Group A Streptococcus Study
Patient Consent Form- Immune Studies I (IVIG treated patients)

I,_____, have an infection caused by a bacterium called group
(name)
A streptococcus. Several doctors and nurses in Toronto are studying this infection in order to better understand how to prevent and treat it. I therefore give my consent to the following:

Mount Sinai Hospital, Toronto, ON

Princess Margaret Hospital, Toronto, ON

Centers for Disease Control Atlanta, Georgia

Va Medical Center Memphis, TN

A. Release of information about my medical history by the doctors and _____ to the study. I understand that it will be used only for the
(name of hospital)
study, and that all information will be anonymously coded so that I cannot be personally identified. I also agree that the laboratory at this hospital may send a sample of the bacterium isolated from me to the study laboratory. If I have had surgery, I also agree that the laboratory may send any samples from tissue taken at surgery that are not needed for my care.

Yes ❍ No ❍ Initials_____

B. I consent to having two blood samples (about 2 tablespoons each) taken to test how my immune system has reacted to the infection. One sample will be taken now and the second will be taken in two to three days. One more sample may be taken if I am treated with a medication called intravenous immunoglobulin. If possible, the samples will be taken at the same time as I am having blood drawn for my usual care. I understand that there may be some discomfort when the blood is taken, and that there may be some bruising afterward.

Yes ❍ No ❍ Initials_____

C. I consent to the study nurse contacting me in approximately four weeks time to discuss a follow-up blood sample (about 2 tablespoons). At that time I will make the decision as to whether or not I will consent to having the blood sample taken.

Yes ❍ No ❍ Initials_____

Pt. Phone # (___)____-_____
(for follow-up purposes ONLY)

Mr. Agron Plevneshi
Study Coordinator
(416) 586-3144
1-800-668-6292

I understand that participation in this study is completely voluntary, and that my care will not be affected in any way if I choose to participate. I also understand that my infection has been reported to the public health department, and they may be in contact with me and or my household if any members should need treatment with antibiotics. I have had a chance to ask any questions that I might have. I understand that if I require further information at any time I may call the study coordinator, Mr. Agron Plevneshi, or any of the study investigators listed on the left side of this letter. I have been offered a copy of this form.

Study Investigators
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Date_____ Signature_____

Witness_____