**Grün – Bitte ergänzen**

**Prüfplan/Protokoll HFV:  
Weiterverwendung biologischen Materials und/oder gesundheitsbezogener Personendaten für die Forschung bei fehlender Einwilligung und Information nach Artikel 34 HFG**

**Titel des Forschungsprojekts**

**Name and Adress of the Projectleader**

Anrede Name Vorname, Position z.B. Oberarzt, Institution

Adresse, Telefonnummer, E-Mail

**Falls zutreffend: Name and Adress of the Sponsors**

Anrede Name Vorname, Position z.B. Oberarzt, Institution

Adresse, Telefonnummer, E-Mail

**Confirmation of Projectleader and Sponsor**

With my signature i do confirm, that all information in this protocol are correct and that we will conduct the study according to the protocol, the local requirements, namely data protection.

Projectleader:

|  |  |  |
| --- | --- | --- |
| Place, Date |  | Signature |

Falls zutreffend und nicht mit der Projektleitung identisch: Sponsor:

|  |  |  |
| --- | --- | --- |
| Place, Date |  | Signature |

**Abbreviation**

HRA Human Resarch Act

HRO Human Research Ordinance

**1. Background and Rational:**

**2. Objectives:**

**3. Design**

Wie wird konkret vorgegangen? Welche Auswertungsmethoden/Techniken werden angewendet?

z.B. Further use of already collected Data.

Was soll untersucht werden? z.B. „Biomarker bei Leberkarzinomen“.

**4. Origin of Data/Material**

We would like to analyse survival data of patients diagnosed with a SAB, which have been treated at the Inselspital Bern between x-y.

Some of the patients have died, moved or are not able to give consent because of the severity of the disease. For this patients it is not possible to collect a consent.

**5. Inclusion Criteria**

**6. Exclusion Criteria**

**7. Scientific methods and sample size**

Describe the intended statistical methods for assessing the primary endpoint and, if applicable, the secondary endpoints. If possible, formulate a hypothesis. The statistical evaluation should confirm or reject the hypothesis. Please use established statistical methods whenever possible. It must be stated what is to be analysed or measured using which method.

State the sample size and justify the amount of data sets and biological samples to be analysed with respect to the primary endpoint and, if applicable, secondary endpoints. For all projects, the sample size of data and material to be analysed must be justified. If different statistical methods (e.g. descriptive statistics or artificial intelligence/algorithms) are used instead of statistical tests to confirm or reject a hypothesis, these should be described and justified.

In the case of multiple endpoints, statistical adjustments for multiple testing should be considered.

**8. For which health-related personal data/biological material should the authorization be granted?**

Personal and medical Data and all radiological Data (CT, MRI, etc.) of approximately xxx Patients diagnosed with SAB treated between x-y.

**9. Application for an exemption according to Art. 34 HRA.**

We would like to analyse datasets of 200 patients diagnosed with SAB within the last 10 years.

Wir wollen 200 Datensätzen von Patienten mit SAB der letzten 10 Jahre untersuchen. From all Patients treated after january 2014 a general consent was collected or patients were informed about data collection. Most of the data was collected before 2014. For some of the patient collective it may not be possible to collect a consent since they moved or died. Due to the high number of patients it would be a big effort to collect to consent of those patients.

When the expacted knowlege gain is going to be useful for future patients or important findings in the area of research are expected, which can only be gained this way. Then this is a good reason in which the interests of the patients can be less weighted.

**10. Confirmation that there is no documented refusal:**

The projectleader confirms, that no health related data and no biological material will be used, if a written or documented oral refusal is existend.

**11. Which group of persons is authorized to release the biological material and the health-related personal data?**

Each person on the staff list has access to all uncoded data of the study.

**11. Who is responsible for the acceptance of the data/material?**

Projectleader.

**12. Who takes responsibility for the reception of this data/biological material?**

Each person on the staff list has access to all uncoded health related data and/ or biological material of the study.

**13. Which group of persons should be authorized to access the health-related personal data within the scope of this research project?**

Projectleader

**14. Who is responsible for the protection of the data that have been released?**

Projectleader

**15. Reporting obligations**

A change of the projectleader has to be reported antecedent to the responsible ethic committee. The completion or abruption of the study project has to be reported to the ethic committee within 90 days.

**16. Data protection  
Uncoded data, coding and storage of the key**

Our study coordinator, Nicole Söll, will document all data from the hospital documentation system and will transfer the data in a database with a neutral number. She will also conduct a coding list with which the data can be connected to the patient. The coding list will be sent afterwards tot he project leader (XXX). All coded data will be analysed as stated in this protocol and under compliance with data protection.

**17. Information on the storage of data and samples**

We will transfer all data from the medical records into Redcap. This way all changes can be recorded and be traced. Access is only possible with a personal username and password.

All identifying data (name, address, date of birth and patient identification number, etc.) will be stored separated from study data.

Data will be stored at the university of neurosurgery for 10 years after data analysis.

**18. Ethical and regulatory requirements**

This is a retrospectively study. For patients there will be no risk, liability or discomfort. Patients of this study will not have a benefit from this data analysis.

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.

**19. Results / transparency / publication**

Are the results scientifically valid and justifiable (e.g. is there a correlation or even a causality)? Can the results be generalised?

If applicable: Are the results being shared? Which other stakeholders are involved? Is an administrative fee paid for this?

Where and how are the results disseminated? (e.g. as coded or anonymised data?).

**20. Funding / Data sharing / Declaration of interest**

Describe the funding sources, the publication policy of the project, the data sharing practices and possible conflicts of interest. If applicable, refer to contracts or documents in which this information is recorded. For multicentre projects, if there is no contract or written agreement between the institutions, the details of the collaboration can be provided here.

**21. Literature**