

ERC Right-to-Try Policy

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1. Purpose

To describe the requirements for planning, approving and implementing ERCs Right-To-Try Program in the United States.

2. Policy Statement

- 2.1. ERC Belgium (ERC) is a biopharmaceutical company focused on developing vaccine-based immunotherapy for oncology patients, and has a promising pipeline that has demonstrated safety and efficacy in early clinical testing for patients suffering from brain cancers. ERC seeks to eliminate cancer cells completely, leading to a cure through its cell-based immunotherapy approach that treats patients suffering from glioma or glioblastoma by directly stimulating the patient's immune system with whole cancer cells and cell extracts. ERC has developed a unique, patented process using whole cells and lysates of autologous (patient's own tumour) and allogeneic tumour cells (from other individuals);
- 2.2. ERC believes that participating in clinical trials is the best way for patients to access medicines prior to approval. In pursuit of our objective to develop highly effective and safe therapeutic approaches, the successful completion of a clinical trial program of investigational products is the most effective way of ensuring timely review and decision making by health authorities on a given product. This will ultimately result in access to new, safe, and effective approved therapies for patients. For this reason, ERC prioritizes access to an investigational new drug through active and accruing clinical trials and encourages appropriate patients interested in the investigational new treatment to enroll.
- 2.3. In some circumstances when the ability to participate in a clinical trial is not possible, patients with life-threatening diseases or conditions may seek special access to investigational product outside of a clinical trial setting.

3. Scope

- 3.1. This policy applies to ERC personnel and service providers, working on behalf of ERC, involved in planning, approving and implementing Right-to-Try;
- 3.2. This policy is intended to provide information and the process regarding early access to ERC's investigational treatments outside a clinical trial and within a Right-to-Try setting;
- 3.3. Any use of an ERC investigational therapy outside a clinical trial must be in accordance with local laws and regulations governing such programs, including ERC's policies and procedures. Where permitted by local regulation, ERC may solicit financial contribution to cover the cost of manufacturing the investigational product supplied under Right-to-Try, packaging and investigational product delivery, products to support investigational product administration, pharmacy/nursing costs and other administrative costs associated with managing requests as described herein and in supporting documentation provided to a requesting physician and their patient;
- 3.4. This policy does not apply to investigator-initiated studies.

4. Policy Details

4.1. Eligibility: Access to an investigational treatment under Right-to-Try may be considered only when all of the conditions within this Right-to-Try Policy have been met. ERC will comply with both Federal Right-to-Try Law and State Right-to-Try requirements as applicable to a specific case. Minimal requirements include the following:

4.1.1. Investigational treatment criteria:

- The product candidate is under investigation in one or more clinical studies or has been approved for use but not within the patient's country;
- There is sufficient evidence to expect that the investigational treatment will have an acceptable safety profile for the intended patient; and,
- The use of the investigational product will not interfere with or compromise the clinical development of the product. This includes the review and decision that there is adequate manufacturing capacity for supply of the investigational product to perform necessary clinical studies in addition to supply of the product to patients under Right-to-Try;
- The investigational product made available under Right-to-Try must not be promoted or represented as being a treatment for the condition, or safe or effective for the purposes for which it is under investigation.

4.1.2. Patient eligibility criteria:

- The patient suffers from a life-threatening disease or condition;
- The patient has undergone appropriate treatment without success and/or no comparable or satisfactory alternative treatment is available or exists to treat the disease or condition;
- The requesting physician and ERC medical team both believe the potential benefit justifies the potential risks of the new use, the potential risks are not unreasonable in the context of the disease or condition being treated, and there is clear rationale to anticipate that the patient will benefit from the use of the investigational product;
- The patient is ineligible or otherwise unable to participate in an existing clinical trial of the investigational product, which includes lack of access due to geographic limitations; and,
- The patient shall meet other pertinent criteria for access to the investigational product as established by ERCs medical affairs team.

