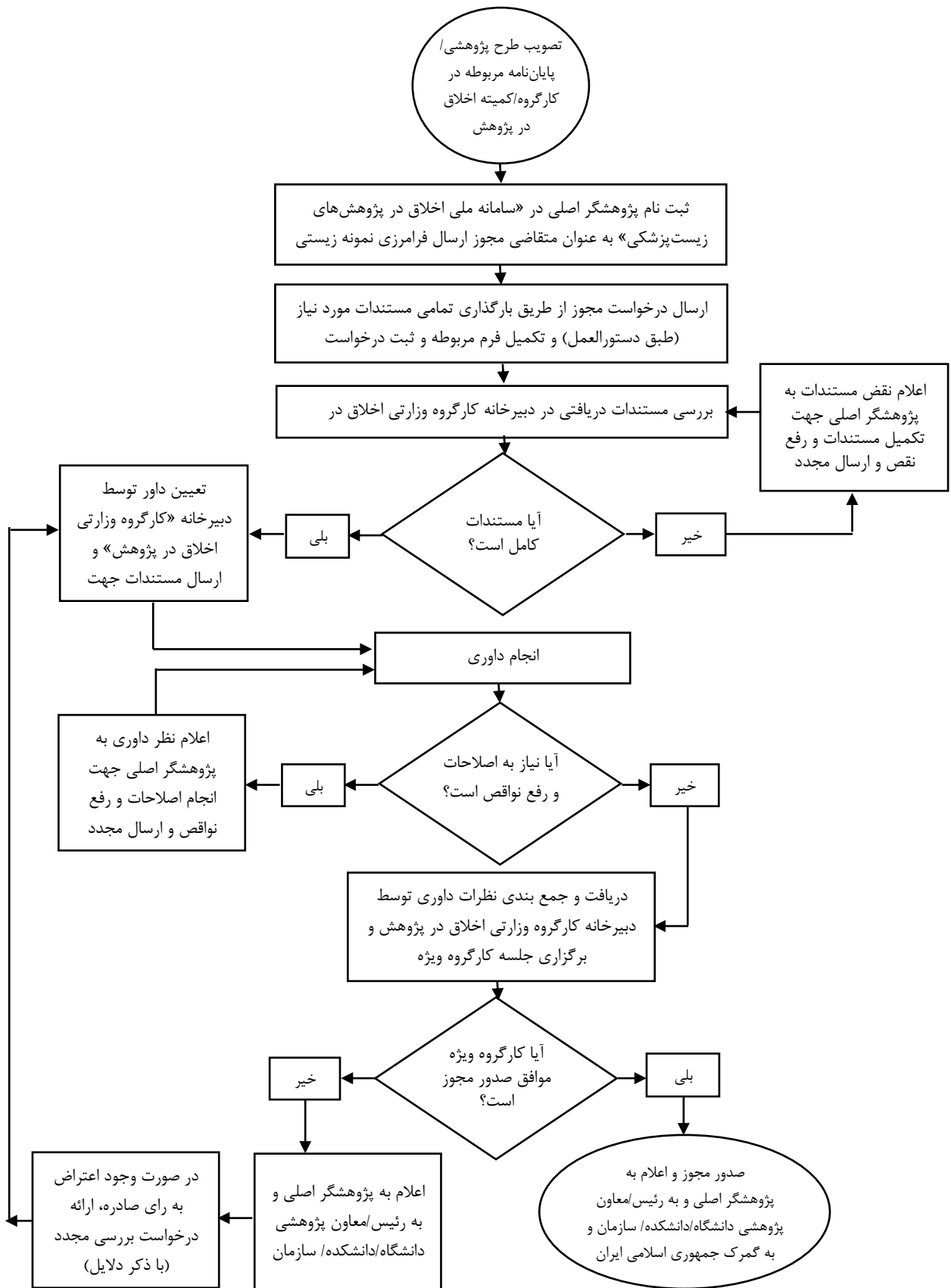


پیوست هفتم

**فرآیند، توافقنامه و پرسشنامه مرتبط با ارسال فرامرزی نمونه
زیستی با هدف پژوهشی**



نمودار شماره ۳ - فرایند ثبت درخواست، ارزیابی و صدور مجوز ارسال فرامرزی نمونه زیستی با هدف پژوهشی

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
<p>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.</p>
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: <input type="checkbox"/> Unidentifiable <input type="checkbox"/> Coded
g. Special protective packaging required: <input type="checkbox"/> Yes <input type="checkbox"/> 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. Recipient agrees to treat in confidence, for a period of ----- years from the date of its disclosure, any of Provider's written information about this Material that is stamped "CONFIDENTIAL", except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation.

10. Any oral disclosures from Provider to Recipient shall be identified as being CONFIDENTIAL by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure.

11. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given CONFIDENTIAL information to Recipient such public disclosure may be made only after Provider has had thirty days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information.

12. The Provider can request access to unpublished primary data that is going to be used in a joint 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 Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

Provider's Signature:

Recipient's Signature:

Place and Date:

Place and Date:

پرسشنامه درخواست بررسی طرح پژوهشی متقاضی دریافت مجوز جهت ارسال نمونه زیستی با هدف پژوهشی به خارج از کشور

کارگروه وزارتی اخلاق در پژوهش‌های زیست پزشکی بر اساس اسناد بین‌المللی و نیز کدها و الزامات اخلاقی مصوب وزارت بهداشت، درمان و آموزش پزشکی، به عنوان تنها مرجع صدور مجوز «انتقال فرامرزی نمونه‌های زیستی با هدف پژوهشی» بوده و طرح‌های پژوهشی متقاضی دریافت مجوز مذکور را مورد ارزیابی قرار می‌دهد. لذا ضروری است که پرسشنامه زیر در سامانه ملی اخلاق در پژوهش‌های زیست‌پزشکی به منظور بررسی و صدور مجوز انتقال نمونه زیستی به خارج از کشور، تکمیل شده و به انضمام مستندات مورد نیاز از طریق سامانه مذکور به دبیرخانه کارگروه وزارتی اخلاق در پژوهش ارسال گردد.

۱- اطلاعات طرح پژوهشی/پایان‌نامه
عنوان طرح پژوهشی/ پایان‌نامه:
میزان 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):
تاریخ شروع احتمالی پژوهش (خارج کشور):
تاریخ خاتمه احتمالی پژوهش (خارج کشور):
کد مصوبه مرجع علمی صلاحیت‌دار:
شناسه اخلاق در پژوهش:
نوع نمونه زیستی:
تعداد/ مقدار نمونه زیستی:
نحوه و مسیر انتقال نمونه‌های زیستی به خارج از کشور (هوایی/ زمینی/ دریایی):
آیا نمونه زیستی ارسال می‌شود یا توسط فرد منتقل می‌شود؟ در صورتی که نمونه زیستی توسط فرد منتقل می‌شود؛ نام و نام خانوادگی، آدرس و شماره تلفن همراه وی ذکر گردد.
دلایل انتقال نمونه زیستی به خارج از کشور را توضیح دهید:
آیا امکان انجام این آزمایش در داخل کشور وجود دارد؟
اگر امکان انجام آزمایش در داخل کشور وجود دارد، علت ارسال نمونه به خارج از کشور چیست؟

۲- مشخصات پژوهشگر اصلی (داخل کشور)
نام و نام خانوادگی:
محل کار (وابستگی سازمانی):
رشته تحصیلی:
مقطع تحصیلی:
آدرس محل سکونت:
شماره تلفن همراه:
آدرس پست الکترونیک:

نام و محل کار استاد راهنما (مخصوص پایان‌نامه های دانشجویی):

۳- مشخصات پژوهشگر همکار (خارج از کشور)	
نام و نام خانوادگی:	
دانشگاه/ مرکز تحقیقاتی محل کار:	
رشته تحصیلی:	
آدرس محل کار:	
شماره تماس (تلفن محل کار):	
حوزه فعالیت:	
آدرس پست الکترونیک:	

