20.	Current smoker, greater than 10 pack year history, or participant who quit smoking less than one year prior to screening.	0 ☐	1 ☐
21.	Use of any prohibited concomitant medications during the washout period.	0 ☐	1 ☐
22.	Participant with clinically significant abnormality on 12-lead electrocardiogram (ECG) on screening visit.	0 ☐	1 ☐
23.	Treatment with an experimental, non-approved drug, or investigational drug within the past 30 days.	0 ☐	1 ☐
24.	Participant with a history of noncompliance to medical regimens and participant who is considered potentially unreliable.	0 ☐	1 ☐

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

EXCLUSION CRITERIA - CONTINUED

	No	Yes
25. Previous treatment with a monoclonal antibody for any reason including anti-IgE in any form (e.g., omalizumab).	0 ☐	1 ☐
26. Participant with known hypersensitivity to trial drug ingredients (i.e., sucrose, histidine, polysorbate 20) or related drugs (i.e., monoclonal antibody, polyclonal gammaglobulin).	0 ☐	1 ☐

If any items are marked 'Yes', the participant is NOT ELIGIBLE to participate in the study.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

DEMOGRAPHICS

Date of Birth: ____/_____/_____
dd mmm yyyy

Sex (mark one): 1 ☐ Male 2 ☐ Female

Primary Race (mark one):

1 ☐ White
2 ☐ Black or African American
3 ☐ Asian
4 ☐ American Indian or Alaska Native
5 ☐ Native Hawaiian or Other Pacific Islander
99 ☐ Other, specify: _____

Secondary Race (mark one if applicable):

1 ☐ White
2 ☐ Black or African American
3 ☐ Asian
4 ☐ American Indian or Alaska Native
5 ☐ Native Hawaiian or Other Pacific Islander
99 ☐ Other, specify: _____

Ethnicity (mark one):

1 ☐ Not Hispanic or Latino
2 ☐ Hispanic or Latino
96 ☐ Unknown

REPRODUCTIVE STATUS

Urine Pregnancy Test Result:

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

Fertility Status:

Females (mark only one):
1 ☐ Pre-Menarche
2 ☐ Sterile
3 ☐ Post-Menopausal
4 ☐ Potentially Able to Bear Children

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

VITAL SIGNS

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Height: ___ ___ ___ . ___ 1☐ cm 2☐ in

Respirations: ___ ___ breaths/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

PHYSICAL EXAM

Body Code	Assessment	Normal	Abnormal	Not Done	Describe Abnormality
1.	Skin, Hair	0☐	1☐	97☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0☐	1☐	97☐	
3.	Respiratory	0☐	1☐	97☐	
4.	Cardiovascular	0☐	1☐	97☐	
5.	Gastrointestinal/ Abdomen	0☐	1☐	97☐	
6.	Endocrine/Metabolic	0☐	1☐	97☐	
7.	Genitourinary	0☐	1☐	97☐	
8.	Neurological	0☐	1☐	97☐	
9.	Blood/Lymphatic	0☐	1☐	97☐	
10.	Musculoskeletal	0☐	1☐	97☐	
11.	Psychological	0☐	1☐	97☐	
12.	General Appearance	0☐	1☐	97☐	
99.	Other _____	0☐	1☐	97☐	

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

ALLERGY SKIN TEST

Skin Test	Wheal *(mm)* mean value	Erythema *(mm)* mean value
Ragweed		
Positive Control		
Negative Control		

PULMONARY FUNCTION TESTS

Date of Test: ____/_____/_____
dd mmm yyyy

FEV_1: _____ L Percent predicted: _____ %

TOTAL IgE

To be completed at Visit -01 only with IRB approval.

Date of Sample Collection: ____/_____/_____
dd mmm yyyy

Total IgE: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

MEDICAL HISTORY

Are there any clinically significant diseases (including allergies) or medical procedures currently or in the past other than disease under study? 0 ☐ No 1 ☐ Yes*

*If Yes, please record details below:

NOTE: All medical procedures should be marked inactive.

No.	Disease/Medical Procedure	Inactive	Active
1.		0 ☐	1 ☐
2.		0 ☐	1 ☐
3.		0 ☐	1 ☐
4.		0 ☐	1 ☐
5.		0 ☐	1 ☐
6.		0 ☐	1 ☐
7.		0 ☐	1 ☐
8.		0 ☐	1 ☐
9.		0 ☐	1 ☐
10.		0 ☐	1 ☐
11.		0 ☐	1 ☐
12.		0 ☐	1 ☐
13.		0 ☐	1 ☐
14.		0 ☐	1 ☐

Please ensure all significant medical history and medical procedures are reviewed for the following body systems:

Skin, hair
Head, eyes, ears, nose, throat, neck
Respiratory
Cardiovascular
Psychological/Psychiatric
Gastrointestinal/Abdomen
Endocrine/Metabolic
Genitourinary
Neurological
General appearance
Blood/Lymphatic
Musculoskeletal
Hepatic
Allergies

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

ALLERGY HISTORY

1. Date participant first experienced **allergy** symptoms: _____/_____/_____
dd mmm yyyy

What symptoms lead to the diagnosis of allergy? *(check all that apply)*

1 ☐ Sneezing
2 ☐ Runny nose
3 ☐ Itchy nose, throat, and/or palate
4 ☐ Itchy, watery, and/or red eyes
5 ☐ Nasal congestion
6 ☐ Sinus pressure
7 ☐ Other, specify: _____

Specify allergens: *(check all that apply)*

1 ☐ Tree, grass, weed pollen
2 ☐ Mold spores
3 ☐ Dust mites
4 ☐ Animal danders
5 ☐ Cockroaches
6 ☐ Food
7 ☐ Latex
8 ☐ Penicillin and/or other drugs
9 ☐ Stinging insect venoms
10 ☐ Other, specify: _____

2. Has the participant ever had immunotherapy (IT)? 0 ☐ No 1 ☐ Yes
If Yes, please indicate:

Target Antigens *Indicate Code # in box below* *1 = Tree, grass, weed pollen 2 = Mold spores 3 = Dust mites 4 = Animal danders 9 = Stinging insect venoms 99 = Other, specify	Age IT Began *(years old)*	Duration of IT *(months)*
☐ _____		
☐ _____		
☐ _____		
☐ _____		

