Moorfields Eye Hospital NHS
NHS Foundation Trust

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Full title of trial	Prospective non-randomised exploratory study to assess the safety and efficacy of Eylea in cystoid macular oedema associated with Retinitis Pigmentosa
Short title	Aflibercept for Macular Oedema with Underlying Retinitis Pigmentosa (AMOUR) study
Version and date of consent form:	Version 1.1 14th March 2016
Sponsor:	Moorfields Eye Hospital NHS Foundation Trust
Sponsor protocol number	MICM1014
Funder (s) :	Bayer PLC
EudraCT no	2015-003723-65
ACTIVE IMP(s):	Aflibercept (Eylea)
PLACEBO IMP(s):	N/A
Phase of trial	Therapeutic exploratory trial (phase II)
Sites(s)	Single site – Moorfields Eye Hospital

Chief investigator:

Professor Michel Michaelides
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Sponsor Representative:

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CONSENT FORM

Study Title: Aflibercept for Macular Oedema with Underlying Retinitis Pigmentosa (AMOUR) trial

Patient ID:

Researchers: Dr. Stacey Strong, Professor Michel Michaelides, and Professor Andrew Webster

Please initial box

1. I confirm that I have read and understand the information sheet dated version 2.1 dated 14th March 2016 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected. ☐

3. I understand that sections of my medical notes may be looked at by responsible individuals from Moorfields Eye Hospital or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I understand that my GP will be informed of my participation in this research project and of any findings significant to my general health ☐

5. I understand that I will not benefit financially from participating in the study ☐

6. I agree to take part in the above study. ☐

For women of child bearing potential only

7. I understand that if I am a woman of child bearing potential I will be asked to undertake a pregnancy test prior to enrolment. I agree to use adequate contraception throughout the duration of the trial (12 months) and for at least 3 months after my last injection. I agree to be monitored by my GP +/- obstetrics and gynaecology team should I fall pregnant during my participation in the study or within 3 months of my last injection. ☐

_____ _____ _____

Name of patient	Date	Signature
_____	_____	_____
Name of person taking consent (if different from researcher)	**Date**	**Signature**
_____	_____	_____
Researcher	**Date**	**Signature**

When completed: Original for researcher site file; a copy for the participant; a copy for the medical notes.