Dear IRB

_____is under my care for the treatment of HIV. He has developed resistance to all commercially available HIV medications, including Fuzeon and Aptivus (see attached genotype test). His CD4 count has decreased to _____ which is a concerning level that may impair his health and quality of life.

Currently, he cannot construct a viable regimen to control virus replication unless he gets access in a single patient IND program. The studies enrolling in _____ this year will not offer him the certainty of starting at least two new active agents since all trials contain a placebo arm that may expose him to virtual monotherapy.

Mr /Ms _____ will be obtaining TMC 114 (a protease inhibitor) through Tibotec's expanded access program and TMV125 (a non nucleoside reverse transcriptase inhibitor) through the single patient IND process that requires your IRB approval. He/she will be combining these two new agents with a backbone of nucleoside analogs.

A recent small proof-of-concept study presented at the 13th Conference on Retrovirus and Opportunistic Infections showed encouraging results of using this combination in patients with resistance to Tipranavir (Aptivus) and Fuzeon. You can read the actual poster presentation in the attachment to this letter. The results of this small study are very encouraging, with all of the 10 patients exposed to the TMC 114+TMC 125 combination achieving viral load under 400 copies/ml at week 16. Most of these patients (6/10) had resistance to Aptivus (Tipranavir) and Fuzeon. Two started Fuzeon for the first time. The median viral load decline at week 12 was -2.76 logs. The median CD4 cell increase was 87 cells/ml.

Attached please find the signed consent form describing risks of both drugs. Mr/Ms _____ understands the potential risks and benefits of this decision and is willing to undergo obtaining this combination.

Please let me know if you need any clarification by calling me at _____

Sincerely,

_____, MD