PERSIAN Cohort Study

Data Access and Authorship Rules
The Prospective Epidemiological Research Studies in IrAN (PERSIAN Cohort) Data Access and Authorship Rules

دستورالعمل دسترسی به اطلاعات و قوانین نویسندگی و انتشار در مطالعه کهورت پرشین
One of the most important goals in the PERSIAN Cohort is the empowerment of medical universities throughout Iran to perform high quality clinical research, while enhancing the health of populations. Creating collaborations between universities, both national and internationally is another goal in order to improve research capabilities. One of the important outputs of any study is presentation of the results in international communities and publication in prestigious scientific journals. For this reason, this document has been developed to encourage and guide scientists towards using the PERSIAN Cohort data, while providing rules to ensure consistent and uniform publications.

\[ \text{Impact Factor} \]

\[ 1 \]
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## Term Definitions

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<th>Role</th>
<th>Description</th>
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<tr>
<td>Local Principal Investigator (LPI)</td>
<td>The principal investigator at each Medical University, chosen by the Ministry of Health (MOH), who is responsible for the execution of the study at the affiliated cohort center.</td>
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<tr>
<td>Central Principal Investigator (CPI)</td>
<td>The principal investigator chosen by the Ministry of Health, who is responsible for execution of the study throughout the country.</td>
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<tr>
<td>Single-Center Study Proposals</td>
<td>Studies in which data from only one cohort center is used.</td>
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<tr>
<td>Multi-Center Study Proposals</td>
<td>Studies in which data from more than one cohort center is used.</td>
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<tr>
<td>Principal Investigator (PI)</td>
<td>The principal investigator of the proposed study, requesting to use PERSIAN data/samples.</td>
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<tr>
<td>Technical Reviewer</td>
<td>Local or centrally appointed technicians required to check every publication for adherence to guidelines outlined in this document, prior to publication.</td>
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### Local Scientific Committee (LSC)

<table>
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<th>شورای علمی، پژوهشی دانشگاهی کهورت</th>
<th>Committee including principal investigators, deputy of research, head of the research center carrying out the cohort study at each Medical University as well as 2-3 other faculty members chosen by the LPI, who are responsible for the evaluation of single-center study proposals and approval of all affiliated publications</th>
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<tr>
<td>تیم متشکل از مجریان دانشگاهی، معاون تحقیقات و فناوری وقت، رییس مرکز تحقیقات میزبان کهورت (در صورت تصویب کهورت در مرکز تحقیقاتی)، 2-3 نفر از اعضای هیئت علمی به پیشنهاد PIs که مستیلیت بررسی پروپوزال طرح‌های تک مرکزی و تایید مقالات منتج از آنها را بر عهده دارد.</td>
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### Central Scientific Steering Committee (CSSC)

<table>
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<tr>
<th>شورای علمی، پژوهشی مرکزی کهورت</th>
<th>Committee including four PERSIAN Cohort LPI and four CPI responsible for the evaluation of multi-center study proposals and approval of all affiliated publications, among other duties. The LPI in CSSC are selected every 2 years by other LPI.</th>
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<tr>
<td>تیم متشکل از ۴ نماینده از تیم مرکزی کهورت پرشین و ۴ نماینده منتخب از مجریان دانشگاهی می‌باشند که مستیلیت بررسی پروپوزال طرح‌های چند مرکزی و تایید مقالات منتج از آنها را بر عهده دارند.</td>
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مجریان دانشگاهی با حکم ۲ ساله در شورای عضوی می‌باشند.
All data is stored in a centralized server accessible by the CSSC. LPI at each university also has access to data from his/her affiliated cohort center. Researchers requesting PERSIAN Cohort data/samples, can gain access to the data in one of two ways depending on the type of proposal—single-center study proposals and multi-center study proposals—as described below.

Single-Center Study Proposals:

Data from each cohort site is the intellectual property of the affiliated Medical University and the LSC must decide about its use. Each university can analyze and publish its own data without any restrictions.

- **Note 1:** All proposals must be submitted on the PERSIAN Cohort Access Portal and complete the standard review processes for a single-center study.
  
  توجه 1: کلیه پروپوزالها می‌باشند در پورتال کهورت پرشین ثبت گردند و کلیه مراحل ارسال و داوری طرح های تک مرکزی را طی نمایند.

