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Disclosure and Consent for Administration of Xolair (omalizumab) to the Patient

You have a right, as a patient, to be informed about your condition and the recommended treatments (including risks and benefit) to help you make informed decisions about your healthcare. If you have any questions about the information below, please ask Dr._____. Also, please understand - you are not required to take omalizumab. You may continue to receive care by this office, even if you decide against the omalizumab therapy.

1. I hereby request that Dr._____, as my physician, treat my condition - explained to me as moderate to severe persistent bronchial asthma related to allergies **or** chronic idiopathic urticaria (CIU) - with a drug called omalizumab or Xolair.

2. I have been informed that the FDA has issued a special warning known as a "Black Box" warning for the drug Xolair. Xolair has been associated with a small but significant increase in anaphylaxis (severe and potentially life-threatening allergy symptoms) in patients who took this drug, compared to patients who were given a placebo injection (having no Xolair in the injection). I am aware of the data that show at most 0.2% of an estimated exposed 57,300 patients experienced anaphylaxis. This frequency is estimated to be about 115 patients of the 57,000.

3. I understand that Xolair was approved in 2003 to treat adults and adolescents (12 years of age and above) who (1) have moderate to severe persistent asthma; (2) have tested positive for perennial aeroallergen (mold, dander or dust); and (3) have symptoms that are inadequately controlled with inhaled steroids. I understand that in clinical trials, Xolair decreased the rate of asthma exacerbations, which were defined as a worsening of asthma that required treatment with systemic corticosteroids or a doubling of base-line inhaled corticosteroid dose.

4. I understand that in 2014, Xolair was approved for people 12 years and older with chronic idiopathic urticaria who remain symptomatic despite treatment with H1-antihistamine therapy.

5. **General Warnings:** IT HAS BEEN EXPLAINED TO ME AND I UNDERSTAND THAT:

   - I should carry medical contact information and be fully prepared to begin treatment for anaphylaxis. My doctor has explained the definition of anaphylaxis and its treatment to me and I understand this information.
   - Patients who have ever had an allergic reaction to a Xolair injection should not receive Xolair. I will carry my Epi Pen/Auvi Q with me at all times. My physician had demonstrated on how to use the autoinjector.
   - I should not change or stop taking any of my other asthma medications unless otherwise instructed to do so by a healthcare provider; and
   - I may not see immediate improvement in my asthma or CIU after beginning Xolair therapy.

6. Dr._____ has explained to me other treatment options available for my condition, and their risks, including continuation of my current treatment plan (without Xolair).

7. My signature below indicates that this form has been fully explained to me and I have had opportunities to ask questions. My questions have been answered and it is my wish to be treated with Xolair for my moderately-severe or severe allergic bronchial asthma or chronic idiopathic urticaria.

_____

Printed name of patient

_____

Signature of patient or legal guardian if minor Date

_____

Health Care Provider Signature Date