**The Government of the Russian federation**

**The Resolution**

**of September 3, 2010 N 673**

**ON THE APPROVAL OF THE RULES FOR THE IMPORT INTO THE RUSSIAN FEDERATION AND EXPORT FROM THE RUSSIAN FEDERATION OF BIOLOGICAL MATERIALS OBTAINED DURING A CLINICAL STUDY OF A DRUG FOR MEDICINE**

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| List of changing documents  (as amended by the Resolution of the Government of the Russian Federation of 12.05.2011 N 1001, of 09.04.2012 N 882, of 10.15.2014 N 1054, of 12.18.2020 N 2165) |

In accordance with Article 40 of the Federal Law "On the Circulation of Medicines", the Government of the Russian Federation decides:

To approve the attached Rules for the import into the Russian Federation and export from the Russian Federation of biological materials obtained during a clinical trial of a medicinal product for medical use.

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

Chairman of the Government

of the Russian Federation

V. PUTIN

Approved by

the Resolution of the Government of

the Russian Federation

of September 3, 2010 N 673

**THE RULES**

**FOR THE IMPORT INTO THE RUSSIAN FEDERATION AND EXPORT FROM THE RUSSIAN FEDERATION OF BIOLOGICAL MATERIALS OBTAINED DURING A CLINICAL STUDY OF A DRUG FOR MEDICINE**

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| List of changing documents  (as amended by the Resolutions of the Government of the Russian Federation of 12.05.2011 N 1001, of 09.04.2012 N 882, of 10.15.2014 N 1054, of 12.18.2020 N 2165) |

1. These Rules establish the procedure for the import into the Russian Federation and export from the Russian Federation of biological materials (samples of biological fluids, tissues, secretions and products of human vital activity, physiological and pathological secretions, smears, scrapings, swabs, microorganisms, biopsy material) obtained during Clinical Trials of Investigational Medicinal Products (CTIMPS) for medical use (hereinafter - import (export) of biological materials).

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

2. The import (export) of biological materials is carried out for their study in the Russian Federation and (or) outside the Russian Federation on the basis of a conclusion (permit) issued by the Ministry of Health of the Russian Federation in accordance with the decision of the Board of the Eurasian Economic Commission of May 16, 2012 N 45 "On a unified form of a conclusion (permitting document) for the import, export and transit of certain goods included in the unified list of goods to which non-tariff regulation measures are applied in trade with third parties, and methodological instructions for filling it out" (hereinafter - the conclusion).

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

The conclusion is issued for the period of CTIMPS for medical use, during which biological materials will be obtained.

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

The conclusion is issued for submission to the customs authorities of the Russian Federation.

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

3. The following legal entities organizing the conduct of CTIMPS in accordance with the established procedure (hereinafter - applicant organization) can import into the Russian Federation and export from the Russian Federation biological materials obtained during a Clinical Trial of a Medicinal Product (CTIMP) for medical use:

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

a) a developer of a medicinal product for medical use or a legal entity authorized by him to organize CTIMP for medical use;

b) educational institutions of higher education and (or) organizations of additional professional education, the activities of which provide for the possibility of participating in the organization or conduct of CTIMPS for medical use;

(as amended by the Resolution of the Government of the Russian Federation of 10.15.2014 N 1054)

c) scientific organizations whose activities provide for the possibility of participating in the organization or conduct of CTIMPS for medical use.

(as amended by the Resolution of the Government of the Russian Federation of 10.15.2014 N 1054)

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| ConsultantPlus: note.  Paragraph 1, item 4 (as amended of 12.18.2020) regarding the submission (sending) of documents and information using [Public services portal](https://www.gosuslugi.ru/foreign-citizen?lang=en) comes into force on July 1, 2021. |

4. In order for the applicant organization to obtain an conclusion, it is necessary to submit to the Ministry of Health of the Russian Federation in paper form or using [Public services portal](https://www.gosuslugi.ru/foreign-citizen?lang=en) in electronic form (a package of electronic documents) signed with an enhanced qualified electronic signature, the following documents:

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

* 1. an application for the import (export) of biological materials, including the following information:

data on the CTIMP for medical use, indicating the protocol of the clinical trial and the objectives of the CTIMP for medical use contained therein, the timing of the clinical trial in which biological materials are expected to be obtained;

the name of the state in which it is planned to conduct CTIMPS for medical use, the location and full name of the organization where it is planned to import (export) biological materials;

the purpose of import (export) of biological materials;

type of imported (exported) biological material;

the number of units of each type of imported (exported) biological material;

type of packaging for each type of imported (exported) biological material;

b) the rationale for calculating the number of units of each type of imported (exported) biological material based on the protocol of the CTIMP for medical use and the number of patients participating in the CTIMP for medical use, other documents confirming the need for import (export) biological materials in the declared volume, issued in accordance with the legislation of the country of origin of biological materials;

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

c) a copy of a duly issued permission to conduct a CTIMP for medical use, in which biological material is expected to be obtained, if this study is conducted on the territory of the Russian Federation;

(as amended by the Resolution of the Government of the Russian Federation of 12.05.2011 N 1001)

d) copies of constituent documents, certificate of state registration of a legal entity and certificate of registration with the tax authority of the applicant organization. If a foreign legal entity acts as an applicant organization in case of a CTIMP for medical use in the Russian Federation, documents confirming the accreditation of a representative office of a foreign legal entity in the Russian Federation are submitted.

