Also, the sponsor has a legal obligation to process some parts of your data in order to ensure your safety and the integrity of the scientific research to develop new medicines. Such processing is necessary in the public interest in the field of public health e.g., ensuring high standards of quality and safety of health care and of medicinal products.

Your personal data may include sensitive information about your physical or mental health or condition, and health information about you in medical records, and other personal data such as your name, address, telephone number, age, and gender. It may also include information related to the tests and procedures taken as part of receiving olorofim.

F2G Ltd will process your personal data to:

- confirm olorofim works and is safe
- ensure that applicable laws and procedures are being followed
- make any reports required by applicable laws

Your privacy and your personal data will be protected using measures which follow the requirements applicable in your country for the protection of your personal data. Any information about you that is collected during your treatment with olorofim will remain confidential. Your personal data will be stored for 15 years after the end of your treatment. However, this may be longer if olorofim is approved as a prescription medicine.

All information which is collected about you in records that leave your doctors for the purposes of medical, laboratory, statistical or regulatory activities related to research with olorofim will be identified by a patient identifier number. Your doctor may share your non-identifiable personal data with:

- F2G Ltd and Clinigen
- The local regulatory authority
- Government agencies for other countries
- Your family doctor, who may be informed that you are receiving treatment with olorofim and ask them for medical information about you

Your full name or any other directly identifiable information about you will not be included in these records. Only your treating doctor and their team will have access to information that can link you to your patient identifier number; this information will not be shared outside of your doctor's unless necessary for safety purposes.

Your data may be transferred to other countries for processing, including those that do not have data protection legislation as strong as in your country. The sponsor will ensure that all transfers are made in accordance with applicable laws and that there are appropriate security measures in place to protect your personal data, such as Standard Contractual Clauses pursuant to the Commission Decision C (2010) 593, a copy of which is available to you upon request to the study doctor.

You may request access to your personal data, for it to be corrected or deleted, or you may object to the processing of your personal data. However, your rights to access, change or move your information are limited, as we need to manage your information in specific ways. If you withdraw from the Managed Access Programme, we will keep the information about you that we have already obtained. To safeguard your rights, we will use a code number to track your case. This number will be unique to you and will not contain any information about you that would allow anyone to identify you.

Who should you contact for more information?

If you have any questions about receiving treatment with olorofim under compassionate use, please contact your treating doctor or a member of their team.

If you have any questions about your personal data protection rights, or a complaint about the use of your personal information, please liaise with your treating doctor or their team. They will then be able to direct your questions to the Sponsor's Data Protection Officer as needed.

Alternatively, you can contact the Sponsor's Data Protection Officer directly at F2G.dpo@mydata-trust.info

You also have the right to lodge a complaint about the processing of your personal data to your national data protection authority.

Consent Form

Olorofim Managed Access Programme: compassionate use for invasive fungal infections due to *Lomentospora prolificans*, *Scedosporium spp*., *Aspergillus spp*., and other diseases caused by mould fungi in patients lacking alternative treatment options

Investigational drug: Olorofim (F901318)

Sponsor: F2G Ltd, Lankro Way, Eccles, Manchester M30 OLX, UK

Conducted by: Clinigen, Pitcairn House, Crown Square, Centrum 100, Burton-on-Trent, Staffordshire DE14 2WW, UK

Treating Physician (Doctor): insert name_____

Unique reference number: _____

I confirm the following:

• I have read and understand the information sheet for access to olorofim under compassionate use and have had enough time to think about receiving treatment with olorofim.	*Patient initial*
• I am satisfied with the answers given to all my questions.	*Patient initial*
• I voluntarily agree to receive treatment with olorofim, to follow the procedures and to provide the information the treating doctor, nurses or other staff members ask from me.	*Patient initial*
• I understand that I am free to stop taking olorofim at any time without giving a reason and without my medical care or rights being affected.	*Patient initial*
• I agree that if I decide to withdraw from olorofim treatment, the information and data collected about me up to the point when I withdraw may continue to be used.	*Patient initial*
• I have received a copy of this information sheet and consent form to keep for myself.	*Patient initial*
• I agree if my treating doctor is not my family doctor, my family doctor may be told about my treatment with olorofim and asked for medical information about me.	*Patient initial*
• I understand my personal data will be processed as part of the olorofim MAP under the Sponsor's legitimate interests as described above, including: - identified only with my Patient Identifier number. - reviewed, processed and disclosed by and to the Sponsor and its authorized representatives. - reviewed or audited by appropriately authorized organizations. - published and sent to regulatory authorities or health insurers in my country or other countries; and - transferred if required to any country, where laws protecting my personal information may be different to my own.	*Patient initial*

There is no expiration date for this consent form

By signing this document I agree to receive treatment with olorofim as part of the Managed Access Programme for compassionate use, as set out in this information sheet and consent form. My name (or the name of my representative)

Signed (by me or my representative) Date

Only to be completed for patients under the age of 18 years:
By signing this document, we agree for the patient (our child) to receive treatment with olorofim as part of the Managed Access Programme for compassionate use, as set out in this information sheet and consent form.

Parent/legal guardian name

Signed (by parent/legal guardian) | Date

Parent/legal guardian name

Signed (by parent/legal guardian) | Date

Only to be completed for patients who are legally able to consent, but not able to write:

I confirm that I was present during the informed consent discussion that the patient participated in and that I witnessed his/her verbal consent. Informed consent was verbally given by the patient.

Witness name

Signed (by witness) | Date (the witness must date personally)

Treating Physician/Authorized Designee:

- ✓ I have fully and carefully explained olorofim compassionate use to the person named above and confirm that, to the best of my knowledge, they clearly understand the nature, risks and benefits of treatment with olorofim,
- ✓ I confirm that I gave them all opportunities to ask questions about olorofim, and that I answered all the questions they asked correctly and to the best of my ability.
- ✓ I confirm that they have not been forced into giving consent, and that they have given their consent freely and voluntarily.
- ✓ I confirm they have been given a copy of this information sheet and consent form.

Treating Physician/Authorized Designee name:

Signed: | Date: