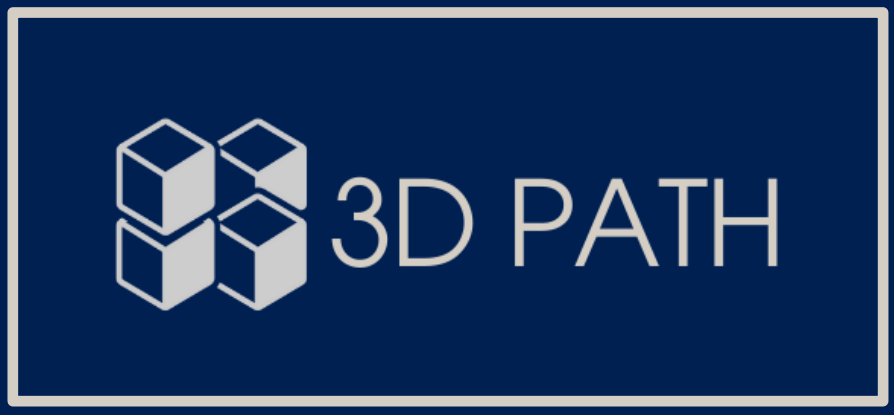

D3.1

Title: Ethics Approval

UBERN

DATE : 2026.02.24

Document control page

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Document	**D3.1: Ethics Approval**
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Official reviewer(s)	**Taiana Deodato (Clepio Biotech)** **Ludovico Silvestri (Clepio Biotech)**

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Executive summary

The documents that are part of the delivery *D3.1- Ethics Approval* consist of the research protocol for the 3DPATH study and the formal approval issued by the Cantonal Ethics Committee of Bern (Project-ID 2025-01652). The Ethics Committee has granted full authorization for the further use of biological material and health-related personal data under the Swiss Human Research Act and Human Research Ordinance.

The approval confirms that the project meets all regulatory and ethical requirements, including compliance with data protection standards, coding procedures, reporting obligations, and submission requirements via BASEC. The authorization is valid for the announced duration of the study, for a maximum of five years, and was granted without conditions or fees.

Together, the documents demonstrate that the study is legally authorized, ethically compliant, and permitted to proceed under Swiss federal research regulations.

1. Documents overview

Both documents attached to this deliverable relate to the same research project "3DPath: A new dimension to the analysis of tissue blocks for pathology." They serve different but complementary purposes:

- The Research Protocol describes the scientific rationale, objectives, study design, methodology, data handling procedures, and governance structure of the project.

- The Ethics Committee Decision is the formal regulatory authorization issued by the Cantonal Ethics Committee of Bern, confirming that the project complies with Swiss human research legislation.

Together, the documents define both the scientific framework and the legal approval status of the project.

2. Content of the research protocol

The Research Protocol named "***3DPath_R3_clean***" is a structured scientific document prepared in accordance with the Swiss Human Research Act (HRA) requirements for the further use of biological material and health-related personal data.

It includes the following main sections:

2.1. Administrative and Regulatory Information

- Project title
- Project leader and institutional affiliation
- Confirmation of sponsor responsibility
- Reference to the legal basis under HRA/HRO

2.2. Scientific Background and Rationale

- Context of conventional 2D histopathology
- Introduction of 3D imaging techniques (light-sheet fluorescence microscopy)
- Explanation of the scientific motivation for comparing 2D and 3D analysis

2.3. Hypothesis, Aims, and Endpoints

- Clear research hypothesis
- Three defined study aims
- Defined primary endpoint (comparison of biomarker status between 2D and 3D)

2.4. Study Design and Methodology

- Description of sample retrieval from archived tissue blocks
- Laboratory procedures for staining and imaging
- Description of computational analysis
- Statistical approach
- Sample size calculation

2.5. Data Source and Participant Criteria

- Origin of biological material (institutional archives)
- Inclusion and exclusion criteria
- Consent framework via Tissue Bank

2.6. Data Protection and Confidentiality

- Coding procedures
- Storage arrangements
- Access control
- Data retention policy
- International collaboration and data handling

2.7. Ethical, Risk, and Regulatory Considerations

- Risk-benefit assessment
- Statement of compliance with HRA/HRO
- Requirement of ethics approval prior to implementation

2.8. Funding and Transparency

- Funding sources
- Collaboration agreements
- Publication and data-sharing plans
- Overall, the protocol functions as the comprehensive scientific and regulatory description of how the study will be conducted.

