# پرسشنامه مرتبط با ارسال فرامرزی نمونه زیستی با هدف پژوهشی

**پرسشنامه درخواست بررسي طرح پژوهشي متقاضي دريافت مجوز جهت ارسال نمونه زيستی با هدف پژوهشي به خارج از کشور**

کارگروه وزارتی اخلاق در پژوهشهاي زيست پزشکي بر اساس اسناد بين المللي و نيز کدها و الزامات اخلاقي مصوب وزارت بهداشت، درمان و آموزش پزشکي، به عنوان تنها مرجع صدور مجوز «انتقال فرامرزی نمونه های زیستی با هدف پژوهشي» بوده و طرحهاي پژوهشي متقاضي دريافت مجوز مذکور را مورد ارزيابي قرار ميدهد. لذا ضروري است که پرسشنامه زیر در سامانه ملی اخلاق در پژوهش‌های زیست‌پزشکی به منظور بررسي و صدور مجوز انتقال نمونه زيستی به خارج از کشور، تکميل شده و به انضمام مستندات مورد نیاز از طریق سامانه مذکور به دبيرخانه کارگروه وزارتی اخلاق در پژوهش ارسال گردد.

|  |
| --- |
| **1- اطلاعات طرح پژوهشي/پایان‌نامه** |
| عنوان طرح پژوهشی/ پایان‌نامه: |
| ميزان بودجه: |
| نام و آدرس سازمان (سازمان‌های) پشتیبان و حامی: |
| نام و آدرس محل انجام پژوهش (داخل کشور): |
| نام و آدرس محل انجام پژوهش (خارج کشور): |
| تاريخ شروع احتمالي پژوهش (خارج کشور): |
| تاريخ خاتمه احتمالي پژوهش (خارج کشور): |
| کد مصوبه مرجع علمی صلاحیت‌دار: |
| شناسه اخلاق در پژوهش: |
| نوع نمونه زيستي: |
| تعداد/ مقدار نمونه زیستی: |
| نحوه و مسير انتقال نمونههاي زيستي به خارج از کشور (هوايي/ زميني/ دريايي): |
| آیا نمونه زیستی ارسال ميشود يا توسط فرد منتقل ميشود؟  درصورتي‌که نمونه زیستی توسط فرد منتقل ميشود؛ نام و نام خانوادگی، آدرس و شماره تلفن همراه وی ذکر گردد. |
| دلایل انتقال نمونه زیستی به خارج از کشور را توضيح دهيد: |
| آيا امکان انجام اين آزمایش در داخل کشور وجود دارد؟ |
| اگر امکان انجام آزمایش در داخل کشور وجود دارد، علت ارسال نمونه به خارج از کشور چيست؟ |

|  |
| --- |
| **2- مشخصات پژوهشگر اصلی (داخل کشور)** |
| نام و نام خانوادگي: |
| محل کار (وابستگی سازمانی): |
| رشته تحصيلي: |
| مقطع تحصيلي: |
| آدرس محل سکونت: |
| شماره تلفن همراه: |
| آدرس پست الکترونیک: |
| نام و محل کار استاد راهنما (مخصوص پايان‌نامه هاي دانشجويي): |

|  |
| --- |
| **3- مشخصات پژوهشگر همکار (خارج از کشور)** |
| نام و نام خانوادگي: |
| دانشگاه/ مرکز تحقیقاتی محل کار: |
| رشته تحصيلي: |
| آدرس محل کار: |
| شماره تماس (تلفن محل کار): |
| حوزه فعالیت: |
| آدرس پست الکترونيک: |

