

Individual Patient Expanded Access Policy

1. PURPOSE

Forty Seven Inc. (Forty Seven) has implemented this policy for the purpose of providing a process for the intake and review of Individual Patient Expanded Access (IPEA) requests for Forty Seven's investigational drugs under clinical development.

2. SCOPE

This policy applies to the provision of access to investigational drugs under clinical development by Forty Seven.

3. POLICY STATEMENT

Forty Seven is committed to help patients defeat their cancer. Forty Seven also recognizes that wherever appropriate, use of an investigational drug by a patient should be in the context of a well-designed clinical trial. Some patients, however, may have exhausted all standard treatment options and are ineligible for an ongoing clinical trial.

Forty Seven has established an IPEA Committee to consider requests for individual patient access to Forty Seven's investigational drugs, outside of clinical trials, where appropriate. The IPEA Committee is composed of medical and drug development professionals who are familiar with the investigational drug(s) under development at Forty Seven.

Forty Seven strives to make decisions regarding expanded access after thorough and careful consideration of the patient's eligibility criteria, the status of the program, and all available relevant medical and scientific information. Forty Seven is committed to making these decisions as ethically and fairly as possible, while minimizing risks to current or future patients.

4. POLICY PRINCIPLES

Forty Seven recognizes that in some circumstances, access to investigational drugs may be warranted provided the following are met:

- Drug is not approved for marketing in the country in which patient will be treated, is in ongoing clinical trials, and is not on clinical hold.
- Drug has completed first in human testing.
- Access to the investigational drug will not interfere with ongoing Forty Seven clinical trials and development programs.



- Forty Seven has adequate drug supply for individual patient expanded access use.
- There is strong scientific rationale to support the potential benefit of the investigational drug in the proposed indication, recognizing that the strongest evidence of possible benefit is the prior demonstration of clinical activity in the same or similar clinical situation.
- Providing a patient with access to the investigational drug is in compliance with local laws and regulations governing such programs.
- A treating physician has requested access on behalf of a patient and agrees to comply with the responsibilities in section 6.

Once a regulatory agency has approved a medicine for commercial use, existing expanded access programs will be phased out.

5. PATIENT ELIGIBILITY CRITERIA

Forty Seven will consider expanded access to an investigational drug for individual patients only if they meet the following criteria:

- Patient suffers from a serious or immediately life-threatening disease.
- There is no comparable or satisfactory alternative therapy or treatment available to the patient.
- Patient is unable to participate in an ongoing clinical study of the investigational drug.
- Patient is willing to give informed consent that they understand the risks of receiving the investigational drug. For patients unable to sign informed consent, consent of a legally authorized representative, as well as assent for minor patients, will be obtained by the sponsor physician, as applicable.
- The potential benefit justifies the potential risks of the treatment and those potential risks are not unreasonable in the context of the disease or condition to be treated.
- The request for access to the investigational drug comes from the patient's licensed, qualified physician.

Meeting the criteria above does not guarantee access to an investigational drug.

6. TREATING PHYSICIAN CRITERIA AND RESPONSIBILITIES

The treating physician requesting access to an investigational drug for their patient must meet the following criteria:

- The physician must be properly licensed and fully qualified to administer the product.



- The physician must comply with any applicable country-specific legal and regulatory requirements related to providing an investigational product under Expanded Access.
 - In the US, Forty Seven follows the FDA guidance (Form FDA 3926) for providing physicians with investigational drug for treating individual patients.
- The physician must determine that the probable risk to the patient from the investigational drug is not greater than the probable risk from the disease or condition.
- The physician must have the approval of the Institutional Review Board (or equivalent ethics committee that approves and monitors clinical trials involving humans) at the patient's treating hospital or clinic.
- The physician must agree to any Forty Seven requirements in terms of medical criteria, safety reporting, drug supply use and accountability, protection of intellectual property and public disclosure/publications. A treating physician may submit questions or requests regarding expanded access to Forty Seven (expandedaccess@fortyseveninc.com).

7. IPEA PROCESS

If expanded access is felt to be the best option for a patient, the treating physician should contact Forty Seven (expandedaccess@fortyseveninc.com) to make a formal request on behalf of the patient.

The request for access can only be considered if the patient's treating physician is committed to and supportive of the requested treatment. Qualified physicians seeking access on behalf of a patient will be instructed to submit sufficient, relevant medical information about the intended patient to assess the potential risks and benefits of the investigational drug.

Once the request is received, the Forty Seven IPEA Committee will evaluate requests and respond within 14 calendar days after careful scientific and clinical review of the medical situation and the program status.

8. CONTACT FOR QUESTIONS

Questions regarding this policy may be directed to Forty Seven at expandedaccess@fortyseveninc.com.