- **Note 2:** If universities are approached by other national or international institutions for data/sample use, they must first make certain that the proposal is actually a single center study and that investigators are not approaching other PERSIAN cohort sites with the same proposal separately. If data from more than one cohort site is needed for a study, the proposal will not be considered a single-center study proposal anymore and must be submitted as a multi-center study proposal to the CSSC.
Steps in Submission and Review of single-center study proposals

Pre-proposals must be submitted on the PERSIAN Cohort Access Portal: www.c.ddrc.ac.ir/persianaccess/. All single-center study proposals submitted, will be sent directly to the corresponding LPI, for evaluation by the LSC.

1. Each pre-proposal will be evaluated by the LSC based on standard criteria to reach one of the following decisions:
   - Rejection of pre-proposal
   - Acceptance for full-proposal review

2. If accepted:
   - Full proposal forms must be completed and submitted on the access portal for scientific evaluation by reviewers.
   - Study PI must indicate adherence to authorship rules set by the PERSIAN Cohort.

The final decision about the study proposal will be made by LSC based on reviewer comments in one of the following ways:

- Rejection of study proposal
- Revisions to the study proposal
- Acceptance of the study proposal
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Once/If accepted:

3. Material Transfer Agreement/Data Transfer Agreement completion

4. Data/Sample release

5. Study execution and progress report submission

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2 Material Transfer Agreement

3 Data Transfer Agreement
6. Review/approval of all publications by the LSC and technical reviewers prior to journal submission
   - Publications will be reviewed to ensure agreement with the study proposals goals and objectives, and adherence to guidelines set in MTA/DTA and authorship rules

7. Publication in scientific journals

8. Return of cleaned data or any new indexes/variables created through the project to the PERSIAN Cohort data server (after publication).
   - Any new variables/indexes developed in a study must be returned to the PERSIAN Cohort to be added in the centralized server for others’ use. This will only occur once the developers have published their findings. Any use of the indexes/variables must reference the original publications.

Note 3: While developing new indexes/variables is encouraged when necessary, researchers cannot re-create the same index/variable that is already available in the PERSIAN Cohort data dictionary and must use what has already been created. This will help keeping the values/definitions of variables consistent in various studies.

Note 4: No data will be released without formal proposal submission in the access portal and completion of steps outlined above.
**Note 5:** There will be no exceptions for completion of the aforementioned steps. Even LPI must also submit a proposal and complete the review processes to use the cohort data/samples.

**Note 6:** In the abstract, keywords and methods section (in the main body) of all single-center study publications, reference to the origin of the data/samples must be made by mentioning the full study name “Prospective Epidemiological Research Studies in IrAN – PERSIAN Cohort.” Prior to publications, a technical reviewer must approve adherence to this note.

**Note 7:** The decision about authorship and the order of authors is to be made by the PI of the proposed study.

**Note 8:** All proposals must be submitted on the PERSIAN Cohort Access Portal to complete standard reviewing as outlined above.
Note 9: In order to increase collaboration of researchers at the Medical Universities affiliated with cohort studies, CSSC is required to link 1-2 individuals from each participating cohort center to the proposed study PI. These individuals will be chosen with assistance from LPI and based on past experiences in the study topic. They will be in direct contact with the PI, assisting in ways dictated by the PI. Upon completion of the study, the names of these individuals is also to be included in all publications, given that they have made their required contribution, and met the Authorship Rules outlined in Part II of this document.

Note 10: In addition to what is mentioned in Note 5 of this document, the phrase “The PERSIAN Cohort” must also be used in the beginning or at the end of the title in all multi-center study publications. A technical reviewer from the CSSC must check adherence to these notes before approval for publication is given by the CSSC.

Note 11: In multi-center study publications, mentioning the names of cohort centers from which data is analyzed and presented is mandatory.
• **Note 12: Student Thesis Proposals:** If data/samples are requested as part of a student thesis, proposal submission will be the responsibility of the supervisor, who will be held responsible for the protection of data/samples and publication of results even if the student graduates or does not finish the project. If the study findings are not published within 6 months of the proposed finish date, it will result in the following consequences: 1) the research topic will be considered available if a similar proposal is received and 2) the supervisor will no longer be eligible to request PERSIAN Cohort data/samples.

