CONSENT FORM

EIDEME: A prospective study to assess the efficacy and safety of a treat and extend regimen of Aflibercept for the treatment of diabetic macular oedema

1. I acknowledge that the nature, purpose and contemplated effects of the project so far as it affects me, have been fully explained to my satisfaction by my ophthalmologist and my consent is given voluntarily.

2. The details of the procedure proposed have also been explained to me, including the anticipated length of time it will take, the frequency with which the procedure will be performed, and an indication of any discomfort, which may be expected. I understand that my involvement means:

    - Regular visits to the eye clinic for assessment and injection of the study treatment

3. I understand that there are the following risks or possible discomfort:
    - Discomfort associated eye dilation
    - Discomfort associated with intravitreal injection.
    - The possibility of eye inflammation associated with intravitreal injection

4. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.

5. I have been given the opportunity to have a member of my family or friend present while the project was explained to me.

6. I am informed that no information regarding any medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.

7. I understand that my involvement in the project will not affect my relationship with my medical advisers in their management of my health. I also understand that I am free to withdraw from the project at any stage and any of my data/specimens that have been collected. My withdrawal will not affect my legal rights, my medical care or my relationship with the hospital or my doctors.

8. I understand that I will be given a signed copy of this patient information sheet and consent form. I am not giving up my legal rights by signing this consent form.

9. I understand that the trial will be conducted in accordance with the latest versions of the *National Statement on Ethical Conduct in Human Research 2007* and applicable privacy laws.

10. I consent to my GP and any other treating specialist being notified of my participation in this study and of any clinically relevant information being noted by the study investigator.

Name of participant _____

To be written by the participant

Signature of participant: _____ Date: _____

To be written by the participant

11. I have explained this project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator _____

Signature of investigator _____ Date _____

Name of witness (if appropriate) _____

Signature of witness _____ Date _____