4.1.3. Treating/requesting physician criteria:

- The physician treating the patient who will receive investigational product through Right-to-Try is properly licensed and fully qualified to administer the product;
- The physician must comply with any and all applicable country specific legal and regulatory requirements related to providing an investigational product under Right-to-Try;
- The physician must comply with all ERC determined medical criteria; safety reporting; specimen storage and distribution; product supply, storage and use; patient confidentiality and data privacy; and the protection of intellectual property;
- The request for the investigational product must be made in writing by the patient's treating physician, unsolicited by ERC or any other individual or organization;
- The physician shall have obtained a written and signed Informed Consent from the patient; and,

- Whereas ERC may require patient or a patient representative to cover all or part of the manufacturing cost of the investigational product, any associated costs of treatment will be the responsibility of the insurer, healthcare system, and/or patient;
 - ERC require ethics approval and oversight for all Right-to-Try cases, whether a requirement for review and approval by an IRB/IEC is defined by the local regulatory jurisdiction or not e.g. U.S. Federal Right-to-Try Law.
- 4.2. The above criteria, set out in Section 4.2, are those that ERC will consider in determining whether or not to offer Right-to-Try. However, ERC cannot guarantee that Right-to-Try will be available, and, even if offered, ERC cannot guarantee the investigational product will be available for a particular patient.

5. Request & Review Process

- 5.1. A request made for Right-to-Try to ERC must be made by a treating physician licensed in the country where the product is to be distributed using a Right-to-Try request form. A request may be made by eligible patients, who must be under the care of an eligible physician in the country where the product is to be distributed before a request can be considered. Supporting documentation defined in the form should also be provided;
- 5.2. Requests for further information about how to apply for Right-to-Try and qualifications and capabilities required to administer ERC investigational product can be made by contacting:
 - 5.2.1. ERC by email at medicalaffairs@erc-immunotherapy.com
- 5.3. Submissions of the Right-to-Try request form shall be sent to the email address noted in the form, for review and consideration;
- 5.4. Once received ERC will acknowledge receipt and assign a Request Reference # which must be used on all future communications about the case. ERC will review the request, and support the conduct of any further pre-screening that may be necessary to determine suitability of the patient, and make a recommendation to the CEO regarding approving or denying the request. A rationale to support that decision will be provided and documented. In making such decision, the following will be taken into consideration:
 - 5.4.1. Existing and available data for the investigational product, including its risk/benefit profile;
 - 5.4.2. The details of the request and an assessment of the potential risk/benefit to that patient or group of patients;
 - 5.4.3. Access to the investigational compound regardless of the patient's financial or social status.
- 5.5. The Right-to-Try decision will be documented and stored by ERC. The decision may be updated if new data and information become available to substantiate a revision. Any revisions will require the same level of approval as the initial plan;
- 5.6. A plan must be put in place to address the timing and conditions under which the program will be terminated;
- 5.7. Before agreement that an investigational product will be supplied for Right-to-Try, all regulatory notifications and/or approvals will be completed, and confirmed that the planned distribution within the jurisdiction complies with applicable local laws and regulations;
- 5.8. On approval of a Right-to-Try case, ERC manufacturing and pharmacovigilance teams are then notified that the program will be implemented;
- 5.9. SOPs for the manufacture, supply, distribution and administration of biological samples and investigational product will be provided to the treating physician. Note SOPs may be modified by the treating physician if appropriate to the individual case subject to review and approval by ERC;

- 5.10. Import licenses are secured as necessary and required before shipment of specimens and investigational product;
- 5.11. Per Federal and State regulations, requesting physicians agree in writing to the following before investigational product is shipped for Right-to-Try:
 - 5.11.1. Inform patients of the risks associated with the investigational product. Obtain the patients informed consent before administration of the investigational product in accordance with local laws and regulations;
 - 5.11.2. Report safety information according to ERCs policies and requirements. All serious adverse events irrespective of treatment relatedness and non-serious adverse reactions must be reported to ERC;
 - 5.11.3. Maintain the confidentiality of information provided about the investigational product and disclose or disseminate such information only as necessary;
 - 5.11.4. Use the investigational product only for Right-to-Try and return/destroy (in compliance with local laws and regulatory requirements) any unused amounts as applicable and as instructed by ERC;
 - 5.11.5. Any activities for which ERC is financially responsible (e.g. administrative, monitoring by healthcare providers, IRB/IEC fees, pharmacy fees, importation licenses).
- 5.12. ERC maintains record of the shipment, receipt, disposition, return, or destruction of the investigational product.

4 Contacts

Role	Contact	Email
Policy Inquiries & Interpretations	Medical Affairs	medicalaffairs@erc-immunotherapy.com

5 Revision History

Revision	Date	Originator	Description of Change
001	Feb 2019	ERC Medical Affairs	First Draft

6 Approval

This policy has been reviewed and approved by the below executives:

Name and Title	Approval Description	Date
Apostolis Stathopoulos, MD, Ph.D		