|  |  |  |
| --- | --- | --- |
| **4- مشخصات طرح پژوهشی/پایان‌نامه** | | |
| ملاحظات کارگروه/كميته | سوالات | ردیف |
|  | خلاصه‌اي از پژوهش به زبان ساده و قابل فهم به زبان فارسي شامل اهمیت و ضرورت پژوهش و علت انتخاب موسسه همکار خارجی را بنویسید (حداکثر 500 کلمه): | 1 |
|  | جمعيت مورد مطالعه کدامند؟ علت انتخاب آنها را توضيح دهيد. | 2 |
|  | آيا محدوديتي براي انتشار نتايج پژوهش وجود دارد؟ | 3 |
|  | داد هها يا نمونههای زیستی به چه مدت و در چه محلی نگهداري ميشوند؟ | 4 |
|  | نحوه نگهداري و نيز روش معدوم کردن نمونه های زیستی (به منظور حفظ محرمانگي اطلاعات) چگونه است؟ | 5 |
|  | چه کساني به اطلاعات شخصي شرکت‌کنندگان در پژوهش، دسترسي خواهند داشت؟ | 6 |
|  | چه راهکارهايي براي حفاظت از اطلاعات و رعايت اصول اخلاقي در پژوهش بر روي نمونه‌هاي زیستی مربوطه انديشيده‌ايد؟ | 7 |
|  | آيا نمونه های زیستی از ابتدا براي اهداف پژوهشي گرفته شده‌اند يا نمونه هايي است که براي اهداف تشخيصي/ درماني جمع آوري شده‌اند؟ | 8 |
|  | چگونه نمونه های زیستی علامت‌گذاري شده و شناخته ميشوند؟ | 9 |
|  | چه نوع بررسي و پژوهشي بر روي نمونه های زیستی/ داده‌ها انجام خواهد شد؟ | 10 |
|  | منافع اين پژوهش (مانند دسترسي به محصول پژوهش يا توانمندسازي) براي ايران چيست؟ | 11 |
|  | نمونه های زیستی مربوطه به چه منطقه/ مناطق جغرافیایی تعلق دارند؟ | 12 |
|  | حقوق معنوي پژوهش بين پژوهشگران ايراني و همكاران بين‌المللي چگونه به مشارکت گذارده مي‌شود؟ | 13 |
|  | سرنوشت اطلاعات يا سرنوشت نمونه های زیستی در انتهاي پژوهش چيست؟ | 14 |
|  | آيا دانشجو يا عضو هيات علمي در اين طرح پژوهشی، به منظور انتقال دانش و يا تكنولوژي به خارج از كشور مسافرت خواهد كرد؟ در صورت پاسخ مثبت، درخصوص فرد مورد نظر و جزئيات سفر علمي توضيح دهيد. در صورت نياز مدارك مربوطه را ضميمه نمائيد. | 15 |
|  | آيا تفاهم‌نامه همكاري بين‌المللي امضا شده است؟ پاسخ مثبت، تصوير تفاهم‌نامه مربوطه را ضميمه كنيد. | 16 |

|  |  |  |  |
| --- | --- | --- | --- |
| **چک ليست مستندات تکميلي** | | | |
| ملاحظات | تائيد توسط پژوهشگر اصلی | | مستند |
|  | بلی | خیر | نامه درخواست معاون پژوهشي موسسه مربوطه جهت درخواست بررسي طرح‌نامه و صدور مجوز ارسال نمونه زیستی به خارج از کشور توسط كارگروه وزارتی اخلاق در پژوهش |
|  |  |  | طرح‌نامه پژوهشی |
|  |  |  | مصوبه مرجع علمی صلاحیت‌دار |
|  |  |  | شناسه کد اخلاق در پژوهش |
|  |  |  | رزومه پژوهشگران اصلی |
|  |  |  | فرم رضايت آگاهانه اهداکنندگان نمونه‌های زیستی (به زبان فارسي) |
|  |  |  | قرارداد يا تفاهمنامه کتبي بين موسسه یا موسسات داخلي با موسسه یا موسسات خارجي حامي پژوهش (فرم MTA) که توسط هر دو پژوهشگر اصلی داخل و خارج از کشور امضاء شده باشد. |
|  |  |  | تفاهم‌نامه و يا قرارداد مالي با موسسه حمایت‌کننده پژوهش |
|  |  |  | پرسشنامه یا فرم جمع‌آوري داده‌ها |
|  |  |  | جزئيات نحوه و مسير انتقال نمونه‌ها و مستندات مربوطه با توجه به شرايط، زمان، نوع نمونه و نوع پژوهش |
|  |  |  | ساير مدارك (نام ببرید): .... |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| اينجانب ............................................... صحت مفاد اين پرسشنامه را تائید کرده و اعلام می‌دارم که تمامی راهنماها، دستورالعملها و کدهاي اخلاق در پژوهش و به‌ويژه «دستورالعمل ملي انتقال فرامرزي نمونه هاي زيست پزشکي با هدف پژوهشي» را مطالعه نموده و خود را متعهد به رعايت آنها ميدانم. | | | | |
| تاریخ | امضا | | نام و نام خانوادگي پژوهشگر اصلي: | |
|  | |  | |  |

