PROCAS

nicer Foundation National Institute for Cancer Epidemiology and Registration

Rules for publications and data analysis within the PROCAS-study (V. 1., 07.01.2019)

(1) All publications and data analyses adhere to international guidelines for good scientific practice.

(2) PROCAS data may be used for scientific (non-commercial) publications and analysis by the study group (see (4)), PROCAS collaboration partners (i.e. physicians involved in recruitment), and external researchers in the context of scientific collaborations.

(3) Researchers (other than members of the study group) may request access to anonymized study data for research purposes on the basis of a detailed research plan (see 6).

(4) All planned publications and analysis must be within the framework of the primary and secondary objectives described in the study protocol BASEC-Nr. 2016-00608 (see attachment I) and the patient's consent form. Requestors who want to address objectives not mentioned in the study protocol need to get ethical approval (Human Research Ordinance (HRO) Paragraph 33) from the involved cantonal ethic committees.

(5) The study group includes the principal investigator (PI) of PROCAS (Volker Arndt - VA), the project coordinators (Salome Adam – SaA & Eva Martin-Diener - EM) as well as the directors of the study cancer registries (Mohsen Mousavi – MM, Bertrand Camey – BC/ Céline Egger Hayoz - CEH, Katharina Staehlin – KS, Isabelle Konzelmann – IK, Sabine Rohrmann - SR). VA, SaA and EM are the PROCAS-study core team.

(6) For all publications and data analysis, a detailed research plan (proposal) with background, study objectives/questions, analytical strategy and planned publication type/journal has to be prepared by the requestor (further details are described in attachment II). The PI (VA) approves the proposal for feasibility, adherence to the objectives as described in the BASEC study protocol (see attachment I), scientific merit, and potential overlap with other requests. After approval by the PI, all potential co-authors will be informed about the proposal and invited to comment on the proposal.

(7) Publications on study strategy, global results, and results pertaining to primary objectives as described in the study protocol (BASEC-Nr. 2016-00608) shall primarily be carried out by the study core team (VA, SaA, EVM). The PI (VA) can delegate this task and the first authorship for these publications.

(8) For all projects aiming for publication, a date is agreed by which a manuscript shall be ready for submission. If the deadline is exceeded by more than three months, the data and the topic will be returned, unless the delay is caused by a delayed provision of the necessary data.

(9) Statistical analyses within the scope of publications shall be approved by an experienced co-author for quality assurance purposes.

(10) The directors of the participating cancer registries must always be involved in canton-specific analyses.

(11) In all publications, the financial support by Swiss Bridge, the role of the cantonal cancer registries of Basel (BS/BL), Fribourg (FR), Graubünden and Glarus (GR/GL), St. Gallen, Appenzell Ausserrhoden and Appenzell Innerrhoden (SGA), Valais (VS), Zürich (ZH) and the role of the urologists, who participated in the recruitment, shall be acknowledged (see (15)).

(12) The authorship depends on the activity of the involved persons. Authors of an original scientific publication are all those, but only those who have significantly contributed to the conception of the study, to the design, to the analysis, to the interpretation of the data or to the formulation of the manuscript and approved its publication.

   a. The authors' affiliation at time of co-operation within the PROCAS study should be mentioned.

   b. Each cancer registry involved in recruitment of study participants is entitled to nominate up to two representatives as co-authors if data from the respective registries are used in publications.

   c. Urologists involved in recruitment and who substantially contribute to the analysis and/or interpretation of the results qualify for individual co-authorship (see (15)).

   d. External cooperation partners (other than urologists involved in the recruitment) who substantially contribute to the analysis and interpretation of the data qualify for co-authorship.

   e. The initiator of the research plan is responsible for statistical analysis and drafting of the manuscript and qualifies for first authorship. The first author or the head of the institution from which the first author comes is usually the corresponding author. The PI (VA) will be the last author.

   f. The order of the other co-authors will be determined by the first author in agreement with the PI (VA).

   g. In case of dispute, the PI (VA) will be appealed to arbitration.

(13) All co-authors receive a draft of the manuscript in time prior submission for approval or correction.

(14) The PI (VA) releases the final manuscript for submission.

(15) All urologists who supported the recruitment in the PROCAS study had been asked in November 2018 whether they are interested in becoming member of the writing group (and qualify for co-authorship) or whether they consent to be mentioned in the acknowledgement.

   a. In case they expressed their interest in becoming a member of the writing group, they shall be asked for each publication at the stage of research plan whether they are interested to actively participate in the pertinent manuscript.

   b. Urologists who initially agreed to be mentioned in the acknowledgement must actively express their withdrawal to the study management in case they no longer want to be named in the acknowledgements.

(16) Anonymous study data may only be passed on to external research institutions by the PI (VA) within the framework of scientific co-operations.

(17) The funding agency (Swiss Bridge) has no role in deciding which results will be published.

(18) This agreement shall always apply unless higher-level agreements (e.g. within the framework of international studies) have priority.

Attachment I

Primary and secondary objectives as described in the study protocol (BASEC-Nr. 2016-00608)

Primary Project Objectives

To describe long-term health-related quality of life of prostate cancer survivors in Switzerland depending on personal and medical factors:

- What is the health-related quality of life among long-term prostate cancer survivors?
- Does health-related quality of life of survivors differ between certain groups? (E.g. age; tumour stage; rural/urban; language group; socioeconomic status; comorbidities etc.)
- What is the impact of the primary treatment (prostatectomy, radiotherapy, hormone therapy, watchful waiting and active surveillance, etc.) on health-related quality of life of prostate cancer survivors?

Secondary Project Objectives

- To identify determinants and mechanisms for negative (as well as positive) effects, such as pain, fatigue, mental health, comorbidities, resources, on health-related quality of life in long-term prostate cancer survivors.
- To compare long-lasting physical effects (such as incontinence, memory problems, pain syndromes, osteoporosis, or fatigue) of prostate cancer survivors with respect to age, tumour stage, and treatment factors.

Primary Outcome

- General and prostate cancer specific health related quality of life (EORTC QLQ-C30, QLQ-PR25, EPIC-26)

Secondary Outcomes

- Fatigue: EORTC QLQ-FA13[12*]
- Mental Health (MHI-5)
- Spirituality: FACIT-sp
- Data about comorbidities

Attachment II

Structure of the research proposal

Project title

Responsibilities and proposal for authorship

Type of planned publication

- How you imagine to disseminate your results (publication in scientific journal, thesis, internal report, conference, etc.)
- Nominate 3 candidate journals (and their impact factor) in case you are planning a publication for a scientific journal

Summary

150 words maximum

Background

- Present state of knowledge in the area of the proposed research with key references

Study objectives and questions

- The hypothesis which this project proposes to test
- The scientific and practical significance of the proposed research

Study design and analysis plan

- Specification of data to be used in the project
- Biostatistical methods and analytical strategy
- Time-table

Other information

- Ethical committee to contact (if applicable)

References