3. Content of the Ethics Committee Decision

The Ethics Committee Decision "***b2025-01652_Zlobecl_Entscheid_Bew"***, is the official regulatory ruling issued by the Cantonal Ethics Committee of Bern. It contains the following key components:

3.1. Identification of the Project

- Project ID number
- Project title
- Project leader and sponsor
- Responsible institution

3.2. Decision Outcome

- Formal statement that authorization is granted.
- Duration of validity (maximum five years)
- Classification of the research category

3.3. Regulatory Classification

- Classification under the Human Research Ordinance
- Designation as further use of biological material and health-related personal data
- Confirmation of compliance with ICH-GCP principles
- Indication of decision procedure (presidential procedure)

3.4. Administrative Information

- Fee information (CHF 0)
- Instructions regarding potential appeal
- Contact and signatories of the Ethics Committee

3.5. Annexes and Obligations

The decision includes annexes outlining:

- Sponsor obligations (e.g., submission of amendments via BASEC)
- Reporting duties (completion, early termination, changes)
- Requirements for document formatting and version control
- Conditions for clinical trial registration (if applicable)
- Explanation of possible categories of decisions
- List of documents reviewed by the Committee

This document establishes the legal authorization and compliance framework for conducting the project.

4. Relationship between the two documents

Both documents function together as:

- The Research Protocol, in English language, which defines what the study is and how it will be conducted.
- The Ethics Decision, in German language, which confirms that the described study has been reviewed and formally authorized under Swiss law.

The Ethics Committee decision explicitly references and approves the submitted protocol and associated documentation.
Together, they demonstrate that:

- The project is scientifically structured.
- The project falls under the legal category of further use of biological material.
- The project meets ethical and data protection requirements.
- The study is authorized to proceed within the approved timeframe.

5. Overall conclusion

The Research Protocol provides the detailed scientific and operational framework for the 3DPath project, while the Ethics Committee Decision provides the formal regulatory approval required to conduct the study.

In combination, the documents establish:

- The identity and responsibility of the sponsor and project leader,
- The legal basis under Swiss Human Research legislation,
- The approved scope of research activities,
- The duration and validity of authorization,
- The applicable compliance and reporting obligations.

These two documents together constitute the full scientific description and official ethical authorization of the 3DPath research project.

Research plan/Protocol for HRO:
Further use of biological material and health-related personal data for research pursuant to Articles 32 and 33 HRA

Title of the research project
3DPath: a new dimension to the analysis of tissue blocks for pathology

Name and address of the project leader
Inti Zlobec
Professor of Digital Pathology
Institute of Tissue Medicine and Pathology
Murtenstrasse 31
CH-3008, Switzerland
Inti.zlobec@unibe.ch
Tel: 078 625 39 35

If applicable: Name and address of the sponsor
- N/A

Confirmation of the project leader and the sponsor
With my signature, I attest that all information in this protocol is correct and that I will comply with the information I have given and with national legislation, namely data protection law.

Project leader: Inti Zlobec

25.10.2025	
Place, date	Signature

If applicable and not identical with the project leader: Sponsor:

Place, date	Signature

Abbreviations

List the abbreviations used in the document, e.g.:

EC	Ethics Committee
HRA	Human Research Act
HRO	Human Research Ordinance
ITMP	Institute of Tissue Medicine and Pathology
LSFM	Light Sheet Fluorescence Microscopy
TBB	Tumor Bank Bern