*If this participant has had ragweed immunotherapy, he/she is not eligible for this trial.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

ALLERGY HISTORY (CONTINUED)

3. Does the participant have any food allergies? 0 ☐ No 1 ☐ Yes 96 ☐ Unknown

If Yes, please indicate:

Food Allergies
Indicate Code # in box below
1 = Peanuts, 2 = Tree nuts, 3 = Fish, 4 = Shellfish, 5 = Eggs, 6 = Milk, 7 = Chicken, 8 = Soy, 9 = Wheat, 10 = Rice, 99 = Other, specify
	Age First Noticed
	(years old)

☐ _____	
☐ _____	
☐ _____	
☐ _____	
☐ _____	
☐ _____	

4. Does the participant have atopic dermatitis? 0 ☐ No 1 ☐ Yes 96 ☐ Unknown

If Yes, age of discovery: _____ years old

Symptoms that led to the diagnosis:_____

_____

5. Does the participant have nasal polyps? 0 ☐ No 1 ☐ Yes 96 ☐ Unknown

If Yes, age of discovery: _____ years old

6. Does the participant have a sensitivity to aspirin? 0 ☐ No 1 ☐ Yes 96 ☐ Unknown

If Yes, indicate the symptoms:

1 ☐ Asthma
2 ☐ Urticaria
3 ☐ Other, specify: _____

7. Has the participant ever smoked cigarettes? 0 ☐ No 1 ☐ Yes

If Yes, age started smoking: _____ years old Average number of packs per day: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

ALLERGY HISTORY (CONTINUED)

8. Did the participant attend Day Care? 0 ☐ No 1 ☐ Yes 96 ☐ Unknown

   If Yes, age Day Care began: _____ months old Length of time in Day Care: _____ years

9. Has the participant had any animal exposure? 0 ☐ No 1 ☐ Yes

   If Yes, please indicate:

Animal
Indicate Code # in box below
1 = Cat
2 = Dog
3 = Pet bird
4 = Rabbit
5 = Rodent, (mouse, guinea pig, rat)
99 = Other, specify
	Quantity of Each Animal from Column 1
	Indicate Code # in box below
	1 = 1
	2 = 2
	3 = 3
	4 = 4
	5 = >4
	6 = Infestation
		Age of First Exposure
		(years)

☐ _____	☐ _____	
☐ _____	☐ _____	
☐ _____	☐ _____	
☐ _____	☐ _____	
☐ _____	☐ _____	
☐ _____	☐ _____	
☐ _____	☐ _____	
☐ _____	☐ _____	
☐ _____	☐ _____	

10. Has the participant had any farm exposure in the first year of life?* 0 ☐ No 1 ☐ Yes 96 ☐ Unknown

    If Yes, length of exposure: _____ months

* Farm exposure is defined as (1) exposure to stables during the first year of life; and/or (2) consumption of milk directly from the farm during the first year of life.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

FAMILY HISTORY

Family History of Autoimmune Disease

1. Have ANY blood relatives been diagnosed with an autoimmune disease? $_{0}$☐ No $_{1}$☐ Yes $_{96}$☐ Unknown

   If Yes, please record all autoimmune diseases below and specify the relationship of the blood relative to the participant for each disease:

No.	Disease	Relationship to Participant
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Family History of Allergy / Asthma

(Blood-related parents only)

2. Does the participant's mother have a history of Allergy or Asthma? $_{0}$☐ No $_{1}$☐ Yes $_{96}$☐ Unknown
   If Yes, specify: $_{1}$☐ Allergy $_{2}$☐ Asthma

3. Does the participant's father have a history of Allergy or Asthma? $_{0}$☐ No $_{1}$☐ Yes $_{96}$☐ Unknown
   If Yes, specify: $_{1}$☐ Allergy $_{2}$☐ Asthma

4. Did the participant's mother smoke during pregnancy? $_{0}$☐ No $_{1}$☐ Yes $_{96}$☐ Unknown

   If Yes, average number of packs per day: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

FAMILY HISTORY (CONTINUED)

5. Has the participant had passive exposure to tobacco smoke? 0 ☐ No 1 ☐ Yes

   If Yes, AGE of initial exposure: _____ years old

   and LENGTH of exposure: _____ years

6. What type of birth did the mother have when the participant was born? 1 ☐ Vaginal 2 ☐ C-Section 96 ☐ Unknown

7. Does the participant have any siblings? 0 ☐ No 1 ☐ Yes

   If Yes, report ALL of your sibling(s) and their age(s):

1 = Brother 2 = Sister	Age

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

MEDICATION HISTORY

Were any medications taken in the 3 months prior to Screening? 0 ☐ No 1 ☐ Yes If Yes, describe below.

List any medication taken in the 3 months prior to Screening (includes over-the-counter and prescription drugs).

Line No.	Drug Name (Brand or Generic)	Indication	Dose	Unit	**Frequency	*Route	Start Date	Stop Date	
					If "99=Other" please specify	If "99=Other" please specify	*(dd/mmm/yyyy)*	*(dd/mmm/yyyy)* mark box (✓) if continuing ↓	
1.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
2.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
3.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
4.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
5.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
6.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
7.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
8.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
9.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐

***Route**: 1 = oral, 2 = intravenous, 3 = intramuscular, 4 = topical, 5 = inhaled, 6 = subcutaneous, 7 = intradermal, 8 = sublingual, 9 = intra-articular, 10 = opthalmic, 11 = intralesional, 12 = rectal, 13 = vaginal, 99 = Other

****Frequency**: 1 = QD, 2 = BID, 3 = TID, 4 = QID, 5 = QHS, 6 = QOD, 7 = PRN, 99 =Other

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -12 to -10 Visit -01**

ELECTROCARDIOGRAM - 12 LEAD

Date ECG Performed: ____/_____/_____
dd mmm yyyy

Overall interpretation of ECG:

0 ☐ Normal
1 ☐ Abnormal, Clinically Significant
2 ☐ Abnormal, Not Clinically Significant
97 ☐ Not Done

Specify Abnormality: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -11 to -9 Visit 00**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Respiratory	0 ☐	1 ☐	2 ☐	97 ☐	
4.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Gastrointestinal/ Abdomen	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Endocrine/Metabolic	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Neurological	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Blood/Lymphatic	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
11.	Psychological	0 ☐	1 ☐	2 ☐	97 ☐	
12.	General Appearance	0 ☐	1 ☐	2 ☐	97 ☐	
99.	Other _____	0 ☐	1 ☐	2 ☐	97 ☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -11 to -9 Visit 00**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

TOTAL IgE

To be completed at Visit 00 if not done at Visit -01.

