Appendix 2

Oxford Health NHS
NHS Foundation Trust

Request to use an unlicensed medicine or a medicine off-label

This form must be completed by any consultant who wishes to use an unlicensed medicine or a licensed medicine in an off-label way (ie for an unlicensed indication or at a dose not covered by the product licence) for any drug that is not included in the unlicensed/off-label medicine list that has been ratified by the Drug & Therapeutics Committee. Supporting literature is required to be attached in support of the request.

Patient Name:	**Date of Birth:**

Diagnosis:

Medicine Details:
Drug and preparation requested (including strength, and formulation)

Clinical indication for use

Dosage (including strength and frequency)

What is the reason for preferred use of the named product?

If a licensed medicine is used off-label, the manufacturer is only likely to be found liable if harm results from a defect in the product. The manufacturer therefore carries limited legal liability for the off-licence use of a product, putting a greater responsibility on individual prescribers and the Trust.
Doctors making requests for the use of unlicensed medicines, or medicines which are unlicensed for a particular indication or at a particular dose, should be satisfied that they have carried out a thorough assessment of the evidence base for the use of the medicine and that they will be acting in a way consistent with practice of a responsible body of their peers of similar professional standing.

If use of the requested product is deemed to have significant risks, the request will be referred to the Clinical Director.

The purpose of this policy is to provide an internal means of assessing the use of these products, thereby safeguarding patients against the risk of injury as well as minimising the likelihood of claims against the Trust.

Declaration by Consultant

1. I have read and understood the information above.
2. I am registering my wish to use this product for the reasons I have given and I will await confirmation from the Drugs & Therapeutics Group prior to prescribing it.
3. I accept responsibility for fully informing the patient of the fact that the prescribed use is currently unlicensed.
4. I will write each prescription for the patient and obtain their consent.
5. I understand that this prescription and its consequence will be covered for vicarious liability under terms of my contract with the Trust providing that I have undertaken 1 – 4 above.

Consultant Name:	Signature:
Directorate:	Date:

The completed form with supporting literature must be sent to the Drugs & Therapeutics Group by email: (dtc@oxfordhealth.nhs.uk)