ECRAID-Base Publication Policy for Partners and Sites

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1. Aim of the ECRAID-Base Publication Policy

The ECRAID-Base Publication Policy is designed to ensure that all project and study results are disseminated to the widest possible audience while adhering to the highest standards of scientific integrity. This policy aims to guarantee fair and appropriate recognition for all contributors involved in ECRAID-Base research. This includes clearly defined authorship order based on contributions such as study design, data collection, analysis, and manuscript preparation. Furthermore, the policy promotes the rapid and efficient publication of research findings to accelerate scientific progress and knowledge sharing.

This policy only applies to project and study results from activities financed through the ECRAID-Base initial grant. It does not necessarily apply to results from activities performed after the ECRAID-Base funding period has ended, nor for results from activities that are funded by partners who are not a part of the ECRAID-Base consortium.

2. Scope of the ECRAID-Base Publication Policy

This policy covers all types of publications resulting from the ECRAID-Base project, including but not limited to full scientific peer-reviewed publications, conference presentations and abstracts, press releases, and any other written materials intended for public dissemination and communications. If you have any questions about whether this policy applies to your publication, please contact the Ecraid Communications Office for advice.

3. Dissemination principles for ECRAID-Base as outlined in the Grant and the Consortium Agreement

According to the rules of the ECRAID-Base Grant Agreement: Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — 'disseminate' their results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

This does not change the obligation to protect results in Article 27 of the Grant Agreement, the confidentiality obligations in Article 36 of the Grant Agreement, the security obligations in Article 37 or the obligations to protect personal data in Article 39 of the Grant Agreement, all of which still apply.

3.1. Principles agreed in the Grant Agreement

A beneficiary that intends to disseminate the results produced or coordinated by its own team must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1 of the Grant Agreement) — need to formally notify the Commission before dissemination takes place.

3.1.1. Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

a) as soon as possible and at the latest at publication, deposit a machine-readable electronic copy of the published version (generated by the journal) or final peer-reviewed manuscript accepted for publication in a repository for scientific publications. An Ecraid Zenodo community has been set up where anyone in the Consortium can upload study-related documents, publications, conference posters, etc. Zenodo is a trusted general-purpose research repository that helps researchers upload and receive credit by making any of their research accessible and citable.

   Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications (section 3.1.2. Open access to research data).

b) ensure open access to the deposited publication — via the repository — at the latest:
   i. on publication, if an electronic version is available for free via the publisher, or
   ii. within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication. The bibliographic metadata must be in a standard format and must include all of the following:

- the terms “European Union (EU)” and “Horizon 2020”;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

3.1.2. Open access to research data

Regarding the digital research data generated in the action (‘**data**’), the beneficiaries must:

a) deposit in a controlled access research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:
   i. the data, including associated metadata, needed to validate the results presented in scientific publications, as soon as possible;
   ii. data which is relevant for addressing a public health emergency, if specifically requested by the European Commission and within the deadline specified in the request;
   iii. ;
   iv. the data should be assigned a DOI by the registry to ensure that ECRAID-Base partners are appropriately credited for their contributions to creating the dataset and appropriate acknowledgement of the funding source for those data.
   v. if a request to access the data via the repository is approved, it is important that the data is associated with an appropriate license, or a data use agreement is signed by the data requester

b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27 of the Grant Agreement, the confidentiality obligations in Article 36, the security obligations in Article 37 of the Grant Agreement or the obligations to protect personal data in Article 39 of the Grant Agreement, all of which still apply.

As an exception, the beneficiaries do not have to ensure open (or controlled access, depending on permissions in the data and data sensitivity) access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1 of the Grant Agreement) would be jeopardized by making those specific parts of the research data openly accessible. In this case, the data access request and the reasons for not giving access must be clearly documented.

As an exception, the beneficiaries do not have to ensure open (or controlled access, depending on permissions in the data and data sensitivity) access to specific parts of their research data under Point (a)(i), if informed consent was not given by research participants for sharing their pseudonymised participant-level data outside of the consortium. This does not apply for certain study sites that have implemented a site-level waiver of consent or have local or national legislation that allows for the sharing of those data, as with a local or national opt-out for sharing data from observational studies or a national non-objection approach facilitate the reuse of pseudonymised health data. When in doubt about whether pseudonymized participant-level data can be shared outside of the ECRAID Base Consortium, please consult WP9.

As an exception, the beneficiaries do not have to ensure open access also to the research data under Point (a)(ii), if the Commission agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.

3.1.3. Information on EU funding — Obligation and right to use the EU emblem

Unless the Commission requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

a) display the EU emblem and
b) include the following text:

“This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 965313”.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Commission. This does not however give them the right to exclusive use. Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

3.1.4. Disclaimer excluding Commission responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains.

3.1.5. Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43 of the Grant Agreement). Such a breach may also lead to any of the other measures described in Chapter 6.

3.1.6. Acknowledgement of ECRAID-Base funding

Unless the EU Commission requests otherwise, any publicity, including that at a conference or seminar, or any type of information or promotional material (brochure, leaflet, poster, presentation, newsletter, etc.), must specify that the project has received EU research funding.

