

## **Study:**

# **“International Alpine Trauma Registry”**

- Participant information sheet

- Informed consent

### **Project coordinator**

Dr. Hermann Brugger

Head of EURAC Institute of Mountain Emergency Medicine

Viale Druso 1

39100 Bolzano

Tel: +39 0471 055 541

Fax: +39 0471 055 549

e-mail: [hermann.brugger@eurac.edu](mailto:hermann.brugger@eurac.edu)

### **Director of data acquisition**

Prim. Dr. Peter Zanon

Head of Department

General Hospital of Bolzano

Via Lorenz Böhler 5

39100 Bolzano

Tel: +39 0471 908 111

e-mail: [peter.zanon@asbz.it](mailto:peter.zanon@asbz.it)

## Information for study participants

### 1. INTRODUCTION

#### **What is the International Alpine Trauma Registry?**

Providing medical care to severely traumatized patients in alpine environments or in remote areas poses a unique challenge due to extreme environmental conditions, demanding terrain and long rescue and transport times.

The primary aim of the **International Alpine Trauma Registry** research project is to enable an international comparison between the different strategies applied during the rescue of traumatized patients. The collected data will help to create a unitary, global database.

By collecting observations of different rescue strategies and other clinical and analysis criteria, we are trying to define and improve care of traumatized patients during rescue operations in mountainous and remote areas.

#### **Where will the study be held and who should participate?**

The data collection will be a multicentre collaboration between emergency medicine departments and intensive care and reanimation units of the hospitals in South Tyrol, the Emergency Service 118/115 of the Province and the archives of the National Corpus of the Mountain Emergency Medical Services. The data will be inserted by a Local Data Manager (LDM) into a central database that is hosted by the Institute of Mountain Emergency Medicine at the European Academy Bolzano (EURAC). This study will involve several doctors from different hospitals. A successful implementation of this project and achievement of the outlined research aims can only be guaranteed by the participation of individuals who meet the scientific requirements corresponding to the needs of the study. You are one of the selected individuals and therefore we kindly invite you to carefully read the following information and confirm your participation by completing and signing the informed consent.

#### **Who are the Local Data Managers?**

The LDM are part of either the medical service staff of the Province or the emergency medicine departments and intensive care and reanimation units of the hospitals in South Tyrol. The LDM were

selected at the beginning of the study and are bound to an agreement of professional confidentiality.

## 2. PROGRAMME OF THE STUDY

The programme of this study includes the following points:

- Finding potential participants;
- The LDM will inform the participants personally about the risks, aims and proceedings of the study through written and oral communication; if consent is given by the participant, he/she must formally sign the informed consent at the end of this document;
- Explanation of the strategies applied for the emergency rescue in accordance to the Case Report Form (CRF); and explanation regarding the insertion of alphanumerical codified data (ID) in the central database of the EURAC.

**How will personal data be handled and what are the expected outcomes of the study?**

Personal data will be codified and inserted into the central database hosted by EURAC. All data will be statistically analysed and results will focus on defining and improving standards of care of traumatized patients during a rescue operation in mountainous and remote areas.

**Will you receive the results of the study?**

The study is directed towards enhancing the medical knowledge in the field of prehospital emergency care of traumatized patients. The results could lead to important insights and progress for this area of healthcare sector. Upon request we will inform you of significant results at the end of the planned research phase.

**Are there risks for the participants?**

During this study the data will be collected post-treatment, and thus the study does not predispose you or any other participant to any risks, nor will participation in the study have any consequences for prehospital or in-hospital treatment.

**Voluntary informed consent**

The participation in the study is voluntary. After having read and understood the aims and contents of this project, participants should sign the informed consent to confirm their participation in the study. Consent may be totally or partially revoked at any time by written or oral communication without the need for further explanation. A revoke of participation should be addressed to the director of data acquisition. A revoke of participation will not result in any kind of disadvantage for the participant; medical care will be effected autonomous from the project and therefore cannot be influenced.

### 3. STORAGE OF PERSONAL DATA AND PROCEEDING OF STUDY

All material containing information on the identity of participants will be stored either in the archives of the hospitals, the Mountain Rescue Service or the Emergency Service of the Province 118/115.

Data in the EURAC central database are codified in such a way that decoding participant data and retrieving personal identity is not possible. Access to the web application is possible only with a password and the connection is protected over a secured system.

During the introduction phase of the study, the registry will be assessed for initial feasibility and applicability and difficulties in data acquisition will be examined. Data acquisition will proceed until 2015.

### 4. FINANCING

This project will be financed by the Institute of Mountain Emergency Medicine at the EURAC. EURAC is a private, innovative research institute that is only partially financed by public funds. Projects conducted within the Institute of Mountain Emergency Medicine are done in collaboration with different South Tyrolean healthcare institutions, the local Mountain Rescue Services and the Medical University of Innsbruck (Austria) as well as other alpine medical organisations, in particular the medical commission of the International Commission for Mountain Emergency Medicine (ICAR MEDCOM).

Furthermore, each project of the Institute is subject to the consensus of an external scientific advisory board that is composed of four researchers with highly regarded international reputations.

## 5. PROTECTION OF DATA PRIVACY AND POSSIBILITY FOR PROSPECTIVE STUDIES

### How will personal data privacy be guaranteed?

All personal data will be collected and stored in accordance with the Act of Parliament 196/03, which states the terms of protection and appropriation of personal data. All data will be used solely for research purposes.