**توافقنامه ارسال نمونه‌ زیستی به خارج از کشور**

**Material Transfer Agreement (MTA)**

|  |  |
| --- | --- |
| **Islamic Republic of Iran**  **Ministry of Health and Medical Education**  **National Committee for Ethics in Biomedical Research**  **Agreement for International Biomaterials Transfer for Research Purposes** | |
| This Agreement has been adopted for using by the Ministry of Health and Medical Education of I.R. Iran (MOH) and its associated academic and research centers, for all transfers of research biomaterial to/from international research centers, agencies and academic members, whether one of the above mentioned centers is identified below as its provider or recipient. This agreement should be completed and signed by both sides and be sent to the approving research ethics committee (REC) as one of the required document for issuing official permission for biomaterial transfer. This agreement should be signed after receiving final ethical approval from accredited research ethics committees. | |
| **I. General Information** | |
| **1. Research Project Information** | |
| Project Title: | |
| Funding Source: | |
| Name and Specific Code of Iranian Approving REC: | |
| Project Ethical Approval Code: | |
| **2.** **PROVIDER** | |
| Scientist: | |
| Name of Organization: | |
| Postal address: | |
| Phone: | |
| Fax: | |
| E-mail: | |
| Website: | |
| **3.** **RECIPIENT** | |
| Scientist: | |
| Name of Organization: | |
| Postal address: | |
| Phone: | |
| Fax: | |
| E-mail: | |
| Website: | |
| **4.** **MATERIAL** | |
| a. Source (originally derived from human, animal, etc.): | |
| b. Collection / Processing site: | |
| c. Preservation Material: | |
| d. Preservation Temperature: | |
| e. Transportation temperature: | |
| f. Status: Unidentifiable Coded | |
| g. Special protective packaging required: Yes No | |
| h. Other Descriptions: | |
| **5.** The Provider states that the samples were collected complying with ethical standards following the international norms and procedures established by an accredited Internal Review Board (Code: ----------------). | |
| **6.** The material will be used by recipient solely in connection with the above mentioned research project purposes. Funding source and approval No: …… | |
| **II. Terms and Conditions of this Agreement** | |
| **A. Use of Material** | |
| The RECIPIENT agree that the MATERIAL:  1. Is to be used solely for academic and/or other noncommercial internal research/non-profitable diagnostic purposes;  2. Will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects unless otherwise officially authorized by the providing entity.  3. Is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision;  4. Will not be transferred to anyone else within the RECIPIENT organization without the prior written agreement from the PROVIDER.  5. Will be used ethically, in substantial compliance with the review procedures and international ethical guidelines or where those are superseded by authoritative, higher national standards, in substantial compliance with such standards | |
| **B. Liability** | |
| 1. The RECIPIENT acknowledges that the MATERIAL may be the subject of a patent application or covered by patent rights in one or more countries.  2. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER or any third party, including with respect to any altered forms of the MATERIAL made by the PROVIDER.  3. In particular, but without limitation, no expressed or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.  4. RECIPIENT hereby agrees to indemnify and hold harmless PROVIDER, its trustees, officers, employees, agents and medical and research staff, including without limitation, against any claim arising from RECIPIENT’s use of this Agreement, including without limitation any claim that RECIPIENT’s use of the MATERIAL violates any of intellectual property or other rights of the third party, or violates any provision of law, or arises from a breach of this Agreement.  5. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable International statutes and regulations, for example, those relating to research involving the use of animals or recombinant DNA. | |
| **C. Ownership** | |
| 1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.  2. The RECIPIENT retains ownership of:  2.1. MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and  2.2. Those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES).  2.3. If either 2 (a) or 2 (b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, such material will be jointly owned.  3. The RECIPIENT agrees to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision.  4. If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license, subject to any pre-existing rights held by others. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party/ies.  5. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties and that its use may require acquisition of rights from third parties. The provider makes no representations and extends no warranties of any kind, either expressed or implied. there are no expressed or implied warranties of the material, its source, merchantability, transfer or fitness for a particular purpose, or that the use of the material will not infringe any patent, copyright, trademark, or other proprietary rights.  6. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage, disposal or transfer of the MATERIAL. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use or transfer of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.  7. The Original Material cannot be transferred to a third party without the written consent of the Provider. The exemption are others working under the Recipient Scientist direct supervision or with the purpose of obtaining a service. The Recipient Scientist agrees to refer to the Provider any request for the Original Material from anyone other than those persons working under the Recipient Scientist’s direct supervision. | |
| **D. Publications** | |
| 1. The Recipient researcher and the Provider researcher agree that the information derived from the Original Material should be published. The Recipient Scientist will generate the information out of the Original Material.  2. The Provider Scientist recognized that the ---------------- (provider or recipient) Scientist has designed the research project, will generate the data, and will analyze it for publication.  3. The Provider Scientist will participate as co-author in the all related publications where the data generated from the Original Material is firstreported.  4. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.  5. The Provider Scientist agrees to participate in developing the manuscripts where he/she is co-author by editing and providing opportune feedback.  6. The Provider Scientist acknowledges that the data derived from the Original Material may be deposited in public databases if it is appropriate (e.g., GenBank) or required by law in the Recipient's country.  7. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the Original Material. The grace period for joint publication review is considered 60 days.  8. In addition in all oral presentations concerning the Research Project, Recipient will acknowledge Provider's contribution of this Material unless requested otherwise.  9. Recipientagrees to treat in confidence, for a period of ------- years from the date of its disclosure, any of Provider's written information about this Materialthat is stamped "CONFIDENTIAL", except for information that was previously known to Recipientor that is or becomes publicly available or which is disclosed to Recipientwithout a confidentiality obligation.  10. Any oral disclosures from Providerto Recipientshall be identified as being CONFIDENTIAL by written notice delivered to Recipientwithin thirty (30) days after the date of the oral disclosure.  11. Recipientmay publish or otherwise publicly disclose the results of the Research Project, but if Providerhas given CONFIDENTIAL information to Recipientsuch public disclosure may be made only after Providerhas had thirty days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information.  12. The Providercan request access to unpublished primary data that is going to be used in a join publication with the Recipient for planning independent research projects or to be included as preliminary data in grant proposals independently developed by the Provider. However, such data cannot be used in publications or disseminated in any form without the Recipient authorization. Published data or data deposited in public databases are considered public domain.  13. Modifications of the original material (e.g. cloned PCR products or primers) will be made available to the Provider if requested provided that such material will be used in good faith by the Provider, without affecting or damaging the research of the Recipient Scientist and that the Recipient will be properly acknowledged by citing the publication where such modifications appear or any other form that both parties agree on. | |
| **E. Termination of Use** | |
| 1. This Agreement will terminate on the earliest of the following dates:  1.1. When the MATERIAL becomes generally available from third parties such as commercial entities or public depositories without breaching the lawful ownership of the PROVIDER, and any patents or pending patent applications by the PROVIDER,  1.2. On completion of the RECIPIENT's current research with the MATERIAL as described under the "Title of the Research Project" in this agreement, or  1.3. Within 60 days of receiving a written official notice by either party to the other.  2. Upon the effective date of termination, or if mutually agreed, any deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS.  3. Sections of B, C, and D of this agreement shall survive termination. | |
| **F. Additional Terms**:  1.  2. | |
| **G. Laws and Restrictions** | |
| 1. This agreement will be construed so as to comply with the laws of both the PROVIDER and the RECIPIENT, except that to the extent they conflict and cannot be harmonized, the contractual provisions of this agreement shall be construed in accordance with the laws of the PROVIDER, and ethical restrictions and prohibitions on uses of the MATERIALS shall be construed in accordance with the laws of the location where research is being conducted.  2. The undersigned Providerand Recipientexpressly certify and affirm that the contents of any statements made herein are truthful and accurate. | |
|  | |
| Recipient’s Signature: | Provider’s Signature: |
| Place and Date: | Place and Date: |