(as amended by the Resolution of the Government of the Russian Federation of 12.05.2011 N 1001)

4(1). The Ministry of Health of the Russian Federation is not entitled to require the applicant organization to submit a copy of the permission provided for in sub-item "c" of item 4 of these Rules, as well as copies of the certificate of state registration of a legal entity and the certificate of registration of the applicant organization with the tax authority provided for in sub-item "d" of item 4 of these Rules. The applicant organization has the right to submit copies of these documents on its own initiative.

(Item 4(1) came into force by the Resolution of the Government of the Russian Federation on 05.12.2011 N 1001, as amended by the Resolution of the Government of the Russian Federation of 04.09.2012 N 882)

5. The Ministry of Health of the Russian Federation within 10 working days from the date of acceptance of the documents provided for in item 4 of these Rules:

(as amended by the Resolution of the Government of the Russian Federation of 04.09.2012 N 882)

a) checks the completeness and reliability of the information contained in the submitted documents, and if the applicant organization fails to provide a copy of the permission provided for in sub-item "c" of item 4 of these Rules, it also checks the availability of such permission on the basis of data from the register of issued permits for CTIMPS;

(sub-item "a" [as amended](https://www.multitran.com/m.exe?l1=1&l2=2&s=as+amended) by the Resolution of the Government of the Russian Federation of 12.05.2011 N 1001)

a(1)) requests and receives, in the order of interdepartmental information interaction from the Federal Taxation Service, information on the fact of entering information about the applicant organization in the Unified State Register of Legal Entities and on the fact of registration of the applicant organization with the tax authority, if the applicant organization, being a Russian legal entity, did not submit a copy of the certificate of state registration of the legal entity and the certificate of registration with the tax authority;

(sub-item "a(1)" came into force by the Resolution of the Government of the Russian Federation of 12.05.2011 N 1001)

b) makes a decision to issue a conclusion or to refuse to issue a conclusion;

(sub-item "b" as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

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| ConsultantPlus: note.  After 07.01.2021, the issuance of conclusions (permits) in paper form is not allowed (the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165). |

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| ConsultantPlus: note.  Sub-item "c" of item 5 (as amended on 12.18.2020) regarding the submission (direction) of documents and information using [Public services portal](https://www.gosuslugi.ru/foreign-citizen?lang=en) comes into force on July 1, 2021. |

c) sends a conclusion to the applicant organization in paper form or in electronic form signed with an enhanced qualified electronic signature to a personal account on Public service portal or notifies the applicant organization of the refusal to issue a conclusion, indicating the reasons for such refusal.

(sub-item "c" as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

6. The item is no longer valid. - The Resolution of the Government of the Russian Federation of 12.18.2020 N 2165.

No fee is charged for issuing a permit for the import (export) of biological materials.

7. Reasons for rejection to issue a conclusion are the submission of incomplete documents and (or) the presence of unreliable information in the materials submitted by the applicant organization.

(as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

8. The application for the import (export) of biological materials and the results of the decision taken by the Ministry of Health of the Russian Federation are subject for registration in the register of issued conclusions, decisions to refuse to issue conclusions, which is maintained by the Ministry of Health of the Russian Federation in the form established by it.

(as amended by the Resolution of the Government of the Russian Federation of 09.04.2012 N 882, of 12.18.2020 N 2165)

9 - 13. The items are no longer valid. - The Resolution of the Government of the Russian Federation of 12.18.2020 N 2165.

14. In case of suspension or termination of a CTIMP for medical use, the Ministry of Health of the Russian Federation makes a decision to suspend the conclusion for the period of suspension of the clinical trial or decides to terminate the conclusion.

(item 14 as amended by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

15. The decision of the Ministry of Health of the Russian Federation to suspend or terminate the conclusion is announced to the applicant organization and the Federal Customs Service within a period not exceeding 5 working days from the date of such decision.

(as amended by the Resolutions of the Government of the Russian Federation of 09.04.2012 N 882, of 12.18.2020 N 2165)

16. The decision to renew the conclusion, if it is adopted by the Ministry of Health of the Russian Federation, shall be announced to the applicant organization and the Federal Customs Service in paper form within a period not exceeding 5 working days from the date of such decision.

(as amended by the Resolutions of the Government of the Russian Federation of 09.04.2012 N 882, of 12.18.2020 N 2165)

17. Information from the conclusions is submitted to the customs authorities in electronic form through the use of a unified system of interdepartmental electronic interaction.

(item 17 came into force by the Resolution of the Government of the Russian Federation of 12.18.2020 N 2165)

Appendix No. 1 to the Rules for the import into the territory of the Russian Federation and export outside the territory of the Russian Federation of biological materials obtained during a clinical trial of a medicinal product for medical use

PERMISSION N \_\_\_\_\_\_\_\_\_

the import (export) of biological materials, obtained during clinical study of a medicinal product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for medical use

It is no longer valid. - The Resolution of the Government of the Russian Federation of 12.18.2020 N 2165.

Appendix No. 2 to the Rules for the import into the territory of the Russian Federation and export outside the territory of the Russian Federation of biological materials obtained during a clinical trial of a medicinal product for medical use

ADDITION TO PERMISSION N \_\_\_\_\_\_\_\_\_

the import (export) of biological materials, obtained during clinical study of a medicinal product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for medical use

It is no longer valid. - The Resolution of the Government of the Russian Federation of 12.18.2020 N 2165.

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