Date of Sample Collection: ____/_____/_____
dd mmm yyyy

Total IgE: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -11 to -9 Visit 00**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Nasal Scraping

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

7. DNA-HLA-SNP Genotype

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

8. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -11 to -9 Visit 00**

NASAL ALLERGEN CHALLENGE

Date of Challenge: ____/_____/_____
dd mmm yyyy

THIRD SALINE CHALLENGE

Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
			Sneezing	Nasal Itching	Sinus Pressure
___ ___:___ ___	___.___ ___	___ ___.___ ___ LN	# Sneezes		
		___ ___.___ ___ RN			
		___ ___.___ ___ TNV			

Nasal Challenge Calculated Endpoints

FEV_1 (L) = ___.___ ___ x 0.8 = ___.___ ___ (EP for FEV_1)

Nasal Rhinogram (cm^3) = ___ ___.___ ___ x 0.7 = ___ ___.___ ___ (EP for TNV)
(TNV)

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -11 to -9 / Visit 00**

NASAL ALLERGEN CHALLENGE

RAGWEED CHALLENGE

	Dilution	Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
					Sneezing	Nasal Itching	Sinus Pressure
1.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
2.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
3.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
4.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
5.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -11 to -9 Visit 00**

NASAL SCRAPING

Cell count: ___ ___

NASAL EXHALED NITRIC OXIDE - NO

Nitric Oxide Value at 50 mL/m: ___ ___ ___**.**___ ppb

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -11 to -9 Visit 00**

ALLERGY SKIN REACTIONS TEST

Time of First Injection: ___ ___:___ ___
(24 Hr. Clock)

Dilution	Injection	15 min. Post-Injection			16-24 Hrs. Post-Injection		
		Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*	Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*
	Injection 1-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 1-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Positive Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Negative Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -9 / Visit 01**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0☐	1☐	2☐	97☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0☐	1☐	2☐	97☐	
3.	Respiratory	0☐	1☐	2☐	97☐	
4.	Cardiovascular	0☐	1☐	2☐	97☐	
5.	Gastrointestinal/ Abdomen	0☐	1☐	2☐	97☐	
6.	Endocrine/Metabolic	0☐	1☐	2☐	97☐	
7.	Genitourinary	0☐	1☐	2☐	97☐	
8.	Neurological	0☐	1☐	2☐	97☐	
9.	Blood/Lymphatic	0☐	1☐	2☐	97☐	
10.	Musculoskeletal	0☐	1☐	2☐	97☐	
11.	Psychological	0☐	1☐	2☐	97☐	
12.	General Appearance	0☐	1☐	2☐	97☐	
99.	Other _____	0☐	1☐	2☐	97☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -9 / Visit 01**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -9 / Visit 01**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -9 / Visit 01**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -9 / Visit 01**

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____
dd mmm yyyy

Time of Injection: ___ ___:___ ___
(24 Hr. clock)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -7 / Visit 1.5**

Is participant receiving 2-week injections of Omalizumab/Placebo? 0 ☐ No 1 ☐ Yes

If Yes, complete the following:

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____
dd mmm yyyy

Time of Injection: ___ ___ : ___ ___
(24 Hr. clock)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -5 / Visit 02**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0☐	1☐	2☐	97☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0☐	1☐	2☐	97☐	
3.	Respiratory	0☐	1☐	2☐	97☐	
4.	Cardiovascular	0☐	1☐	2☐	97☐	
5.	Gastrointestinal/ Abdomen	0☐	1☐	2☐	97☐	
6.	Endocrine/Metabolic	0☐	1☐	2☐	97☐	
7.	Genitourinary	0☐	1☐	2☐	97☐	
8.	Neurological	0☐	1☐	2☐	97☐	
9.	Blood/Lymphatic	0☐	1☐	2☐	97☐	
10.	Musculoskeletal	0☐	1☐	2☐	97☐	
11.	Psychological	0☐	1☐	2☐	97☐	
12.	General Appearance	0☐	1☐	2☐	97☐	
99.	Other _____	0☐	1☐	2☐	97☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -5 / Visit 02**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -5 / Visit 02**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -5 / Visit 02**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -5 / Visit 02**

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____
dd mmm yyyy

Time of Injection: ___ ___:___ ___
(24 Hr. clock)

Dose: ___ ___ ___ mg

RESCUE MEDICATION

Did the participant use any fexofenadine HC1 (Allegra) rescue medication since the previous visit?

0 ☐ No 1 ☐ Yes

If Yes, # of tablets: ___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -3 / Visit 2.5**

Is participant receiving 2-week injections of Omalizumab/Placebo? 0 ☐ No 1 ☐ Yes

If Yes, complete the following:

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____
dd mmm yyyy

Time of Injection: ___ ___ : ___ ___
(24 Hr. clock)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -1 / Visit 03**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Respiratory	0 ☐	1 ☐	2 ☐	97 ☐	
4.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Gastrointestinal/ Abdomen	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Endocrine/Metabolic	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Neurological	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Blood/Lymphatic	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
11.	Psychological	0 ☐	1 ☐	2 ☐	97 ☐	
12.	General Appearance	0 ☐	1 ☐	2 ☐	97 ☐	
99.	Other _____	0 ☐	1 ☐	2 ☐	97 ☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -1 / Visit 03**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -1 / Visit 03**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -1 / Visit 03**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week -1 / Visit 03**

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____
dd mmm yyyy

Time of Injection: ___ ___:___ ___
(24 Hr. clock)

Dose: ___ ___ ___ mg

RESCUE MEDICATION

Did the participant use any fexofenadine HC1 (Allegra) rescue medication since the previous visit?