1. Background

Histopathology is a century-old standard for the diagnosis of cancer and other diseases, and for the choice of personalized treatments. Despite its paramount importance for clinical practice, this method is still limited to the analysis of thin slices, presenting a 2D view of the intrinsically 3D structure of biological tissue. Current histopathology practice poses the risk of severely undersampling relevant tissue features: indeed, a growing amount of data demonstrates that traditional 2D analysis produces inconsistent and unreliable results that may have important implications in treatment choice and other clinical decisions. Despite the compelling evidence of the clinical benefits of volumetric tissue analysis, clinical practice is still anchored to 2D imaging. A transition towards 3D inspection would be a quantum leap in the histopathology field but has been prevented hitherto because of technical limitations. Indeed, light-sheet fluorescence microscopy (LSFM) has been hailed in the last decades as a game changer in the field [1]. However, LSFM-based solutions have profound limitations in terms of throughput, reliability and scalability that prevent their use outside specialised research labs. In 3DPATH, we want to establish LSFM at the University of Bern and determine whether there are use cases depicting the added value of 3D over conventional 2D analysis in the diagnostic, prognostic and therapy response prediction setting. To do this, we will take three major cancer types, each with their own specific interesting clinical issues: lung cancers and the expression of PD-L1, which is used for patients as a marker for immune checkpoint inhibitors[2,3], breast cancers and the expression of HER2, which is used for patients as a marker for targeted therapy[4,5], and colorectal cancers and tumor budding[6,7], which is considered a high-risk factor and often important for adjuvant therapy decisions. In this study, we do not investigate the clinical implications of the changes of the status of 2D expression of PD-L1, HER2 and tumor budding, but only determine whether and to what degree a change in this status occurs.

2. Hypothesis

We test the hypothesis that some cases originally determined to be “negative” for PD-L1 and HER2 in lung and breast cancer when evaluated on regular glass slides in 2D will be evaluated as “positive” after 3D imaging. Similarly for colorectal cancers, we hypothesize that those originally found to be high-grade for tumor budding on 2D tissue slides will become low-grade after evaluation by 3D imaging. Although not explored further in this particular study, if such changes in status could be identified, we believe that this information could have critical impact for future studies in personalized medicine, namely by identifying patients who may be considered for different treatment strategies.

3. Aims

To investigate this hypothesis, we set out 3 aims:
Aim 1: to establish a 3D tissue block staining and imaging protocol at the ITMP. This is done together with our collaborators who are already experts in this technique, with whom we have an EIC Innovation Grant[8].
Aim 2: to determine whether the expression status of PD-L1 and HER2 in lung and breast cancer, respectively as observed in standard 2D immunohistochemistry changes when imaged in 3D
Aim 3: to determine whether the status of tumor budding (high-grade to moderate/low grade) changes as observed in standard 2D to 3D imaging

4. Endpoints

This study has now been revised to include only histopathological information. The endpoint of interest is the change in expression status (positive to negative or negative to positive, or no change) from 2D to 3D imaging for PD-L1 expression, HER2 expression and tumor budding grading (high-grade to moderate/low grade, or vice versa, or no change).

Aim 1: to set up a protocol for immunolabeling using light-sheet microscopy

A) **Establishment of staining protocols**.

We select the following antibodies for immunolabelling of tissues in 3D: PD-L1, HER2, pan-CK, vimentin, CD3 and podoplanin. These markers target our cells of interest and provide some morphological information to better discern the cancer environment.

We begin with validated antibodies regularly used for diagnostic routine and abide closely to our Quality Management System at the ITMP for antibody establishment (e.g. positive and negative controls, etc.). For testing, we require tonsils or lymph node material as well as normal and matching cancer material from lung, breast and colorectal cancers. This material will be acquired from the Tissue Biobank Bern and will cover both frozen and formalin-fixed material. Detailed clearing and staining protocols are reported in our collaborator's [8,9].

Regarding number of samples: this protocol establishment is an iterative process. Based on our collaborators' experience, approximately 10 samples are required per staining panel to reach the expected specificity and staining quality. We estimate the need for 3 panels. We also plan to perform this on both normal tissues and cancer tissues. Accordingly, we expect a maximum of 60 samples. This has already been discussed together with the Tissue Biobank Bern. In a similar study on lymph nodes, only 3 samples were used [10].