Funding statement: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965313".

The statement can be modified slightly depending on the context. For example, "The ECRAID-Base project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965313".

3.1.7. Author's disclosure information

In the interest of full participant disclosure, the following statements should be included in full manuscripts, if applicable:

In addition, as a special form of the EU H2020 grant, <include name of participant> received a direct financial contribution from <include name of participant>.

3.2. Principles agreed in the Consortium Agreement

3.2.1. Dissemination of own Results

During ECRAID-Base and for a period of 1 year after the end of the project (28 February 2026), the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 29.1 of the Grant Agreement subject to the following provisions.

3.2.2. Objections

Prior notice of any planned publication shall be given to the other Parties at least 45 calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Grant Agreement in writing to the Coordinator and to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

An objection is justified if:

i) the protection of the objecting Party's Results, Background and/or Confidential Information would be adversely affected
ii) the objecting Party's legitimate academic interests in relation to the Results or Background would be significantly harmed.

The objection has to include a precise request for necessary modifications.

If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion. In case of (a) the objecting Party shall identify what confidential Information shall be deleted and the publishing Party shall revise the publication to prevent undesired disclosure of the objecting Party's Confidential Information.

The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted.

3.2.3. Dissemination of another Party's unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published.

3.2.4. Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in the Consortium Agreement.

3.2.5. Use of names, logos or trademarks

Nothing in the Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

4. Approval of Material

No publication, abstract, or poster should be submitted nor published before all co-authors have been informed and have given their formal approval by any written media. Depending on the publication type the use of the correct template is required.

All scientific manuscripts for publication should be sent to the Communications Office for proper circulation to the Consortium for review before publication or release (this can be done in parallel with co-authors giving their formal approval). The Communications Office can receive 'near final' versions for their review to help save time during the review process (assuming there are no major changes made to the content).

Revisions to be made following the review and approval process are the responsibility of the (co) authors. In addition, details/references, and abstract of the publication and an electronic copy of the published version or the final manuscript accepted for publication should be provided to the Communications Office at the latest two months following publication.

4.1. Time allowed for approvals

Type of communication	Period for approval	Time following reminder	Approval required from
Full research publication	14 day	1 day	General Assembly
Abstracts/Posters	7 day*	1 day	General Assembly
Media releases	7 day	1 day	General Assembly

***** For abstracts intended for major international conferences, shorter approval times can be discussed. Please contact the Communications Office as soon as possible.

For all media, media inquiries and media releases resulting from publications please keep the Communications Office informed at all times. In case of specific national media inquiries please consult the Communications Office in regards to how to proceed. International news value is determined by the Communications Office in cooperation with the Management Board. If relevant, the Communications Office will develop and issue an international media/press release.

Press releases will be sent out by the Ecraid press office (Communications Office) to relevant international press networks on behalf of the ECRAID-Base Consortium. Drafts will be circulated in English for approval. The timetable above is applicable. In the event that media require a rapid response (less than 7d), approval by co-authors and ECRAID-Base coordinator, Marc Bonten, will be required.

If there is no response following reminder approval is assumed to be granted.

Please note that the purpose of review is to ensure factual correctness of the data, ensure no authors have been omitted, and ensure a harmonised approach to the dissemination of ECRAID-Base research results. Reviewers (unless they are co-authors) should focus on the key messages contained in the publication, not minor edits.

5. Authorship

5.1. General authorship criteria

Final authorship will require the fulfilment of the Uniform Requirements for Authorship and Contributorship from the International Committee of Medical Journal Editors (www.icmje.org):

"*The ICMJE recommends that authorship be based on the following 4 criteria:*

- *Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND*
- *Drafting the work or revising it critically for important intellectual content; AND*
- *Final approval of the version to be published; AND*
- *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.*

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors."

5.2. Authorship criteria for research sites and country coordinators

5.2.1. Lead authors

To ensure representation of the participating centres, in studies that involve patient enrolment, the three research sites with the highest enrolment rates will have one local investigator listed as a lead author. The study PI has the discretion to select fewer sites, depending on the enrolment numbers.

The study PI has the discretion to include lead authors from additional sites and/or national coordinators who have made significant contributions to the study.

Decisions on which sites and lead authors will be included in a publication should be (1) taken *before* the writing process commences, (2) communicated to the respective sites and authors, and (3) included in the publication plan (see section 6).

5.2.2. Contributing Authors

Each research site which has achieved at least 25% of its target enrolment rate can nominate up to five staff members (clinical and laboratory) for inclusion in the contributing author list. Sites should prioritise those with substantial involvement in data collection, analysis, or study management.

5.3. Consortium acknowledgment

Each publication will be authored "*on behalf of ECRAID-Base Consortium*". If the Editor specifically refuses this mention in the authorship, it should be added in acknowledgments. In all cases a link to the publication-specific page on the Ecraid website should be included where all authors are listed. This link is to be provided per request by the ECRAID-Base Communications Office.