ثبت نام پژوهشگر اصلی در «سامانه ملی اخلاق در پژوهش‌های زیست‌پزشکی» به عنوان متقاضی مجوز ارسال فرامرزی نمونه زیستی

ارسال درخواست مجوز از طریق بارگذاری تمامی مستندات مورد نیاز (طبق دستورالعمل) و تکمیل فرم مربوطه و ثبت درخواست

مورد نیاز و تکمیل فرم مربوطه و ثبت درخواست

بررسی مستندات دریافتی در دبیرخانه کارگروه وزارتی اخلاق در پژوهش

اعلام نقض مستندات به پژوهشگر اصلی جهت تکمیل مستندات و رفع نقص و ارسال مجدد

در صورت وجود اعتراض به رای صادره، ارائه درخواست بررسی مجدد (با ذکر دلایل)

()

()

دریافت و جمع بندی نظرات داوری توسط دبیرخانه کارگروه وزارتی اخلاق در پژوهش و برگزاری جلسه کارگروه ویژه

بلی

خیر

تعیین داور توسط دبیرخانه «کارگروه وزارتی اخلاق در پژوهش» و ارسال مستندات جهت داوری

اعلام نظر داوری به پژوهشگر اصلی جهت انجام اصلاحات و رفع نواقص و ارسال مجدد مستندات

آیا مستندات کامل است؟

خیر

بلی

آیا کارگروه ویژه موافق صدور مجوز است؟

آیا نیاز به اصلاحات و رفع نواقص است؟

خیر

بلی

انجام داوری

اعلام به پژوهشگر اصلی و به رئیس/معاون پژوهشی دانشگاه/دانشکده/ سازمان

**فرایند ثبت درخواست، ارزیابی و صدور مجوز ارسال فرامرزي نمونه زيستی با هدف پژوهشي**