B) Image capture

These immunolabelled tissue images will be obtained using two different light-sheet fluorescence microscopy instruments (i.e. from ClepioBioTech and Miltenyi Blaze) and visualized using 3D imaging software (FIJI, 3D Slicer). Several post-processing steps need to be made and the final raw images will be fused into one TIFF volume using FIJI's BigStitcher package. Details can be found in Bishope et al [11]. Additionally, visualized staining patterns using 2D slices of the 3D volumetric image (as per Koyuncu et al [12]) will be evaluated. As a final control, we will perform sequential sectioning of the tissue blocks and evaluate the tissues in 2D. If the 2D slices post-3D staining and imaging match the expected localisation of the antibody, then we consider this to be validated. **The deliverable at Aim 1 here is a validated staining and imaging protocol for panels applied to the three tumor types**

Aim 2: to determine the change in the status of immunohistochemistry expression of PD-L1 and HER2 and tumor budding status from 2D to 3D

Once we have these protocols established, we begin with the actual experiments using a second set of tissue samples (non-overlapping with above). Here, we follow the proposal of Glaser and colleagues [13]and in the graphical explanation below [14]. We identify from our Institute the correct number of patients (see below) with positive and negative samples of PD-L1 and HER2 as well as tissue samples of patients with high-grade and moderate /low-grade tumor budding. We retrieve the tissue blocks from the archives of the ITMP department, perform a new section and staining for PD-L1, HER2 and CK, respectively and evaluate to confirm the original diagnosis of these 3 features. Next, the tissue blocks undergo light-sheet fluorescence imaging using the panels for lung, breast and colorectal cancer validated above. Image acquisitions take place.

The deliverable here is a matched dataset of 2D and 3D images.

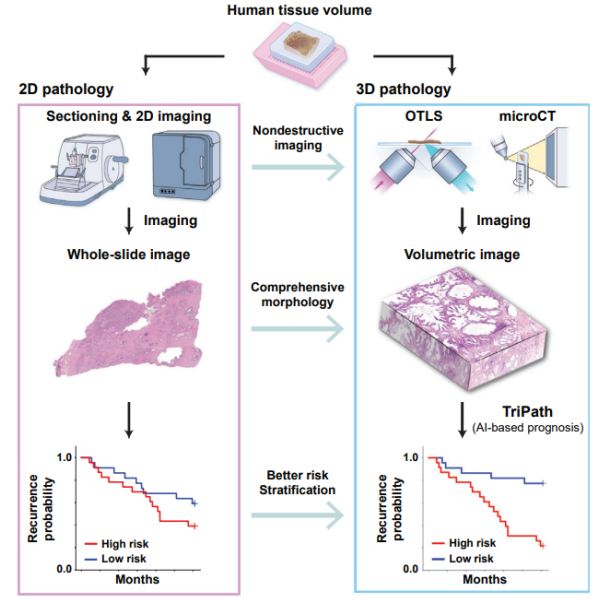

Figure 1: graphical abstract from Song et al[14], showing the comparison of 2D and 3D workflows. We ourselves in this study do not proceed to the prognostic retrospective survival analysis.

Aim 3: to develop computational pipelines to analyse 3D tumour volumes in pathology

We will follow our previously successful strategy outlined in Figure 2 for tumor budding (manuscript in preparation). This will be based on the pan-cytokeratin segmentation of all cancer areas and applies to all cancer types followed by object extraction. By setting thresholds for the size of individual tumor cell clusters we can start to quantify the size of objects which are CK stained- this allows us to capture the truly detached tumor cells and to quantify these. We will use 3D Slicer for this work. Since the staining of our antibodies is specific, we will know by using the additional CK and VIM channel along with PD-L1, whether positivity of PD-L1 occurs in the tumor or stromal compartments. For the purposes of this study, >1% positive staining of PD-L1 in the tumor cells will be considered positive. In a second step, the number of cells will be quantified. Similarly, for HER2, any staining of HER2 will be considered positive. As our project is now much simplified, we no longer need to have any end-to-end deep learning algorithms for clinical endpoint prediction, although some excellent ones exist, for instance TriPath [14].