The following text should be included in the acknowledgements section: "The research leading to these results was conducted as part of the ECRAID-Base project. For further information please visit www.ecraid.eu/ecraid-base."

There is no need to acknowledge ECRAID-Base in publications that are not the result of research carried out under the project.

5.4. Author affiliation(s)

Each qualifying author will be included with at least one affiliation. For authors who are part of the ECRAID-Base consortium, that will be the relevant consortium partner as mentioned in the Consortium Agreement. For authors from research sites, that will be the relevant research site. For country coordinators that will be an affiliation of their choice. If more than one affiliation per author is allowed, those will be freely determined by each author.

5.5. Disputes

In case of disputes related to authorship and/or content, ECRAID-Base coordinators will be informed and will serve to solve these issues, taking in consideration ECRAID-Base consortium interests and the Uniform Requirements for Authorship (see 5.1).

6. Publication plan

An outline of planned publications will be required including leading authors, title, main hypothesis and a small paragraph explaining the analyses and scientific importance. These plans will facilitate early publication, monitoring of scientific productivity, and prevention of conflicts. They will also be used to guarantee an optimal scientific strategy in analysis and publication, to identify and prevent potential conflicts of interest, and to avoid any serious overlap or duplication.

This plan will be developed in collaboration with each Work Package and approved by the Coordinating Committee on an annual basis.

7. Publication reporting

As soon as a new publication has been published, the team responsible is expected to provide detailed information to the Grant Management and Communications teams. This information will be entered into the European Union's Funding & Tenders portal. It should include:

- DOI
- Type of publication (Article in Journal; Publication in Conference proceedings/Workshop; Book/Monograph; Chapter in a Book; Thesis/Dissertation; Other) *
- Repository link
- Link to the publication
- Title *
- Authors *
- Title of the journal / proceedings / book series / book
- Relevant pages
- ISBN
- Publisher *
- Place of publication *
- Year of publication *
- Is this publication available in Open-Access, or will it be made available? (Yes – available in Green Open Access; Yes – available in Gold Open Access; No)
- Embargo period, if any:
- Is this a peer-reviewed publication? (Yes / No) *
- Is this a joint public/private publication? (Yes / No) *

* Mandatory information

8. Ancillary publications

Abstracts or publications partially including ECRAID-Base data should mention it appropriately (both in Authorship and in Methods). When patients enrolled in an ECRAID-Base study are also included in another study (abstract or manuscript) which does not use data from the ECRAID-Base study, ECRAID-Base does not need be mentioned.

9. Clinical studies

In order to allow publication of clinical trials in high index journals, the pre-registration of all clinical trials ina database will be done prior to trial initiation (e.g. clinicaltrials.gov or clinicalresearch.org).

10. Publication of POS site-level data

10.1. Standard Operating Procedure (SOP) for data requests from within or outside of the ECRAID-Base Consortium

A dedicated SOP has been developed outlining:

- Procedures for requesting access to POS site participant-level data, including the designated contact person.
- Expected response time for data requests.
- Authorship expectations for publications arising from POS site-level data analysis, including requirements for collaboration and acknowledgement of the main study.
- The proper registration and citation of study data to ensure sites and investigators are properly credited for their work to produce the dataset.

10.2. Primary publication

POS site-level data may not be published independently if it compromises the integrity or novelty of the main study publication or if the publication of such data would violate subject privacy or does not align with participant consent.

10.3. Secondary publication

POS site-level data can be used in secondary publications provided it does not overlap significantly with the main publication and adheres to the data sharing and authorship rules outlined in the SOP (see 10.1).

POS sites can collaborate on publications using combined site-level data, subject to the same SOP guidelines and non-interference with the main publication.

10.4. Theses and dissertations

POS site-level data may be used for MD or PhD theses and dissertations, provided the data will not be published, relevant ethics review has been secured, and the study PI is informed beforehand.

10.5. Local research questions

Research sites have prioritised access to their eCRF data for addressing local research questions. The SOP will detail the process for such access.

10.6. Amendments

Research sites may request amendments to a study.

11. Ethics

All manuscripts and posters must include text to confirm that

- all animal research has been conducted according to local ethical legislations
- all clinical research has been conducted to GCP and according to local legislations

12. Publication and Intellectual Property

All ECRAID-Base participants are encouraged to publish results in a timely fashion. It is acceptable to delay publication in order to allow stakeholders to achieve suitable Intellectual Property protection however this should be no longer than 6 months from the completion of the data analysis.

13. Archive

A copy of all publications (including full citation details) made on the behalf of ECRAID-Base should be archived on the Ecraid website once published. This is the responsibility of the primary author. Publications can be sent to the Communication Officer.

14. Information

Work package 12 ‘Communications’ is led by the Ecraid Communications Office (communications@ecraid.eu)

Work package lead: Claire-Marie Martis (claire-marie.martis@ecraid.eu)
Project communications officer: Marko Markov (marko.markov@ecraid.eu)