



Operational Procedures and Principles  
for Substudies

July 2008



## **1. Principles**

These operational procedures and principles are based on the scientist's agreement and the publication rules as they have been formulated in the SAPS 3 scientific manual. An excerpt of this manual can be found at the end of this file.

In addition SAPS 3, SAPS3, SAPS III and SAPSIII have been used interchangeably during the project. It is stated explicitly that they all mean the same project, referred to from now on as SAPS 3.

## **2. Coordinator**

Each substudy has to name a responsible coordinator. This person is the primary contact partner, responsible for the conduction of the study and the contact to the SAPS 3 Outcome Research Group (SORG).

## **3. Research Proposals**

Each coordinator has to submit a detailed research proposal. This proposal must include:

- A formulated hypothesis.
- Detailed exclusion / inclusion criteria for cohort building (if it is different from the Basic SAPS 3 cohort).
- The statistical analyses needed. This is a dynamic process and some information can be already derived from the SAPS 3 hospital cohort univariate analysis (already available on the website). Further information can be then requested when needed.

## **4. Data handling**

Data handling and processing will be done by the statisticians from the SAPS 3 Outcome Research Group. Due to issues of confidentiality of the data, no raw data will be provided.

## **5. Order of processing**

Substudies will be processed in the order of the arrival and acceptance of the research proposal. The SORG, however, retains the right to re-order studies if this seems necessary.

## **6. Ownership of data**

The ownership of the pooled data stay with the SORG. Authors of substudies are allowed to use the data for their accepted study, but they do not gain ownership over these data or analyses. Authors are not allowed to use these data for another study without permission of the SORG.

## **7. Reports**

### **7.1. Status reports**

On demand, substudies have to report about the status of their project. A regular report has to be given by each substudy-group at the SAPS 3 board meetings in Brussels and during the Annual Congress each year.

## 7.2. Web-Reports

Each substudy-group has, once results are available, the duty to provide a copy of their results and also presentations for the SASP 3 website.

## 8. Publication

As soon as a substudy is ready for publication it has to be submitted to the Publication Advisory Board (PAB), as described in the Scientific Manual of the SASP 3 project. Publication of any data, even preliminary, without the allowance of the PAB is prohibited.

Publication in this context includes not only original papers in scientific journals, but also any other form of written (abstracts, reviews etc.) or orally given presentations.

## 9. Citation of the Main Study

Each substudy has the duty to cite the original SASP 3 reports: There are two main manuscripts, Part 1 reporting about objectives, methodology and cohort description and Part 2 about the development of the prognostic model at ICU admission. They are both referred to as the SASP 3 main publications. Both publications have to be cited in each published substudy. They are currently referred to as:

**Metnitz PhGH**, Moreno RP, Almeida E, Jordan B, Bauer P, Abizanda-Campos R, Iapichino G, Edbrooke D, CapuzzoM, Le Gall JR on behalf of the SASP 3 Investigators. SASP 3 - From Evaluation of the Patient to Evaluation of the Intensive Care Unit. Part 1: Objectives, Methods and Cohort Description. Intensive Care Med 2005; In press.

Moreno RP, **Metnitz PhGH**, Almeida E, Jordan B, Bauer P, Abizanda-Campos R, Iapichino G, Edbrooke D, CapuzzoM, Le Gall JR on behalf of the SASP 3 Investigators. SASP 3 - From Evaluation of the Patient to Evaluation of the Intensive Care Unit. Part 2: Development of a Prognostic Model for Hospital Mortality at ICU Admission: The SASP 3 Admission Score. Intensive Care Med 2005; In press.

## 10. Authorship

The coordinator of each substudy is the responsible person for the number and order of authors on his/her substudy. It must be clear, that only persons contributing specifically to the study are allowed to be named as authors. For this reason, each manuscript, submitted to the PAB must contain a detailed description of each authors participation in the study. Please refer for the publication rules about authors duties and rights, followed by biomedical journals.