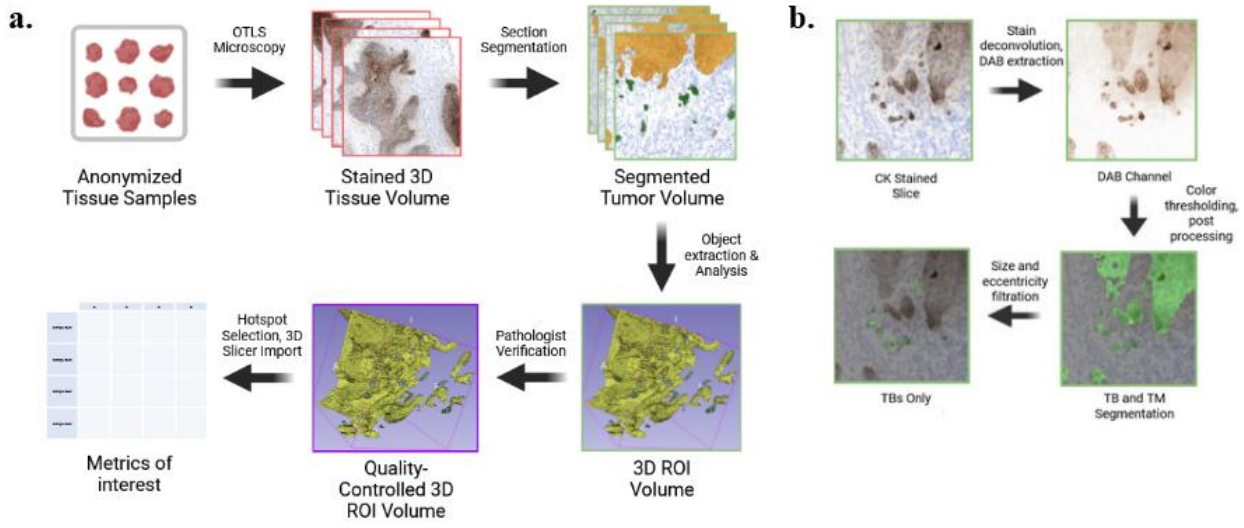

Figure 2 (taken from our manuscript under preparation) Flowcharts for the analysis of tumor buds within the regions of interest. **(a)** A flowchart illustrating the total procedure to produce the quality controlled 3D volumes and the metrics of interest. **(b)** The section segmentation protocol, used to segment cytokeratin positive objects from the pan-CK stained volumes

Finally, we will statistically compare the status of the PD-L1, HER2 and tumor budding from the 2D evaluation to the status of these in 3D. Using McNemar's test, and Type I error of 0.05, Type II error of 0.8, we will determine whether there is a statistically significant change in the status of the markers.

2.3. Independent variables

We are no longer performing any survival analysis. We are only interested in whether the status of immunohistochemistry expression or tumor budding changes from the 2D to the 3D evaluation.

4. Origin of the data/biological material

All tissue blocks will be retrieved from the ITMP's archives. No patient-related or clinical-related information is any longer necessity. We will identify the patient materials through our Biobank.

5. Inclusion criteria

Only patients with colorectal cancer, lung cancer and breast cancer admitted to the Inselspital after 2014 and having signed the general consent for further use of biological material will be considered for the study. We will select consecutively diagnosed patients from the year 2024.

6. Exclusion criteria

Patients who have not signed the general consent form.

7. Informed consent and information of participants

Consent status information is arranged by the Tissue Bank Bern, following their guidelines. Working with TBB ensured proper patient coding and compliance to the HFG.

8. Sample size and accuracy calculation

We use McNemar's test of paired proportions, a Type I error of 0.05 and a Type II error of 0.8. For lung cancer patients, where we expect 30-50% are negative for PD-L1[15], we expect that no positive samples in 2D will become negative in 3D, but we expect up to 20% of samples to go from negative expression in 2D to a positive expression in 3D. The appropriate number of patients is 37. For breast cancers, where the total number of samples negative for HER2 is 80%[5], we estimate that up to 30% of tissues might transform from negative positive before and after 3D imaging. This requires 24 samples. For tumor budding in colorectal cancers, approximately 40% of cases show high-grade budding. We know from our pilot project that 85% of buds in 2D are in fact negative for budding in 3D[16]. Using this as a basis, and expecting that the proportion of change from negative to positive high-grade budding is also possible, but low (10%), we need 11 samples to achieve this goal. These numbers are also similar to another study on lymph node metastasis detection comparing 2D to 3D which shows that differences are detected with 10 cases [17]. Unfortunately, given that our project is novel, not much literature exists to provide additional hints.

