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Subcutaneous Immune Globulin (Scig) Home Infusion Patient Consent and Participation Agreement

A. Identification of Procedure

Hizentra which is subcutaneous immune globulin (SCIG) is indicated as replacement therapy for patients with primary humoral immunodeficiency (PI). This includes but is not limited to the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

B. Statement of Request

The purpose of the procedure, the benefits involved, the risks involved, and the possibility of complications have been fully explained to me. Possible alternative methods of treatment had also been discussed. I acknowledge that no guarantees have been made to me concerning the results of the procedure.

Infusion of human immunoglobulins risks include: Hizentra is contraindicated in patients with a history of anaphylactic or severe systemic reaction to human immune globulin preparations or its components. Because it contains the stabilizer L-proline, Hizentra is also contraindicated in patients with hyperprolinemia. It is also contraindicated in patients with immunoglobulin A deficiency who have antibodies against IgA and a history of hypersensitivity.

Hizentra is derived from human plasma (human blood product). The risk of transmission of infectious agents, including viruses and, theoretically, the Cruetzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

Other adverse reactions include local reactions (i.e., swelling, redness, heat, pain, and itching at the injection site), headache, vomiting, diarrhea, abdominal pain, back pain, myalgias, chills, fever, and fatigue; aseptic meningitis syndrome (brain swelling), renal dysfunction/failure, thrombotic events (blood clotting), hemolysis (destruction of red blood cells), and transfusion-related acute lung injury (TRALI).

Risk Factors can include: advanced age, prolonged immobilization, a history of blood clotting or hyperviscosity (blood thickness), use of estrogens, installed vascular catheters, and cardiovascular risk factors.

C. Signatures

Counseling Physician: I have reviewed and discussed with this patient the proposed procedure including its benefits, potential risks involved, and expected results. I have also discussed potential problems related to possible results of non-treatment and alternative therapies.

Counseling Physician's Signature *Date*

Patient: I understand the nature of the proposed procedure, potential risks involved, and expected results and hereby request such procedure to be performed.

Patient's Name (printed) *Date*

Patient's Signature *Date*

Parent or Guardian: (When patient is a minor or unable to give consent)

Parent/guardian of _____ understands the nature of the proposed procedure, potential risks involved, and expected results and hereby request such procedure be performed.

Parent or Legal Guardian's Signature *Date*