In addition to the authors listed by the substudy coordinator, the following coauthors have to be mentioned:

- One member of the SORG;
- One Statistician of the SASP 3 Staff;

Additionally, at least one member of the SORG might claim his right to be listed as coauthor on the substudy, given the fact, that his input was valuable.

## **11. Acknowledgements**

Each manuscript must contain an “Acknowledgement” section, which lists the mandatorily the following issues:

- The other members of the Statistical Staff (not mentioned as coauthors), acknowledging their work.
- Acknowledgement of the Grant:  
“Statistical analysis was supported by a grant from the Fund of the Austrian National Bank, Project # 10995 ONB.”
- Acknowledgements for all the participating ICUs and their respective coordinators (general statement, without listing of names).

Other acknowledgements are possible and are subject and responsibility of the coordinator of the substudy.

## **12. Disagreement**

In case of a severe injury of the Scientist’s Agreement or the Publication rules (as outlined in the Scientific Manual), the SORG keeps the right to cancel the project or to appoint another substudy coordinator.

## Appendix A.

### List of accepted substudies.

Title	Authors	Status	Email address of coordinator
Quality of life after intensive care	Maurizia Capuzzo, Ferrara, Italy.	Published	<a href="mailto:cpm@unife.it">cpm@unife.it</a>
Variability in outcome and resource use in European ICU's	Hans U. Rothen, Kay Stricker, Jukka Takala, Bern, Switzerland.	Published	<a href="mailto:Hans.Ulrich.Rothen@insel.ch">Hans.Ulrich.Rothen@insel.ch</a>
SAPS 3 - modelling 28 days mortality	Rui Moreno, Lisbon, Portugal; Philipp Metnitz, Vienna, Austria.	Published	<a href="mailto:r.moreno@mail.telepac.pt">r.moreno@mail.telepac.pt</a>
The PIRO Concept	Rui Moreno, Lisbon, Portugal; Philipp Metnitz, Vienna, Austria.	Published	<a href="mailto:philipp@metnitz.biz">philipp@metnitz.biz</a>
Epidemiology of end-of-life practices in ICU patients	Elie Azoulay, Jean-François Timsit, Paris, France; Charlie Sprung, Israel	Submitted	<a href="mailto:elie.azoulay@sls.ap-hop-paris.fr">elie.azoulay@sls.ap-hop-paris.fr</a>
Risk-adjusted outcome in ALI	António Artigas, Barcelona, Spain	In Preparation	<a href="mailto:aartigas@cspt.es">aartigas@cspt.es</a>
Ventilation practices according to case-mix across the world	João Gouveia, Lisbon, Portugal; Marco Ranieri, Torino, Italy.	Submitted	<a href="mailto:mranieri@teseo.it">mranieri@teseo.it</a>
Prognosis, treatment and outcome in patients with acute and chronic renal failure	Philipp Metnitz, Vienna, Austria; Michael Joannidis, Innsbruck, Austria.	Submitted	<a href="mailto:philipp@metnitz.biz">philipp@metnitz.biz</a>
Outcome in patients with cancer	Elie Azoulay, Paris, France;		<a href="mailto:elie.azoulay@sls.ap-hop-paris.fr">elie.azoulay@sls.ap-hop-paris.fr</a>
The oldest old in the ICU	António Artigas, Barcelona, Spain.		<a href="mailto:aartigas@cspt.es">aartigas@cspt.es</a>
Outcome in trauma patients	Philipp Metnitz, Walter Mauritz, Vienna, Austria		<a href="mailto:sprung@cc.huji.ac.il">sprung@cc.huji.ac.il</a>
The effects of ICU organization and management on prognosis	Rui Moreno, Lisbon, Portugal; Philipp Metnitz, Vienna, Austria.		<a href="mailto:r.moreno@mail.telepac.pt">r.moreno@mail.telepac.pt</a>
Predicting outcome after ICU discharge	Rui Moreno, Lisbon, Portugal; Philipp Metnitz, Vienna, Austria.		<a href="mailto:r.moreno@mail.telepac.pt">r.moreno@mail.telepac.pt</a>
The effects of prior therapy on ICU outcome	Rui Moreno, Lisbon, Portugal; Philipp Metnitz, Vienna, Austria.		<a href="mailto:r.moreno@mail.telepac.pt">r.moreno@mail.telepac.pt</a>
Circadian variations in the outcome of ICU patients	Rui Moreno, Lisbon, Portugal; Philipp Metnitz, Vienna, Austria.		<a href="mailto:r.moreno@mail.telepac.pt">r.moreno@mail.telepac.pt</a>
Hepatic dysfunction / failure in critically ill patients	Ludwig Kramer, Philipp Metnitz, Vienna, Austria.		<a href="mailto:ludwig.kramer@meduniwien.ac.at">ludwig.kramer@meduniwien.ac.at</a>
Gender differences in outcomes in intensive care patients	Andreas Valentin, Vienna, Austria.		<a href="mailto:andreas.valentin@univie.ac.at">andreas.valentin@univie.ac.at</a>