9. Reporting obligations

The ethics committee is notified of any change of project leader in advance.
The project leader notifies the ethics committee of the completion or early termination of the research project within 90 days.

10. Data protection
Any acquisition of tissue-related data is made directly through the Tissue Bank Bern, who interact daily with the IDSC and Cancer Registry for the purposes of, among others, preparing research datasets with patient-related data. This process does not involve members of the research group. This also ensures proper patient coding, and only the codes (i.e. study ID or sample ID) are known to the researchers, in order to be able to match the 2D and 3D samples.

Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, personal data is only identified by a unique participant number. Coding is done using a method based on the current state of the art (Art. 26 HRO). The key is stored separately from the personal data by a person or organisational unit that is designated in the application to the ethics committee, and which is not involved in the research project. Data may not be made freely available to the public unless it is aggregated data.

Biological material in this project is not identified by participant name but by a unique participant number. Coding is done using a method based on the current state of the art (Art. 26 HRO). The key is stored separately from the biological material by a person or organisational unit that is designated in the application to the ethics committee, and which is not involved in the research project.

Tissue blocks will also be shipped to our partners in Florence at Clepio Biotech S.r.1, Via Madonna del Piano,6 50019 Sesto Fiorentino, Italy.

There are a team of people working on this project, including 2 PhD students, 1 post doc (50%) and 2 Master students. By the time the students will, however, receive the data, it will have already been coded. They do not access to any uncoded data at any time during this project.

11. Information on the storage of data and samples / completion of the research project
The coded sample images will be uploaded to the research storage of the University, for processing on the High Performance Cluster Ubelix. No patient-related data will be uploaded to the Ubelix.

12. Retention period
All data will be kept for minimally 10 years, after the date of publication.

13. Ethical and regulatory requirements
Risk-benefit assessment:
It is very unlikely / negligeable that a discovery will be made during the course of this project that might impact a patient. First, the study is retrospective and clinical decisions have already been taken. We are not evaluating any genetic backgrounds, only morphology and biomarker expression. The benefit could be large it the future: it allows us to potentially identify situations where diagnostic criteria (histopathological feature identification or biomarker expression) changes in 3D space, leading perhaps to changes in outcome in patients ,which we can show in our cohorts. Prognostic evaluations are not part of this study.

This project complies with the regulatory requirements of the HRA and the HRO. The prerequisite for carrying out the research project is the approval of the competent ethics committee.

14. Results / transparency / publication
This is a new field of research- knowledge will be shared, code will be published on Github and where possible, images (no identifiers) will be published on open platforms such as Zenodo.

Publications are planned. However, data with regards to the histopathology and outcome of patients will only be shared open request, after publication. There is already a collaboration agreement in place for the EIC project, all the questions regarding IP and publications have been discussed and signed off with the grants office and Unitectra.

15. Funding / Data sharing / Declaration of interest

This project is primarily funded through the EIC Horizon 2024-Transition-01 call (Proposal number: 101213930) and funded in Switzerland through the SERI to the PI here (Inti Zlobec). Some additional funding has been obtained from the Uni Bern Foundation for maintenance and method establishment of a second light-sheet device (UM Blaze). The generation of 3D images using light-sheet microscopy will be partially performed in Florence and partially in Bern. Analysis of the images will be performed in Bern. The attached collaboration agreement details the rights and responsibilities regarding data sovereignty.

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Kanton Bern
Canton de Berne

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Universität Bern
Murtenstrasse 31
3008 Bern

Bern, 18. November 2025, CA

Bewilligung der KEK Bern

Project-ID	2025-01652
Projekttitel	3DPath: a new dimension to the analysis of tissue blocks for pathology
Projektleitung	Prof. Dr. phil. nat. Inti Zlobec
Sponsor	Prof. Dr. phil. nat. Inti Zlobec
Zentren	• Prof. Dr. phil. nat. Inti Zlobec, Institut für Gewebemedizin und Pathologie, Universität Bern

Entscheid

☒ Die Bewilligung wird erteilt
Diese Bewilligung gilt für die angekündigte Dauer der Studie, höchstens jedoch für 5 Jahre ab Datum dieser Verfügung.