The medical data will be identified through an alphanumeric code (ID) and is separated from personal data, e.g. name and address. Any associations between personal data and study outcomes will be identifiable only by the study director and the delegated assistant. All collected information is considered strictly confidential and is protected by an agreement of privacy and confidentiality. Data and materials can only be transmitted to the collaborators in a codified version.

If results are published in medical journals or communicated in public conferences, personal data of the participants will be removed completely or only shown in a codified way. Participants have the right to request information on which and how personal information is archived.

All materials containing information on the identity of participants will be stored in the archives of the hospital, the Mountain Rescue Service or the Emergency Service 118/115 of the Province. This enables transparency in the case of doubts or questions.

## 6. STUDY OUTCOME

There are no benefits of participation in the study, financially or otherwise. On the long-term we expect to obtain important medical knowledge that will lead to advantages for the population. Furthermore, this study will contribute to an improvement of care and a definition of standards for mountain emergency rescue operations for seriously traumatized patients.

Any financial income during the study will be utilized exclusively for funding of further projects in the biomedical field.

## 7. RIGHTS OF THE PARTICIPANT

The participant may contact the holder and/or person responsible for the handling of personal data as outlined in Art. 7 of the Code of Privacy:

Art. 7. Right of access to personal data and other rights

1. The participant has the right to obtain proof of the existence of personal data regarding him/her, even if not registered yet, as well as proof of the communication of such data in an intelligible form.
2. The participant has the right to obtain:
  - a) the origin of personal data;
  - b) the finality and the modality of treatment;
  - c) the rationale applied in the case of treatment using electronic instruments;
  - d) identification of the research leader, the personnel and/or the holder-in-charge, according to Art. 5, Par. 2; and
  - e) information regarding the subjects or categories of subjects to whom personal data can be communicated, or information of the representative of the State, of the people in charge or of those responsible.
3. The participant has the right to obtain:
  - a) notification of modification or integration of data;
  - b) the cancellation, codification or blockage of data, in the case of a violation of the law, including those for which a conservation in relation to the aims for which such data have been collected or subsequently treated is not necessary; and
  - c) the certification that operations a) and b) have been made explicit, also regarding content, to those to whom data has been communicated or disseminated, with the exception of the case where such fulfilment is impossible or implies an adoption of means manifestly disproportionate in respect to the defended right.
4. The participant has the right to refuse or to accept, totally or partially.  
The modality of exercise of these rights is regulated by Art. 8, 9 and 10 of the same code.

**8. THE HOLDER AND THE PERSON IN CHARGE OF THE DATA**

The European Academy Bolzano is the official “holder of the handling of personal data” under the auspices of the President and legal representative of the EURAC, Dr. Werner Stuflesser.

For further information during the study it is possible to contact the person responsible for the handling of personal data, the scientific director Dr. Hermann Brugger and his collaborators (contact information is contained on the first page).

The study protocol proposed here has been approved by the Ethical Committee of the Autonomous Province of Bolzano.

## Informed consent

As a participant or legal guardian of a participant, I have been informed about the operational sequence, purpose, aim and risks of the project, as well as about the expectations of participation from one of the study representatives. I have read and comprehend the participant information sheet. For any further questions or doubts I may contact the responsible personnel, who are obligated to respond satisfactorily.

I consent to participate in the project, **International Alpine Trauma Registry**, and upon consent I thereby agree to the following:

- Finding of potential participants;
  - Acknowledgement and signing of the informed consent, which relates to data acquisition;
  - Explanation of the strategies applied for the emergency rescue in accordance to the Case Report Form (CRF) and explanation regarding the insertion of alphanumeric codified data (ID) in the central database of the EURAC.
1. I agree that my personal and medical data will be saved separately and anonymously. This will happen within the scale of this study and in strict accordance with the current data protection law (Datenschutzgesetz, Legislativdekret of June 30<sup>th</sup> 2003, Nr. 196). I agree that my personal data will be used exclusively for research purposes.
  2. I agree that my personal data will be analysed by the Institute of Mountain Emergency Medicine at the European Academy Bolzano. I agree that my data can be transmitted, in an anonymous form, to other similar research institutes.
  3. I agree that my personal data will be stored in the hospital archives and that I might be contacted in case of doubts or questions. Furthermore, I agree that I might be invited to participate in further studies.
  4. I fully understood the information related to the study and am willing to support the study with my participation. I officially permit the collaborators of the study to collect the required data.
  5. I am aware that the participation in this study will not provide any direct or personal advantage for me.
  6. I declare that I agree with the above mentioned points:



yes

no

7. My consent of participation can be totally or partially revoked at any time by written communication, or first oral and then written communication, without the need for further explanation.

Your willingness to participate in this study is a very important contribution to the furthering of the medical sciences. We extend our sincerest appreciation and gratitude for your participation.

Name: \_\_\_\_\_ Date of birth : \_\_\_\_\_  
(Participant)

Signature: \_\_\_\_\_ Signature: \_\_\_\_\_  
(Participant or legal tutors)

Date: \_\_\_\_\_

I declare that I have been provided with a detailed and complete patient information sheet pertaining to this project.

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

(Professional staff)

Date: \_\_\_\_\_