0 ☐ No 1 ☐ Yes

If Yes, # of tablets: ___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 0 / Visit 04**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Respiratory	0 ☐	1 ☐	2 ☐	97 ☐	
4.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Gastrointestinal/ Abdomen	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Endocrine/Metabolic	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Neurological	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Blood/Lymphatic	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
11.	Psychological	0 ☐	1 ☐	2 ☐	97 ☐	
12.	General Appearance	0 ☐	1 ☐	2 ☐	97 ☐	
99.	Other _____	0 ☐	1 ☐	2 ☐	97 ☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 0 / Visit 04**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

RESCUE MEDICATION

Did the participant use any fexofenadine HC1 (Allegra) rescue medication since the previous visit? 0 ☐ No 1 ☐ Yes

If Yes, # of tablets: ___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 0 / Visit 04**

RUSH IMMUNOTHERAPY

Date of Injection: ____/_____/_____
dd mmm yyyy

Timepoint *(hr)*	Pre-Injection Measurements				Time of Injection *(24 hr. clock)*	Dose *(mL)*
	Blood Pressure Systolic/Diastolic *(mmHg)*	Pulse *(beats per min.)*	Respiratory Rate *(breaths per min.)*	Peak Expiratory Flow		
0	___ ___ ___/___ ___ ___	___ ___ ___	___ ___		___ ___:___ ___	0.30
0.5	___ ___ ___/___ ___ ___	___ ___ ___	___ ___		___ ___:___ ___	0.10
1.0	___ ___ ___/___ ___ ___	___ ___ ___	___ ___		___ ___:___ ___	0.30
1.5	___ ___ ___/___ ___ ___	___ ___ ___	___ ___		___ ___:___ ___	0.05
2.0	___ ___ ___/___ ___ ___	___ ___ ___	___ ___		___ ___:___ ___	0.15
3.0	___ ___ ___/___ ___ ___	___ ___ ___	___ ___		___ ___:___ ___	0.30
4.0	___ ___ ___/___ ___ ___	___ ___ ___	___ ___		___ ___:___ ___	0.05
5.0	___ ___ ___/___ ___ ___	___ ___ ___	___ ___		___ ___:___ ___	0.10

POST-INJECTION ADVERSE EVENTS*

Timepoint *(hr)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each timepoint.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
0									
0.5									
1.0									
1.5									
2.0									
3.0									
4.0									
5.0									
7.0									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 1 / Visit 05**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 1 / Visit 05**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 1 / Visit 05**

NASAL EXHALED NITRIC OXIDE - NO

Nitric Oxide Value at 50 mL/m: ___ ___ ___.___ ppb

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 1 / Visit 05**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 1 / Visit 05**

Is participant receiving 2-week injections of Omalizumab/Placebo? 0 ☐ No 1 ☐ Yes

If Yes, complete the following:

URINE PREGNANCY TEST RESULTS

Visit Date: ____/_____/_____
dd mmm yyyy

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____
dd mmm yyyy

Time of Injection: ___ ___:___ ___
(24 Hr. clock)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 2 / Visit 06**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 2 / Visit 06**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 3 / Visit 07**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Respiratory	0 ☐	1 ☐	2 ☐	97 ☐	
4.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Gastrointestinal/ Abdomen	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Endocrine/Metabolic	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Neurological	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Blood/Lymphatic	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
11.	Psychological	0 ☐	1 ☐	2 ☐	97 ☐	
12.	General Appearance	0 ☐	1 ☐	2 ☐	97 ☐	
99.	Other _____	0 ☐	1 ☐	2 ☐	97 ☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 3 / Visit 07**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 3 / Visit 07**

NASAL EXHALED NITRIC OXIDE - NO

Nitric Oxide Value at 50 mL/m: ___ ___ ___.___ ppb

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 3 / Visit 07**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 3 / Visit 07**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 3 / Visit 07**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment (*24 Hr. clock*)	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 4 / Visit 08**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 4 / Visit 08**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 5 / Visit 09**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 5 / Visit 09**

NASAL EXHALED NITRIC OXIDE - NO

Nitric Oxide Value at 50 mL/m: ___ ___ ___.___ ppb

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 5 / Visit 09**

ALLERGY SKIN REACTIONS TEST

Time of First Injection: ___ ___:___ ___
(24 Hr. Clock)

Dilution	Injection	15 min. Post-Injection			16-24 Hrs. Post-Injection		
		Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*	Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*
	Injection 1-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 1-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Positive Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Negative Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 5 / Visit 09**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 5 / Visit 09**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 5 / Visit 09**

Is participant receiving 2-week injections of Omalizumab/Placebo? 0 ☐ No 1 ☐ Yes

If Yes, complete the following:

URINE PREGNANCY TEST RESULTS

Visit Date: ____/_____/_____
dd mmm yyyy

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____
dd mmm yyyy

Time of Injection: ___ ___:___ ___
(24 Hr. clock)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 6 / Visit 10**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 6 / Visit 10**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 7 / Visit 11**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Respiratory	0 ☐	1 ☐	2 ☐	97 ☐	
4.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Gastrointestinal/ Abdomen	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Endocrine/Metabolic	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Neurological	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Blood/Lymphatic	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
11.	Psychological	0 ☐	1 ☐	2 ☐	97 ☐	
12.	General Appearance	0 ☐	1 ☐	2 ☐	97 ☐	
99.	Other _____	0 ☐	1 ☐	2 ☐	97 ☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 7 / Visit 11**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 7 / Visit 11**

NASAL EXHALED NITRIC OXIDE - NO

Nitric Oxide Value at 50 mL/m: ___ ___ ___.___ ppb

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 7 / Visit 11**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 7 / Visit 11**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 7 / Visit 11**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment (*24 Hr. clock*)	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 8 / Visit 12**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 8 / Visit 12**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 9 / Visit 13**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

NASAL EXHALED NITRIC OXIDE - NO

Nitric Oxide Value at 50 mL/m: ___ ___ ___.___ ppb

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 9 / Visit 13**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 9 / Visit 13**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 9 / Visit 13**

Is participant receiving 2-week injections of Omalizumab/Placebo? 0 ☐ No 1 ☐ Yes

If Yes, complete the following:

URINE PREGNANCY TEST RESULTS

Visit Date: ____/_____/_____
dd mmm yyyy

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____
dd mmm yyyy

Time of Injection: ___ ___:___ ___
(24 Hr. clock)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 10 / Visit 14**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 10 / Visit 14**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 11 / Visit 15**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Respiratory	0 ☐	1 ☐	2 ☐	97 ☐	
4.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Gastrointestinal/ Abdomen	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Endocrine/Metabolic	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Neurological	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Blood/Lymphatic	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
11.	Psychological	0 ☐	1 ☐	2 ☐	97 ☐	
12.	General Appearance	0 ☐	1 ☐	2 ☐	97 ☐	
99.	Other _____	0 ☐	1 ☐	2 ☐	97 ☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 11 / Visit 15**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

NASAL EXHALED NITRIC OXIDE - NO

Nitric Oxide Value at 50 mL/m: ___ ___ ___.___ ppb

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 11 / Visit 15**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 11 / Visit 15**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 11 / Visit 15**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment (*24 Hr. clock*)	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

OMALIZUMAB / PLACEBO DOSING

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

Dose: ___ ___ ___ mg

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 12 / Visit 16**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 12 / Visit 16**

IMMUNOTHERAPY / PLACEBO

Date of Injection: ____/_____/_____ (*dd mmm yyyy*)

Time of Injection: ___ ___:___ ___ (*24 Hr. clock*)

POST-INJECTION ADVERSE EVENTS*

Time of Assessment *(24 Hr. clock)*	Did participant experience any of the following Adverse Events? 0 ☐ No 1 ☐ Yes If Yes, check all that apply at each assessment.								
	Wheezing	Flushing	Urticaria	Angio-Edema	Mean Drop of BP ≥ 15 mm	Light-headedness	Itching	Abdominal Pain	Nausea
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									
___ ___:___ ___									

*All events reported should also be reported on the Adverse Events page.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Respiratory	0 ☐	1 ☐	2 ☐	97 ☐	
4.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Gastrointestinal/ Abdomen	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Endocrine/Metabolic	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Neurological	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Blood/Lymphatic	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
11.	Psychological	0 ☐	1 ☐	2 ☐	97 ☐	
12.	General Appearance	0 ☐	1 ☐	2 ☐	97 ☐	
99.	Other _____	0 ☐	1 ☐	2 ☐	97 ☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

If Positive, exclude participant from study.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

NASAL ALLERGEN CHALLENGE

Date of Challenge: ____/_____/_____
dd mmm yyyy

THIRD SALINE CHALLENGE

Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
			Sneezing	Nasal Itching	Sinus Pressure
___ ___:___ ___	___.___ ___	___ ___.___ ___ LN	# Sneezes		
		___ ___.___ ___ RN			
		___ ___.___ ___ TNV			

Nasal Challenge Calculated Endpoints

FEV_1 (L) = ___.___ ___ x 0.8 = ___.___ ___ (EP for FEV_1)

Nasal Rhinogram (cm^3) = ___ ___.___ ___ x 0.7 = ___ ___.___ ___ (EP for TNV)
(TNV)

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

NASAL ALLERGEN CHALLENGE

RAGWEED CHALLENGE

Dilution		Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
					Sneezing	Nasal Itching	Sinus Pressure
1.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
2.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
3.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
4.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
5.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

NASAL SCRAPING

Cell count: ___ ___

NASAL EXHALED NITRIC OXIDE - NO

Nitric Oxide Value at 50 mL/m: ___ ___ ___.___ ppb

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

ALLERGY SKIN REACTIONS TEST

Time of First Injection: ___ ___:___ ___
(24 Hr. Clock)

Dilution	Injection	15 min. Post-Injection			16-24 Hrs. Post-Injection		
		Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*	Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*
	Injection 1-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 1-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Positive Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Negative Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

ELECTROCARDIOGRAM - 12 LEAD

Date ECG Performed: ____/_____/_____
dd mmm yyyy

Overall interpretation of ECG:

0 ☐ Normal
1 ☐ Abnormal, Clinically Significant
2 ☐ Abnormal, Not Clinically Significant
97 ☐ Not Done

Specify Abnormality: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 13 / Visit 17**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Nasal Scraping

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

7. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 19 / Visit 18**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 19 / Visit 18**

NASAL ALLERGEN CHALLENGE

Date of Challenge: ____/_____/_____
dd mmm yyyy

THIRD SALINE CHALLENGE

Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
			Sneezing	Nasal Itching	Sinus Pressure
___ ___:___ ___	___.___ ___	___ ___.___ ___ LN	# Sneezes		
		___ ___.___ ___ RN			
		___ ___.___ ___ TNV			

Nasal Challenge Calculated Endpoints

FEV_1 (L) = ___.___ ___ x 0.8 = ___.___ ___ (EP for FEV_1)

Nasal Rhinogram (cm^3) = ___ ___.___ ___ x 0.7 = ___ ___.___ ___ (EP for TNV)
(TNV)

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 19 / Visit 18**

NASAL ALLERGEN CHALLENGE

RAGWEED CHALLENGE

	Dilution	Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
					Sneezing	Nasal Itching	Sinus Pressure
1.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
2.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
3.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
4.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
5.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 19 / Visit 18**

NASAL SCRAPING

Cell count: ___ ___

ALLERGY SKIN REACTIONS TEST

Time of First Injection: ___ ___:___ ___
(24 Hr. Clock)

Dilution	Injection	15 min. Post-Injection			16-24 Hrs. Post-Injection		
		Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*	Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*
	Injection 1-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 1-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Positive Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Negative Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 19 / Visit 18**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Nasal Scraping

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

7. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 31 / Visit 19**

VITAL SIGNS

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1 ☐ °C 2 ☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1 ☐ kg 2 ☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Respiratory	0 ☐	1 ☐	2 ☐	97 ☐	
4.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Gastrointestinal/ Abdomen	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Endocrine/Metabolic	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Neurological	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Blood/Lymphatic	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
11.	Psychological	0 ☐	1 ☐	2 ☐	97 ☐	
12.	General Appearance	0 ☐	1 ☐	2 ☐	97 ☐	
99.	Other _____	0 ☐	1 ☐	2 ☐	97 ☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 31 / Visit 19**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 31 / Visit 19**