Klassifizierung

☒ Forschungsprojekt gemäss HFV

- ☐ Forschung mit Personen
- ☒ Weiterverwendung des biologischen Materials oder der gesundheitsbezogenen Personendaten
- ☐ mit Verstorbenen
- ☐ mit Embryonen / Föten
- ☐ mit ionisierender Strahlung

Entscheidverfahren

☐ ordentliches Verfahren ☐ vereinfachtes Verfahren ☒ Präsidialverfahren

Die Ethikkommission bestätigt, dass sie nach ICH-GCP arbeitet.

Gebühren

Betrag: CHF 0.– **Tarifcode:**

Gemäss der geltenden Gebührenordnung von swissethics. Rechnungsstellung folgt durch die Kantonale Gesundheits-, Sozial- und Integrationsdirektion (GSI).

Rechtsmittelbelehrung

Gegen diese Verfügung kann innert 30 Tagen seit Eröffnung bei der Gesundheits-, Sozial-und Integrationsdirektion des Kantons Bern Beschwerde erhoben werden. Die Beschwerdefrist kann nicht verlängert werden. Die Beschwerdeschrift ist im Doppel bei der Gesundheits-, Sozial-und Integrationsdirektion, Rathausplatz 1, Postfach, 3000 Bern 8 einzureichen.

Eine allfällige Beschwerde, die in mindestens zwei Exemplaren einzureichen ist, muss einen Antrag, die Angabe von Tatsachen und Beweismitteln, eine Begründung sowie eine Unterschrift enthalten; der angefochtene Entscheid und andere greifbare Beweismittel sind beizulegen.

Sie muss

(a) angeben, welche Entscheidung anstelle der angefochtenen Verfügung beantragt wird und
(b) aus welchen Gründen diese andere Entscheidung verlangt wird sowie
(c) die Unterschrift der beschwerdeführenden Partei oder der sie vertretenden Person enthalten.

Der Beschwerdeschrift beizulegen sind die Beweismittel, soweit sie greifbar sind, und die angefochtene Verfügung. (Art. 32 und 60 ff. des Gesetzes vom 23. Mai 1989 über die Verwaltungsrechtspflege [VRPG; BSG 155.21]).

Kopie an

☐ BAG

☐ DLF

☐ Andere

Prof. em. Dr. med. Martin Fey
Präsident KEK Bern

Dr. Mario Amacker, PhD
Leiter wissenschaftliches Sekretariat

Anhang: -Pflichten des Sponsors/der Prüfperson oder der Projektleitung
-Mögliche Entscheide und ihre Bedeutung
-Eingereichte Dokumente

Anhang

Pflichten des Sponsors/der Projektleitung

Einreichung Dokumente: revidierte Dokumente und neue Dokumente zur Studie/zum Projekt sollen ausschliesslich über das Web-Portal BASEC eingereicht werden, auf der entsprechenden Formularseite des betreffenden Gesuches. Obsolete Dokumente sind dabei zu entfernen und Datums- und Versionsangaben entsprechend zu ergänzen. Die erfolgten Änderungen müssen im Korrekturmodus abgefasst werden und zusätzlich als ‚clean'-Version eingereicht werden. Die Studieninformationen und -einwilligungen, das Protokoll und die Amendments müssen in durchsuchbaren PDF-Dateien eingereicht werden, insbesondere müssen gescannte Dokumente eine Texterkennung durchlaufen haben (OCR). Das unterschriebene und datierte Begleitschreiben muss die Antworten auf eventuell von der EK gestellte Fragen enthalten. Revidierte Dokumente sind auch den weiteren Zulassungsbehörden zuzustellen, sofern diese involviert sind.

Anmerkung: Die zuständige Ethikkommission überprüft im Rahmen des Bewilligungsverfahrens Aufklärungsbogen und Einwilligungserklärung in einer der Amtssprachen Deutsch, Französisch oder Italienisch. Aufklärungsbogen und Einwilligungserklärung in einer anderen Sprache werden von der Ethikkommission lediglich zur Kenntnis genommen. Für die korrekte Übersetzung ist der Sponsor oder die Projektleitung verantwortlich.

