NORTH TEXAS ALLERGY & ASTHMA ASSOCIATES

Locations throughout Dallas – Specializing in personalized care since 1927
Main: (214) 369-1901 ~ Fax: (214) 369-1905

INFORMED CONSENT FOR MEPOLIZUMAB (NUCALA)

TO THE PATIENT: You have the right, as a patient, parent, or legal guardian, to be informed about the condition and the recommended medical or diagnostic procedure to be used, so that you may make the decision whether to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to frighten or alarm you; it is simply an effort to make you better informed, so you may give or withhold your consent to the procedures recommended to you.

I (we) am (are) of sound mental and physical condition, and I (we) am (are) able to give informed consent. I (we) acknowledge that I (we) am (are) fully aware of the care, treatment, and/or services that I (we) am (are) going to receive that is subject to of this consent form. I (we) voluntarily request North Texas Allergy & Asthma Associates ("NTAAA") staff physicians, and other health care providers as they may deem necessary, to perform the following medical and/or diagnostic procedures, and I (we) voluntarily consent and authorize these treatments/procedures as deemed necessary upon examination.

Treatment/Procedure to be performed: **Mepolizumab (Nucala)**

My (our) physician has prescribed Nucala subcutaneous injection therapy for patients 12 and older with severe eosinophilic asthma. Nucala is not used to treat sudden breathing problems and additional information is available online (www.nucala.com).

I (we) understand the risks and benefits that I (we) can reasonably expect from administration of Nucala. It may result in complications of hypersensitivity (allergic) reactions such as angioedema (swelling), bronchospasm (wheezing), low blood pressure, hives, other rashes and even death. These generally have occurred within hours of administration, but in some instances can be delayed. I also understand that, as with every procedure, there is a possibility of unexpected complications. Nucala may increase the risk of herpes zoster (shingles), **Thus it is important that your Chickenpox/Shingles vaccination is up to date** (2 doses of the vaccine are recommended for most children or adults born after 1980). If you do not know your vaccination status, please discuss this with your doctor prior to starting Nucala. Nucala may also increase the risk of parasitic (helminth) infections. Any parasitic infections should be treated prior to starting Nucala OR if a parasitic infection occurs, Nucala should be stopped while the infection is treated. Before starting Nucala, please tell the physician if you are or plan to be pregnant or breast feed.

I (we) understand that as a patient taking Nucala, my physician may stop certain medications (Beta-Blockers because of the inability to treat an allergic reaction or MAO Inhibitors which may cause high blood pressure when adrenalin or other prescription medications are administered). Furthermore, I (we) understand that it is required for me to wait in the waiting room **AT LEAST 30 MINUTES** after each injection. If I (we) leave early, I (we) understand that it is against medical advice and will hold my treating physician, NTAAA, and their staff free of any liability. I (we) understand that any time Nucala is given; there is a rare chance of nicking a tiny blood vessel causing a bruise, numbness or pain. If swelling is over a size of a quarter (2 inches) at the site of injection, I (we) will notify the nurse or physician before receiving my next injection. I (we) will inform the physician if we develop an allergic reaction to Nucala or any other ingredient in Nucala. Please inform us of any side effect that bothers you or does not go away. I (we) understand that I (we) may contact the physician's office if I (we) have any further questions.

Potential Reactions during the injection:

- IMMEDIATE REACTIONS: The risks of an immediate allergic reaction include: Itching, rash, hives, swelling of the lips, tongue, or throat, chest pain, chest tightness, shortness of breath, wheezing, abdominal pain, nausea, vomiting, diarrhea, palpitations, dizziness, confusion, anaphylaxis, shock and rarely death.
- DELAYED REACTIONS: Can include: rash, itching, liver or kidney involvement, fevers, chills, joint pains, and ulcerations.
- OTHER: There is a risk of other types of allergic reactions as a result of side effects of the medication, food or chemical. Non-allergic drug side effects may occur and depend on the drug. Common side effects include nausea, mild diarrhea, headaches, and acid reflux.

I (we) have completed this form with accurate information. I (we) have been given an opportunity to ask questions about my condition and treatment, alternative forms of treatment, risks of non-treatment, the procedures to be used, and the risks and hazards involved of the procedure, and I (we) believe that (we) have sufficient information to give this informed consent. I (we) acknowledge that this disclosure and informed consent has been fully explained to me, that I (we) have read it or have had it read to me and that I (we) understand its contents. I (we) have had all my (our) questions, if any, answered to my (our) satisfaction, and I (we) consent to this treatment/procedure.

Date: _____ Time: _____ Patient Name: _____ Signature: _____

Date: _____ Time: _____ Doctor Name: _____ Signature: _____

Date: _____ Time: _____ Witness Name: _____ Signature: _____

IF A MINOR, PLEASE COMPLETE THIS SECTION (Parent or legal guardian):

Relationship: _____ Name: _____ Signature: _____