توجه 12: طرح های تحقیقاتی دانشجویی: در صورتی که داده/نمونه‌های درخواستی برای یک طرح تحقیقاتی/پایان‌نامه دانشجویی باشد، برای پرسنال میباشد توسط استاد راهنمایی دانشجو در پورتال کهورت پرشین ارسال گردد. مسئولیت حفاظت از داده/نمونه‌های و همچنین انتشار نتایج حتی اگر دانشجو فارغ التحصیل شود و یا طرح را به اتمام نرساند، با استاد راهنما میباشد. در صورتی که نتایج ۶ ماه پس از زمان ذکر شده در پروبوزال منتشر نشود، عواقب ذیل را به همراه خواهد داشت: ۱) در صورت دریافت طرحی مشابه، موضوع برای سایر محققین در دسترس قرار خواهد گرفت و ۲) استاد راهنما مجاز به درخواست مجدد داده/نمونه از کهورت پرشین نخواهد بود.
The authorship rules of the PERSIAN Cohort comply with the International Committee of Medical Journal Editors (ICMJE)’s *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*. Based on these recommendations, an individuals must meet the following four criteria to be considered an author:

1. **Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;** AND
   - فرد باید همکاری مؤثر و قابل توجهی در ارائه ایده پژوهشی یا طراحی مطالعه یا جمع آوری داده‌ها یا آنالیز و تفسیر داده‌ها یاد... 

2. **Drafting the work or revising it critically for important intellectual content;** AND
   - فرد باید در نوشتن نسخه اولیه دست نوشته و یا در پیامدهای و موردر نقد آن همکاری کند، به گونه‌ای که همکاری کننده باید به‌طور کلی از لحاظ محتوای علمی دستخوش تغییر و تکامل شود. واضح است افرادی واجد این شرط می‌شوند که صلاحیت علمی لازم برای موردر نقد آنها بر اساس تجربه علمی و سابقه تحصیلی یا کاری خود داشته باشند... 

3. **Final approval of the version to be published;** AND
   - فرد باید نسخه نهایی دست نوشته را قبل از انتشار، مطالعه و آن را تأیید کرده باشد...
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

As encouraged by the ICMJE “all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.” Therefore, in order to increase collaboration of researchers at the Medical Universities affiliated with cohort studies, who meet criteria 1, it is the policy of the PERSIAN Cohort to link 1-2 individuals from each participating cohort center to the proposed study PI based on past experiences in the study topic. They will be in direct contact with the PI, and assisting in ways dictated by the PI. Upon completion of the study, the names of these individuals is also to be included in all publications, given that they have made their required contribution, and meet the remaining criteria mentioned above.

Note 13: Omitting the names of individuals who meet all 4 criteria from the author list is prohibited.

Note 14: Adding the names of individuals who do not meet all 4 criteria to the author list is prohibited.
**Note 15:** Ensuring names that meet the authorship criteria are not omitted, or that names are not added that do not meet the criteria is the moral responsibility of all authors in the author list.

- **Note 16:** Mere inclusion in the PI’s research team does not entitle an individual to authorship.

- **Note 17:** Performing activities such as providing financial support or consultation (statistical or scientific), allowing use of laboratory facilities or running lab tests, referral of individuals to take part in the study, etc. will not suffice as being an author even if no payment has been received for the services given.

- **Note 18:** All individuals who have been involved in the study in any way who do not meet all 4 criteria must be mentioned in the “acknowledgement section.”

- **Note 19:** In all acknowledgement sections of studies using PERSIAN Cohort data (single- or multi-centered), the following sentence regarding the PERSIAN Cohort funding must be included:

  “The Iranian Ministry of Health and Medical Education has contributed to the funding used in the PERSIAN Cohort through Grant no. 700/534.”
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Note 20: The decision on who shall be the first and corresponding authors should be agreed upon by researchers involved in the study and from those with the greatest contribution to the research conducted.

Note 21: Determining the order of authors is the responsibility of the study PI.

Note 22: If the study is a student thesis, the student must be the first author and academic supervisor(s) as corresponding author(s).

Note 23: Depending on journal policies, more than one person can be first and/or corresponding authors.

Note 24: Inclusion of anyone’s name and affiliation must be done after his/her approval.

The abovementioned guidelines must be met in all publications using PERSIAN Cohort data/samples, including but not limited to: abstracts, scientific articles, posters, presentations, etc.