NASAL ALLERGEN CHALLENGE

Date of Challenge: ____/_____/_____
dd mmm yyyy

THIRD SALINE CHALLENGE

Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
			Sneezing	Nasal Itching	Sinus Pressure
___ ___:___ ___	___.___ ___	___ ___.___ ___ LN	# Sneezes		
		___ ___.___ ___ RN			
		___ ___.___ ___ TNV			

Nasal Challenge Calculated Endpoints

FEV_1 (L) = ___.___ ___ x 0.8 = ___.___ ___ (EP for FEV_1)

Nasal Rhinogram (cm^3) = ___ ___.___ ___ x 0.7 = ___ ___.___ ___ (EP for TNV)
(TNV)

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 19 / Visit 18**

NASAL ALLERGEN CHALLENGE

RAGWEED CHALLENGE

	Dilution	Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
					Sneezing	Nasal Itching	Sinus Pressure
1.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
2.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
3.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
4.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
5.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 31 / Visit 19**

NASAL SCRAPING

Cell count: ___ ___

ALLERGY SKIN REACTIONS TEST

Time of First Injection: ___ ___:___ ___
(24 Hr. Clock)

Dilution	Injection	15 min. Post-Injection			16-24 Hrs. Post-Injection		
		Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*	Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*
	Injection 1-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 1-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Positive Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Negative Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 31 / Visit 19**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Nasal Scraping

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

7. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 43 / Visit 20**

VITAL SIGNS

Visit Date: ____/_____/_____
dd mmm yyyy

Sitting
Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg
Systolic Diastolic

Temperature: ___ ___ ___ . ___ 1☐ °C 2☐ °F

Pulse: ___ ___ ___ beats/min

Weight: ___ ___ ___ . ___ 1☐ kg 2☐ lb

Respirations: ___ ___ breaths/min

PHYSICAL EXAM

Body Code	Assessment	Change from Previous Visit				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened	Not Done	
1.	Skin, Hair	0☐	1☐	2☐	97☐	
2.	Head, Eyes, Ears, Nose, Throat, Neck	0☐	1☐	2☐	97☐	
3.	Respiratory	0☐	1☐	2☐	97☐	
4.	Cardiovascular	0☐	1☐	2☐	97☐	
5.	Gastrointestinal/ Abdomen	0☐	1☐	2☐	97☐	
6.	Endocrine/Metabolic	0☐	1☐	2☐	97☐	
7.	Genitourinary	0☐	1☐	2☐	97☐	
8.	Neurological	0☐	1☐	2☐	97☐	
9.	Blood/Lymphatic	0☐	1☐	2☐	97☐	
10.	Musculoskeletal	0☐	1☐	2☐	97☐	
11.	Psychological	0☐	1☐	2☐	97☐	
12.	General Appearance	0☐	1☐	2☐	97☐	
99.	Other _____	0☐	1☐	2☐	97☐	

If Assessment is considered to be worsened, please indicate condition on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 43 / Visit 20**

URINE PREGNANCY TEST RESULTS

Test Results: 0 ☐ Negative 1 ☐ Positive 98 ☐ N/A

Date of Urine Pregnancy Test (if applicable): ____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 43 / Visit 20**

NASAL ALLERGEN CHALLENGE

Date of Challenge: ____/_____/_____
dd mmm yyyy

THIRD SALINE CHALLENGE

Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
			Sneezing	Nasal Itching	Sinus Pressure
___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
		___ ___.___ ___ RN	# Sneezes		
		___ ___.___ ___ TNV			

Nasal Challenge Calculated Endpoints

FEV_1 (L) = ___.___ ___ x 0.8 = ___.___ ___ (EP for FEV_1)

Nasal Rhinogram (cm^3) = ___ ___.___ ___ x 0.7 = ___ ___.___ ___ (EP for TNV)
(TNV)

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 43 / Visit 20**

NASAL ALLERGEN CHALLENGE

RAGWEED CHALLENGE

Dilution		Time (10 min. Post Challenge) *(24 Hr. Clock)*	FEV_1 (L)	Acoustic Rhinogram *(cm)* LN = left nares RN = right nares TNV = total nasal volume (LN & RN)	Symptom Scores 0 = None 1 = Mild 2 = Moderate 3 = Severe		
					Sneezing	Nasal Itching	Sinus Pressure
1.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
2.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
3.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
4.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			
5.		___ ___:___ ___	___.___ ___	___ ___.___ ___ LN			
				___ ___.___ ___ RN	# Sneezes		
				___ ___.___ ___ TNV			

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 43 / Visit 20**

NASAL SCRAPING

Cell count: ___ ___

ALLERGY SKIN REACTIONS TEST

Time of First Injection: ___ ___:___ ___
(24 Hr. Clock)

Dilution	Injection	15 min. Post-Injection			16-24 Hrs. Post-Injection		
		Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*	Time of Measurement *(24 Hr. Clock)*	Wheal *(mm)*	Erythema *(mm)*
	Injection 1-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 1-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 2-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 3-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 4-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-A	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Injection 5-B	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Positive Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___
	Negative Control	___ ___:___ ___	___ ___	___ ___	___ ___:___ ___	___ ___	___ ___

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 43 / Visit 20**

HEMATOLOGY

Date of Specimen Collection:____/_____/_____
dd mmm yyyy

Laboratory tests performed at: 1 ☐ PI Lab 2 ☐ Other, specify laboratory name: _____

CBC Test	Value	Unit	Other Units	Result Not Available
RBC		(10^6 cells/μL)		97 ☐
Hemoglobin		(g/dL)		97 ☐
Hematocrit		(%)		97 ☐
MCV		(μm^3)		97 ☐
Platelet Count		(10^3 cells/μL)		97 ☐
MCH		(%)		97 ☐
MCHC		(%)		97 ☐
WBC		(10^3 cells/μL)		97 ☐
DIFFERENTIAL:				
Segmented Neutrophils		(%)		97 ☐
Bands		(%)		97 ☐
Lymphocytes		(%)		97 ☐
Monocytes		(%)		97 ☐
Eosinophils		(%)		97 ☐
Basophils		(%)		97 ☐
Other, specify _____				97 ☐

If abnormal lab value is considered to be clinically significant, please indicate on the Adverse Event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 43 / Visit 20**

