[Logo of the hospital / institution]

The outcome of intoxicated patients in Europe (TOXIC-Europe study)

Dear Sir or Madam,

You are invited to participate to a research study about intoxications. Your participation is voluntary and your permission is required to participate. You are receiving this letter because you have been admitted to the *{name of the unit}* of the *{name of the hospital}* with a (possible) intoxication. Before deciding whether or not to take part in this study, we would ask you to carefully read the following information, which explains what the study involves.

1. General information about the study and use of data
This research is performed by the {*name of the unit*; for example: "intensive care unit"} of the *{name of hospital}*. The study is part of a European study on the outcomes of patients with intoxication who have been admitted in intensive care units in various European countries. We ask as many people as possible to participate in the study.

The aim of this study is to find out how sick people with intoxications have been and how they are doing in the first 30 days after they have been admitted. There is no direct benefit for yourself from participating in this study. However, your participation can contribute to more knowledge about the treatment of intoxications.

Your personal data will be collected, used and stored for this research. This concerns information such as age, gender and information about your health such as the presence of diseases before you became ill, treatment with medication, duration of ventilation. The processing of your data is necessary in order to answer the research questions and to publish the results. The data cannot be traced back to you in reports and publications on the research. When processing your data, we adhere to the General Data Protection Regulation. We ask your permission for the use of your data. If you participate, we will ask for your permission to use data from your file for the study.

Your participation in the study is voluntary. You can always change your mind and withdraw your consent. You do not have to say why you are stopping, but you must report this immediately to the researcher. The data collected up to that point will be used for the research.

2. Do you have any questions?
If you have any questions, you can contact the researcher. If you have any complaints about the research, you can discuss this with the researcher. If you prefer not to do this, you can turn to the complaints mediators. These can be reached via tel. *{phone number}* or digitally via: *{hyperlink}*.

3. Signing of the consent form

When you have had sufficient reflection time, have understood the information and agree to participate, we would like to ask you to sign the consent form and to return it to us [signed, by means of the enclosed return envelope] *{the last part of this sentence (between squared brackets) is optional, depending of the situation in your unit / hospital}*. The signed consent form is kept by the researcher. You may make a copy of the consent form for your own use.

Best regards,

Prof.Dr. / Dr. *{name}, {function} {name of the hospital}* can be reached by telephone number *{phone number}*

Appendix 1: Additional information about the processing of your data

Confidentiality of your data

Your data is given a code to protect your privacy. Your name and other data that can directly identify you are omitted. Data can only be traced back to you with the key to the code. The key to the code remains safely stored in the local research facility. The data sent to the European researchers contains only the code, but not your name or other data that identifies you. The data cannot be traced back to you in reports and publications about the research either.

Access to your data for verification

Some people can access your data at the research location (*{name of the hospital}*) to the data without code, too. This is necessary to be able to check whether the research has been carried out properly and reliably.

People who can view your data are a monitor who works for the researcher and … *{please, indicate the name(s) of other people who might check the study data; for instance, in the Netherlands: people from the " Health and Youth Care Inspectorate"}*. They keep your information secret. We ask you to give permission for this access.

Retention period of data

Your data must be kept for 15 years at the research location and 15 years with the researcher.

Withdrawing of consent

You can always withdraw your consent to the use of your personal data.

The research data that has been collected up to the moment you withdraw your consent will still be used in the research.

Sharing of data

As part of collaborations in this study, your data may be transferred for analysis to other countries.

However, your privacy will be protected on an equivalent level. Your data will only be transferred encrypted.

More information about your rights when processing data

For general information about your rights when processing your personal data, you can consult the website of the … *{indicate the name of the Data Protection Authority in your country; for instance, in the Netherlands, this is the "Dutch Data Protection Authority"}*.

If you have any questions about your rights, please contact the person responsible for processing your personal data. For this research this is the *{name of the hospital and name of the city and country}*. Contact details of the principal investigator: Dr. … *{name of the local Principal Investigator, and his/her phone number}* .

If you have any questions or complaints about the processing of your personal data, we recommend that you first contact the Data Protection Officer of *{name of the hospital, email address for instance}* or the Data Protection Authority of *{name of the country}*.

Appendix 2: Subject Consent Form

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- I have read the information letter. I had also the possibility to ask questions. My questions have been sufficiently answered. I had enough time to decide whether to participate.
- I know participation is voluntary. I also know that I can decide at any time not to participate or to stop the study. I don't have to give a reason for that.
- I consent to the collection and use of my data to answer the research question in this study.
- I know that some people may have access to my data for the verification of the study. I give permission for this access by these persons.
- I consent to the forwarding of my data in the context of this investigation. Data must be transferred encrypted and without my name and other personal information that can directly identify me.
- I want to participate to this investigation.

Name of subject:

Signature: **Date: __ / __ / __**