## Appendix B.

Excerpt from the Scientific manual of the SAPS 3 project.

### 10. PUBLICATION RULES

#### ***10.1. Publication Advisory Board***

A publication advisory board (PAB) will be installed to provide systematic and objective guidelines for any publication resulting either from the SAPS III research project or from parts of it. The PAB consists of two members and one chairman, which are all designated by the Steering Group. The project leader has the right to refuse nominations. In this case, the Steering Group has to nominate another person.

The PAB's first task will be to distribute the SAPS III research project proposal. It will continue to exist until no further publications or other deliverables, regarding the SAPS III project are produced.

The responsibilities of this board are to review all manuscripts, which are derived from the SAPS III project, data from the SAPS III project or any part of the SAPS III project. The PAB gives and the respective authors receive, recommendations from this board, regarding:

- The adequacy in the use of the data.
- The scientific quality of the manuscript.
- The accordance of the submitted manuscript with the author's rights, as outlined below.

The recommendations of the PAB are mandatory for all authors. The PAB will always be responsible to answer any request within the shortest time possible.

#### ***10.2. Authors Rights and Duties***

Authors wishing to publish manuscripts that contain data or knowledge derived from the SAPS III research project or parts from it, must agree to the following rules:

- All authors rights regarding publications of deliverables, derived from the SAPS III project, including data from the SAPS III project or any other knowledge or part of the SAPS III project belong to the SAPS III Outcome Research Group (SORG).
- Any participant may prepare a publication regarding the SAPS III project, involving the pooled data in the databank, after the PAB has been consulted and approved the publication project.

- All types of manuscripts and other deliverables have to be submitted to the PAB prior to any other publication.
- Further submission of a manuscript is only permitted with an official, written allowance of the PAB.
- Recommendations of the PAB have to be respected by the authors.

## **11. SCIENTISTS AGREEMENT**

The success of the SAPS III research project is strongly dependent upon open and transparent communication between all the participants in this project. For this reason, all participants must agree on the following issues.

### ***11.1. Information Handling***

All information and data which are collected, transferred and exchanged during the SAPS III research project - or in close relation with this project - are restricted to the participants in the project and are exclusively used to serve this project. Permission of the SORG is necessary, when restricted information will have to be provided to individuals, institutions or authorities outside the project.

### ***11.2. Databank***

The SORG will develop a SAPS III project databank, which will contain all the data related to the SAPS III research project. This databank will contain all collected and pooled data from participating ICUs.

- The individual data, provided by a participating ICU are primarily property of the ICU who generated the data.
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- The SORG has the right to use all data that are pooled in the databank for scientific and other purposes.
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- All participants of the SAPS III research project have the right to access the data, pooled in the databank, for research purposes after the research project has been reviewed and approved by the PAB (see chapter 10, Publication Rules).
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- A copy of the databases generated by the project can only be provided to third-part entities after specific approval by the participating ICUs.