CLINICAL STUDIES

1. Clinical Chemistry

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

2. Urinalysis

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, Date of Collection: _____/_____/_____
dd mmm yyyy

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	**Week 43 / Visit 20**

TOLERANCE ASSAY STUDIES

Date of Collection: ____/_____/_____
dd mmm yyyy

Affix barcode label from blood sample here:

1 ☐ Mark if none

Was label lost or damaged? 0 ☐ No 1 ☐ Yes

If Yes, please provide label number: _____

1. Nasal Scraping

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

2. Antigen Specific Antibodies/HAHA

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

3. Frozen PBMC-ELISPOT

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

4. Peripheral Blood Gene Expression Profile Real Time PCR

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

5. Flow Cytometry - Surface Staining

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

6. Basophil Histamine Release (Univ. of WI, Creighton only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

7. Apoptosis (TUNEL) (Univ. of Iowa only)

Was sample collected? 0 ☐ No 1 ☐ Yes

If Yes, # of Tubes Collected: _____

Protocol No.	Investigator No.	Participant No.	Participant Initials
ITN019AD	**001**	___ ___ ___	___ ___ ___

ADVERSE EVENTS

Has the participant experienced any adverse events? 0 ☐ No 1 ☐ Yes If Yes, describe below.

Event No.	Adverse Event	Start Date Stop Date	Outcome	Any Treatment Required?	Severity*	Action Taken	Relation To Study Therapy	Wk 1-12 Only: Relation To Omalizumab⁺ or Immunotherapy⁺	Was Event Serious? **
	(Please list one event per line)	*dd/mmm/yyyy*	(write code below) 1 = Unresolved 2 = Resolved 3 = Resolved w/Sequelae 4 = Death	(write code below) 0 = None 1 = Concomitant Medications 2 = Non-Drug Therapies 3 = Concomitant Medications and Non-Drug Therapies	(write code below) 1 = Mild 2 = Moderate 3 = Severe 4 = Life Threatening 5 = Death	(write code below) 0 = None 1 = Temporary Discontinuation 2 = Permanent Discontinuation	(write code below) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	(write code below) 1=Omalizumab/ Placebo 2=Immunotherapy/ Placebo 3=Uncertain	(definition below) (write code below) 0 = No 1 = Yes
1.		____/_____/_____ ____/_____/_____							
2.		____/_____/_____ ____/_____/_____							
3.		____/_____/_____ ____/_____/_____							
4.		____/_____/_____ ____/_____/_____							

* Please refer to NCI CTC or protocol for severity grading.

⁺ or Placebo

** A serious adverse event (SAE) is defined as any adverse event occurring at any dose in a participant that suggests a significant hazard, contraindication, side effect, or precaution. This includes, but may not be limited to any of the following events: death, life-threatening, in-patient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect, other conditions as specified in the protocol or an event that required intervention to prevent permanent impairment or damage. If the AE is serious, contact PPD Development and complete a serious adverse event form.

Immune Tolerance Network

Protocol No.	Investigator No.	Participant No.	Participant Initials
ITN019AD	**001**	___ ___ ___	___ ___ ___

ADVERSE EVENTS

Event No.	Adverse Event	Start Date Stop Date	Outcome	Any Treatment Required?	Severity*	Action Taken	Relation To Study Therapy	Wk 1-12 Only: Relation To Omalizumab+ or Immunotherapy+	Was Event Serious? **
	(Please list one event per line)	*dd/mmm/yyyy*	(write code below) 1 = Unresolved 2 = Resolved 3 = Resolved w/Sequelae 4 = Death	(write code below) 0 = None 1 = Concomitant Medications 2 = Non-Drug Therapies 3 = Concomitant Medications and Non-Drug Therapies	(write code below) 1 = Mild 2 = Moderate 3 = Severe 4 = Life Threatening 5 = Death	(write code below) 0 = None 1 = Temporary Discontinuation 2 = Permanent Discontinuation	(write code below) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	(write code below) 1=Omalizumab/ Placebo 2=Immunotherapy/ Placebo 3=Uncertain	(definition below) (write code below) 0 = No 1 = Yes
1.		____/_____/_____ ____/_____/_____							
2.		____/_____/_____ ____/_____/_____							
3.		____/_____/_____ ____/_____/_____							
4.		____/_____/_____ ____/_____/_____							

* Please refer to NCI CTC or protocol for severity grading.

+ or Placebo

** A serious adverse event (SAE) is defined as any adverse event occurring at any dose in a participant that suggests a significant hazard, contraindication, side effect, or precaution. This includes, but may not be limited to any of the following events: death, life-threatening, in-patient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect, other conditions as specified in the protocol or an event that required intervention to prevent permanent impairment or damage. If the AE is serious, contact PPD Development and complete a serious adverse event form.

Protocol No.	Investigator No.	Participant No.	Participant Initials
ITN019AD	**001**	___ ___ ___	___ ___ ___

CONCOMITANT MEDICATION

Were any concomitant medications taken? 0 ☐ No 1 ☐ Yes If Yes, describe below.

List any non-study medication taken at entry and during the course of the study (includes over-the-counter and prescription drugs).

Line No.	Drug Name (Brand or Generic)	Indication	Dose	Unit	**Frequency	*Route	Start Date	Stop Date	
					If "99=Other" please specify	If "99=Other" please specify	*(dd/mmm/yyyy)*	*(dd/mmm/yyyy)* mark box (✓) if continuing ↓	
1.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
2.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
3.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
4.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
5.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
6.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
7.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
8.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
9.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
10.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
11.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐

***Route**: 1 = oral, 2 = intravenous, 3 = intramuscular, 4 = topical, 5 = inhaled, 6 = subcutaneous, 7 = intradermal, 8 = sublingual, 9 = intra-articular, 10 = opthalmic, 11 = intralesional, 12 = rectal, 13 = vaginal, 99 = Other

****Frequency**: 1 = QD, 2 = BID, 3 = TID, 4 = QID, 5 = QHS, 6 = QOD, 7 = PRN, 99 =Other

Protocol No.	Investigator No.	Participant No.	Participant Initials
ITN019AD	**001**	___ ___ ___	___ ___ ___

CONCOMITANT MEDICATION

List any non-study medication taken at entry and during the course of the study (includes over-the-counter and prescription drugs).

