BCPM Ethics and Data Exchange call

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Deadlines

Release date:	Tuesday, April 5, 2022
Application due:	Friday, July 8, 2022, 17:00 CET
Decision announcement:	Friday, October 7, 2022
Start of projects:	October or November 2022
Maximum project duration:	24 months

Submission instructions

Project proposals are to be submitted using the official template (see the *Call for Projects* section on www.bcpm.unibe.ch). Applications must be submitted as a single PDF document to info@bcpm.unibe.ch. The subject line of the e-mail should read "BCPM Project Application". Receipt will be confirmed by e-mail.

Incomplete or non-compliant applications, or those received after the deadline will not be considered. Please direct questions to Timo Staub (timo.staub@bcpm.unibe.ch, +41 31 632 83 25).

Purpose

Precision medicine research often requires the (re-)use of clinical and genomic data coming from various patient cohorts, but Swiss approval processes and work culture with respect to ethics and data sharing are usually centered around institutional data ownership and focused on clinical trials. As a result, PM research projects are burdened with many administrative hurdles.

The issue was recognized and discussed during the BCPM ethics symposium on 24 November 2021, and beyond. The Swiss Personalized Health Network (SPHN) is addressing the subject by establishing contract templates (DTUAs), technical solutions (BioMedIT) and multi-institutional data exchange projects (national data streams). The Insel DLF is active in data warehousing and data sharing with the University of Bern. The Swiss Biobanking Platform (SBP) offers accreditation and contractual frameworks for the research on patient samples. Various research projects and patient registries have found ways to deal with the situation. However, specialists agreed that the issue re-mains an open one, and better solutions and optimized collaboration models are needed.

The current call wants to address the issue via a hands-on approach based on best practices and lessons learned at the University of Bern and the Inselspital. Projects might address (but are not limited to) ideas such as the establishment of framework contracts, content recommendations for ethics application, or any other idea, some of which have been mentioned on November 24 (see table in annex 1).

Successful pilot projects should offer a prospect for future impact (see review criteria below).

Budget

The total budget for this call is CHF 150'000. Applicants may request between
CHF 20'000 and CHF 50'000.

Applicant Eligibility

- This RFA is open to researchers or administrative or legal specialists with a primary appointment at the University of Bern and/or the Inselspital.
- The call addresses applicants who have professional knowledge and/or experience about ethics and data exchange in the medical field (work at an ethics committee, extensive experience with ethics applications, knowledge about current practices with respect to genomic data sharing, etc.).
- This is an interdisciplinary call. Therefore, a researcher from a faculty such as law or economics might collaborate with actors involved in precision medicine projects in Bern, or involved in research regulations or ethical approvals in general.
- Investigators who already received funding from the BCPM in prior calls are not eligible for this call.

Proposal Eligibility

- Proposals must be compliant with the specifications mentioned in the application template.
- A link to precision medicine is required.

Review Criteria

Applications will first be screened for overall completeness and formal compliance. Only eligible applications will be considered. Proposals will then be evaluated by experts, as they will be nominated by the BCPM Scientific Review Board (SRB).

Projects will be evaluated on the following basis:

- Likelihood that the project will foster precision medicine with respect to data exchange, data administration and ethics.
- Knowledge about current processes and legislation in the field of precision medicine, ethics, data exchange and data management.
- Ideally, a focus either on the situation in Switzerland, or a focus on the situation in Bern (data exchange between Inselspital and University).
- Methodology: Have the most appropriate methods for the realization of the project been chosen?

- Feasibility: Is the project feasible in terms of finances, human resources, organizational issues and time frame?

Expenditure Guidelines

Allowable expenditures:

- Salary support for PIs, co-PIs and any other participants (only in Bern).
- User fees for legal and/or data security consulting in Bern (are to be kept to a minimum).
- Organization of workshops, symposia or meetings (e.g., together with Swissethics).

Non-allowable expenditures:

- Secretarial/administrative personnel
- Capital costs/equipment, including maintenance/service contracts
- Office furniture and supplies
- Construction, renovation, or maintenance of buildings/laboratories
- Rental of laboratory or office space
- Personal computers
- Non-medical services to patients
- Purchasing of periodicals and books
- Dues and membership fees in scientific societies.

Grant Guidelines

To responsibly manage funds, the following guidelines have been instituted. **Acceptance of an award indicates agreement to abide by these guidelines.** Failure to abide by these guidelines will jeopardize eligibility for future grants and/or BCPM Membership:

1. Proposals must respect the application template given with the call. Ideally, we also get background information, methods, significance, and synergy opportunities between project PIs.
2. If a grant is awarded, the PIs must agree to provide a final progress report, including an overview about the results which have been reached. A presentation might also be required.
3. Publications resulting from the research supported by this grant must contain the acknowledgment "Supported by the Bern Center for Precision Medicine".
4. Any additional publications or grants resulting from the present grant must be reported.
5. The funds awarded shall be used solely for the purposes specified in the grant, in strict compliance with the application submitted and as executed by the recipient.
6. Grant money from the BCPM comes from a University business credit (Betriebskredit), and cannot be transferred to a University third party credit (Drittmittelkredit). It can only be transferred to another Betriebskredit. If relevant, BCPM funds may be managed at the Inselspital,

but you are not allowed to re-direct BCPM funds from the Inselspital back to a Drittmittelkredit at the University.

7. Grant recipients must respond to requests for information from the scientific leadership and administrative staff about their project.

8. Recipients might be asked to participate in progress update meetings or conferences to describe their research.

Annex 1: Symposium Results (in German)

The ideas below resulted from the symposium of November 24, 2021:

Besprochene Probleme	Mögliche Lösungen
• Involvierte Juristen verstehen die biologischen und technischen Zusammenhänge nicht und wollen kein Risiko für ihre Arbeitgeber, entscheiden deshalb im Zweifelsfalle immer gegen den Datenaustausch. • Fehlendes Vertrauen der Institutionen untereinander (manchmal durch HFG-Vorschriften durchaus begründet). • Lange und komplizierte/bürokratische Bewilligungsprozesse (Ethik-Anträge, DTUA mit Klinikanwälten). • Niemand fühlt sich in den Spitalhierarchien zuständig, wechselnde Verantwortlichkeiten ("Chasing of signatures"). • Unsicherheiten bezüglich genomischer Daten (was ist wirklich anonymisiert). • Unterschiedliche Erfassung/Codierung der klinischen Daten in den Spitälern. • Klinische Daten älter als 2014 (vor HFG, ohne neuen/informed Consent).	• Gespräch mit Ethik-Kommission oder Swissethics. • Involvieren der kantonalen Datenschützer. • Definieren grösserer Framework-Projekte (Rahmenprojekte, Templates). • Definieren grösserer Datanaustausch-Verträge zwischen den Kliniken (Rahmenverträge). • Mitwirken bei der anstehenden Revision des HFG. • Regulatorische Frameworks und gegenseitige Akkreditierung (analog zu Krankheitsegister, Swiss Biobanking Platform). • Reziproke Anstellung/Verpflichtung von Mitarbeitenden (z.B. Doppelanstellungen Insel-Uni Bern, wie bei Pathologie oder CGL). • Oft gemachten Ethik-Auflagen in der Praxis vorweg nehmen (z.B. Nutzen von REDCap). • Bessere Kategorisierung/Präzisierung genomischer Daten (z.B. Germline vs. Cancer Mutations). • Mit oben zusammenhängend: Präzisierung, wann Daten als anonymisiert gelten können. • Einheitliche Codierung, vie von SPHN geplant.