۴- مشخصات طرح پژوهشی/پایان‌نامه		
ردیف	سوالات	ملاحظات کارگروه/کمیته
۱	خلاصه‌ای از پژوهش به زبان ساده و قابل فهم به زبان فارسی شامل اهمیت و ضرورت پژوهش و علت انتخاب موسسه همکار خارجی را بنویسید (حداکثر ۵۰۰ کلمه):	
۲	جمعیت مورد مطالعه کدامند؟ علت انتخاب آنها را توضیح دهید.	
۳	آیا محدودیتی برای انتشار نتایج پژوهش وجود دارد؟	
۴	داده‌ها یا نمونه‌های زیستی به چه مدت و در چه محلی نگهداری می‌شوند؟	
۵	نحوه نگهداری و نیز روش معدوم کردن نمونه‌های زیستی (به منظور حفظ محرمانگی اطلاعات) چگونه است؟	
۶	چه کسانی به اطلاعات شخصی شرکت‌کنندگان در پژوهش، دسترسی خواهند داشت؟	
۷	چه راهکارهایی برای حفاظت از اطلاعات و رعایت اصول اخلاقی در پژوهش بر روی نمونه‌های زیستی مربوطه اندیشیده‌اید؟	
۸	آیا نمونه‌های زیستی از ابتدا برای اهداف پژوهشی گرفته شده‌اند یا نمونه‌هایی است که برای اهداف تشخیصی/ درمانی جمع‌آوری شده‌اند؟	
۹	چگونه نمونه‌های زیستی علامت‌گذاری شده و شناخته می‌شوند؟	
۱۰	چه نوع بررسی و پژوهشی بر روی نمونه‌های زیستی/ داده‌ها انجام خواهد شد؟	
۱۱	منافع این پژوهش (مانند دسترسی به محصول پژوهش یا توانمندسازی) برای ایران چیست؟	
۱۲	نمونه‌های زیستی مربوطه به چه منطقه/ مناطق جغرافیایی تعلق دارند؟	
۱۳	حقوق معنوی پژوهش بین پژوهشگران ایرانی و همکاران بین‌المللی چگونه به مشارکت گذارده می‌شود؟	
۱۴	سرنوشت اطلاعات یا سرنوشت نمونه‌های زیستی در انتهای پژوهش چیست؟	
۱۵	آیا دانشجو یا عضو هیات علمی در این طرح پژوهشی، به منظور انتقال دانش و یا تکنولوژی به خارج از کشور مسافرت خواهد کرد؟ در صورت پاسخ مثبت، درخصوص فرد مورد نظر و جزئیات سفر علمی توضیح دهید. در صورت نیاز مدارک مربوطه را ضمیمه نمایید.	

۱۶	آیا تفاهم‌نامه همکاری بین‌المللی امضا شده است؟ پاسخ مثبت، تصویر تفاهم‌نامه مربوطه را ضمیمه کنید.
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چک لیست مستندات تکمیلی		
ملاحظات	تائید توسط پژوهشگر اصلی	
	بلی	خیر
مستند		
نامه درخواست معاون پژوهشی موسسه مربوطه جهت درخواست بررسی طرح‌نامه و صدور مجوز ارسال نمونه زیستی به خارج از کشور توسط کارگروه وزارتی اخلاق در پژوهش		
طرح‌نامه پژوهشی		
مصوبه مرجع علمی صلاحیت‌دار		
شناسه کد اخلاق در پژوهش		
رزومه پژوهشگران اصلی		
فرم رضایت آگاهانه اهداکنندگان نمونه‌های زیستی (به زبان فارسی)		
قرارداد یا تفاهم‌نامه کتبی بین موسسه یا موسسات داخلی با موسسه یا موسسات خارجی حامی پژوهش (فرم MTA) که توسط هر دو پژوهشگر اصلی داخل و خارج از کشور امضاء شده باشد.		
تفاهم‌نامه و یا قرارداد مالی با موسسه حمایت‌کننده پژوهش		
پرسشنامه یا فرم جمع‌آوری داده‌ها		
جزئیات نحوه و مسیر انتقال نمونه‌ها و مستندات مربوطه با توجه به شرایط، زمان، نوع نمونه و نوع پژوهش		
سایر مدارک (نام ببرید):		

اینجانب صحت مفاد این پرسشنامه را تائید کرده و اعلام می‌دارم که تمامی راهنماها، دستورالعمل‌ها و کدهای اخلاق در پژوهش و به‌ویژه «دستورالعمل ملی انتقال فرارزی نمونه‌های زیست‌پزشکی با هدف پژوهشی» را مطالعه نموده و خود را متعهد به رعایت آن‌ها می‌دانم.

نام و نام خانوادگی پژوهشگر اصلی: _____

امضا _____

تاریخ _____