Meldepflichten: Die rechtlich bindenden Melde- resp. Bewilligungspflichten an die Ethikkommission für wesentliche Änderungen, einen vorzeitigen Studienabbruch, unerwünschte Ereignisse u.a. sind einzuhalten (Verordnungen des Bundes). Der Abschlussbericht ist spätesten ein Jahr nach Studienende der Ethikkommission einzureichen.

Für klinische Versuche der Kat. B und C muss das Gesuch innerhalb von zwei Jahren nach Erteilung der Bewilligung durch die erste Bewilligungsbehörde bei der zweiten Bewilligungsbehörde (bei Swissmedic bzw. bei der Ethikkommission) eingereicht werden (Art. 23 Abs. 1bis KlinV).

Registrierungspflicht: Der Sponsor muss – falls es sich um einen klinischen Versuch handelt – diesen in einem WHO-Primärregister oder im Register der Nationalen Medizinbibliothek der USA (clinicaltrials.gov) erfassen und anschliessend diese Nummer im BASEC-Portal eingeben. Die Übertragung der erforderlichen Daten in das Portal des Bundesamts für Gesundheit (HumRes) wird nach Bewilligung der Ethikkommission automatisch erfolgen. Die Informationen über den klinischen Versuch sind in beiden Registern öffentlich zugänglich. Zusätzlich veröffentlicht swissethics wenige Informationen wie Titel, Projekttyp oder Leit-Ethikkommission aller durch die kantonalen Ethikkommissionen bewilligten Gesuche auf swissethics.ch.

Mögliche Entscheide und ihre Bedeutung

Die Bewilligung wird erteilt: Das Vorhaben kann gemäss bewilligtem Forschungsplan und im Rahmen der anwendbaren rechtlichen Bestimmungen durchgeführt werden. Weitere Bewilligungspflichten (Swissmedic/BAG) sind zu beachten

Die Bewilligung wird mit Auflagen erteilt: Das Vorhaben kann gemäss bewilligtem Forschungsplan gestartet werden und im Rahmen der anwendbaren rechtlichen Bestimmungen durchgeführt werden. Die Auflagen sind zu erfüllen und die Gesuchsunterlagen innert 30 Tagen entsprechend anzupassen. Weitere Bewilligungspflichten (Swissmedic/BAG) sind zu beachten

Die Bewilligung kann noch nicht erteilt werden: Das Vorhaben kann noch nicht gestartet werden. Die nachfolgenden Bedingungen sind zu erfüllen bzw. die Fragen zu beantworten und die revidierten Dokumente erneut bei der Ethikkommission einzureichen. Die Ethikkommission überprüft die revidierten Dokumente und erteilt die Bewilligung, wenn die Bedingungen erfüllt bzw. die Fragen zufriedenstellend beantwortet sind.

Die Bewilligung wird nicht erteilt: Das Vorhaben kann in der vorliegenden Form nicht durchgeführt werden. Eine Neueinreichung ist möglich.

Auf das Gesuch wird nicht eingetreten: Begründung siehe vorne, z.B. nicht zuständig oder nicht bewilligungspflichtig.

Eingereichte Dokumente für das Hauptzentrum

Prof. Dr. phil. nat. Inti Zlobec, Institut für Gewebemedizin und Pathologie, Universität Bern

Dokument	Dok.Datum	Version
1. Cover Letter		
ethics-reply-zlobec-10-11-2025.pdf	10/11/2025	
3. Participant information sheet and informed consent (ICF)		
einwilligungserklarung-mit-lbb-v3-en-2.pdf	01/08/2020	3
4. Study plan (protocol), signed and dated		
3dpath-r3-clean.pdf	10/11/2025	4
3dpath-r3-highlighted.pdf	10/11/2025	4
6. Investigator's CV, dated		
cv-zlobec-2-pages.docx	21/07/2025	
9. Agreement between sponsor/commissioned institution / grant provider or other third parties and the investigator		
3dpath-consortium-agreement-final-ubern-signed.pdf	16/06/2025	
14. Information on secure handling of biological material and personal data, and in particular on the storage thereof		
see doc/cat: **4**, page/ref: **5-6**		
30. Proof of secure and correct coding		
see doc/cat: **4**, page/ref: **7**		