Line No.	Drug Name (Brand or Generic)	Indication	Dose	Unit	**Frequency	*Route	Start Date	Stop Date	
					If "99=Other" please specify	If "99=Other" please specify	*(dd/mmm/yyyy)*	*(dd/mmm/yyyy)* mark box (✓) if continuing ↓	
1.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
2.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
3.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
4.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
5.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
6.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
7.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
8.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
9.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
10.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐
11.					☐ _____	☐ _____	_____/_____/_____	_____/_____/_____	1 ☐

***Route**: 1 = oral, 2 = intravenous, 3 = intramuscular, 4 = topical, 5 = inhaled, 6 = subcutaneous, 7 = intradermal, 8 = sublingual, 9 = intra-articular, 10 = opthalmic, 11 = intralesional, 12 = rectal, 13 = vaginal, 99 = Other

****Frequency**: 1 = QD, 2 = BID, 3 = TID, 4 = QID, 5 = QHS, 6 = QOD, 7 = PRN, 99 =Other

Protocol No.	Investigator No.	Participant No.	Participant Initials
ITN019AD	**001**	___ ___ ___	___ ___ ___

PROTOCOL DEVIATION

Deviation Date: ____/_____/_____
dd mmm yyyy

Deviation identified by (mark one):

1 ☐ Principal Investigator
2 ☐ Study Coordinator
3 ☐ Site Monitor
4 ☐ Medical Monitor
5 ☐ ITN Associate Leader/NIAID Project Manager
6 ☐ Data Manager

Timing of deviation:

1 ☐ Deviation occurred prior to treatment
2 ☐ Deviation occurred during treatment
3 ☐ Deviation occurred after treatment

Protocol version: ___.___ (Example 1.0)

Protocol section number: ___ ___.___.___.___.___ (Example 3.2.1.)

Inclusion or exclusion criteria number (if applicable): ___ ___

Details of protocol deviation:

_____

_____

_____

_____

_____

Steps taken to resolve this deviation:

_____

_____

_____

Will the participant continue in this trial?

0 ☐ No*
1 ☐ Yes, continue therapy/intervention
2 ☐ Yes, follow-up only

Complete the Termination form.

_____ Date: ____/_____/_____
Signature of Investigator or designee *dd mmm yyyy*

Protocol No.	Investigator No.	Participant No.	Participant Initials
ITN019AD	**001**	___ ___ ___	___ ___ ___

PROTOCOL DEVIATION

Deviation Date: ____/_____/_____
dd mmm yyyy

Deviation identified by (mark one):

1 ☐ Principal Investigator
2 ☐ Study Coordinator
3 ☐ Site Monitor
4 ☐ Medical Monitor
5 ☐ ITN Associate Leader/NIAID Project Manager
6 ☐ Data Manager

Timing of deviation:

1 ☐ Deviation occurred prior to treatment
2 ☐ Deviation occurred during treatment
3 ☐ Deviation occurred after treatment

Protocol version: ___.___ (Example 1.0)

Protocol section number: ___ ___.___.___.___.___ (Example 3.2.1.)

Inclusion or exclusion criteria number (if applicable): ___ ___

Details of protocol deviation:

_____

_____

_____

_____

_____

Steps taken to resolve this deviation:

_____

_____

_____

Will the participant continue in this trial?

0 ☐ No*
1 ☐ Yes, continue therapy/intervention
2 ☐ Yes, follow-up only

Complete the Termination form.

_____ Date: ____/_____/_____
Signature of Investigator or designee *dd mmm yyyy*

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	

STUDY DRUG DISCONTINUATION

Discontinuation of study therapy/intervention date: ____/____/_____
dd mmm yyyy

Indicate the primary reason for Study Drug discontinuation:

1 ☐ Participant Withdrew Consent

2 ☐ Adverse Event, specify Adverse Event page #: _____ Adverse Event #:_____

3 ☐ Insufficient Therapeutic Response

4 ☐ Investigator Decision

5 ☐ Missed Study Visit

6 ☐ Protocol Deviation

99 ☐ Other, specify: _____

If a protocol deviation occurred, complete a Protocol Deviation form.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	

TREATMENT UNBLINDING

Complete this form if any individual or study center personnel received access to the treatment code who were not identified in the protocol as receiving such access.

Date unblinding occurred: ____/_____/_____
dd *mmm* *yyyy*

Reason for unblinding:
1 ☐ Accidental unblinding
2 ☐ Adverse Event

Give summary of unblinding event: _____

_____

_____

_____

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	

DEATH FORM

1. Date of Death: ____/_____/_____
   dd mmm yyyy

2. Cause of death: _____

3. Was an autopsy performed? $_0$☐ No $_1$☐ Yes

Please contact the PPD MA/PVG at 1-800-201-8725 within 24 hours of the death and submit a Serious Adverse Event form to the PPD MA/PVG.

Protocol No.	Investigator No.	Participant No.	Participant Initials	Visit
ITN019AD	**001**	___ ___ ___	___ ___ ___	

TERMINATION FROM PROTOCOL

Date of last follow-up: ____/____/_____
dd mmm yyyy

Indicate the primary reason the participant will no longer be followed:

1 ☐ Follow-Up Completed per Protocol

2 ☐ Participant Refusal

3 ☐ Death

4 ☐ Lost to Follow Up

5 ☐ Adverse Event, specify Adverse Event page #: _____ Adverse Event #:_____

99 ☐ Other, specify: _____

INVESTIGATOR STATEMENT

I certify that I have carefully examined all entries on the case report form and that all information entered on these pages by myself or my associates is correct.

Principal Investigator's Signature: _____ Date: ____/_____/_____
dd mmm yyyy

Immune Tolerance Network

PROTOCOL ITN019AD

"Phase II, Double Blinded, Placebo Controlled, Efficacy and Safety Evaluation of Allergen Immunotherapy Co-Administered with Omalizumab, an Anti-IgE Monoclonal Antibody"

Investigator No.	Participant No.	Participant Initials
001	___ ___ ___	___ ___ ___

3151 S. 17th Street
Wilmington, NC 28412