Appendix to the Protocol

Consortium Agreement of the PACYFIC study group

RULES for PUBLICATION, AUTHORSHIP, and OWNERSHIP of DATA

Introduction

The Consortium Agreement of the PACYFIC study group has been formulated to create an open, transparent, and well-organized framework for collaboration between all participating parties. Publication and authorship rules and ownership of data of the PACYFIC study and possible side studies are specified in this agreement. It has been drafted, based on generally accepted criteria for collaborative consortia.

The PACYFIC study group is composed of:

- A Steering Committee
- Collaborating parties and contributors
- Principal investigators of participating centers

The Steering Committee consists of:

- Dr DL Cahen, Gastroenterologist, Erasmus University Medical Center Rotterdam, The Netherlands (principle investigator for the primary PACYFIC study protocol (appendix 2)
- Prof Dr MJ Bruno, Gastroenterologist, Head of Department, Erasmus University Medical Center Rotterdam, The Netherlands (principle investigator for the primary PACYFIC study protocol (appendix 2
- Prof. Dr MM Lerch, Gastroenterologist, Greifswald University Hospital, Heidelberg, Germany
- Dr MGH Besselink, Surgeon, Academic Medical Center, Amsterdam, The Netherlands
- Dr M del Chiaro, Surgeon, Karolinska University Hospital, Stockholm, Sweden

Other contributors and collaborating parties are:

- Dr K Biermann, Pathologist, Erasmus University Medical Center Rotterdam, Netherlands
- Prof. Dr LHJ Looijenga, Medical Cell Biologist, Erasmus University Medical Center Rotterdam, Netherlands
- Prof. Dr MP Peppelenbosch, Head of the Laboratory of Gastroenterology and Hepatology, Erasmus University Medical Center Rotterdam, Netherlands
- Dr BE Hansen, Statistician, Erasmus University Medical Center Rotterdam, Netherlands
- Dr JHE Verhagen-Oldenampsen, Data manager Clinical Trial Center, Erasmus University Medical Center Rotterdam, Netherlands
- Dr IMCM de Kok, Epidemiologist, Dept of Public Health, Erasmus University Medical Center Rotterdam, Netherlands
- Dr M van Ballegooijen, Associate professor Public Health Care, Erasmus University Medical Center Rotterdam, Netherlands

- Prof. Dr P Fockens, Gastroenterologist, Head of Department, Academic Medical Center, Amsterdam, The Netherlands
- Dr THL Bollen; Radiologist, Antonius Hospital, Nieuwegein, The Netherlands
- Dr EMA de Bleiker, Associate professor Psychosocial Research and Epidemiology, Netherlands Cancer Institute, Amsterdam, The Netherlands.

I. General rules

1. Competences and responsibilities of the steering committee

The steering committee (SC) is responsible for all publications and data handling of the PACYFIC study and related side projects.

a) Every study proposal, concerning data/samples that were generated during or as a result of the PACYFIC study, must first be discussed and approved by the steering committee.
b) Before (sets of) data/samples that were generated during or as a result of the PACYFIC study may be used for a new side study, those center(s) that generated or collected these data will be asked to consent and sign a participation agreement.
c) Every manuscript or abstract that is generated with (a subset) of data from the PACYFIC study MUST be submitted to the steering committee for approval of the author list and scientific content, prior to submission for publication.
d) Prior to submission, a draft manuscript will always be sent for review to all PACYFIC study group members involved in that particular study. Study group members must respond within 6 weeks after they have received the manuscript.
e) Any conflict between investigators should be reported immediately to the steering committee.

The Steering Committee commits itself to use the following rules regarding ‘policy and ownership of data and biological samples’ and ‘authorship, acknowledgement, and financial support and sponsorship”, to ensure that reasonable expectations of the PACYFIC study group partners are met.

2. Policy and ownership of data and biological samples

a) General rules for data and body tissue storage

Participating physicians will be asked to collect and record study data in an online case record form (eCRF). Data that are collected during the course or as a result of the PACYFIC study will be stored in a secured database, managed by the coordinating center (Erasmus MC Rotterdam, the Netherlands).

Human samples that are collected during the course of the study will be stored locally. If local facilities are not sufficient, samples may be sent to the coordinating center Erasmus University Medical Center Rotterdam, for central storage. In case a participating

institution decides to withdraw its participation from the PACYFIC study, the samples provided by that group will be returned or destroyed, if that party so requests.

b) General rules for ownership

All data collected in the central database under the PACYFIC study (CRF's) shall be owned by the coordinating center (Erasmus MC Rotterdam, the Netherlands). Further sub-studies are encouraged, provided that each participating center may only use the data it has generated in the PACYFIC Study in further research, e.g. in sub-studies, if prior Steering Committee approval is obtained, in accordance with section I. 1 above of this Consortium Agreement.

All tissue samples that are collected during the course of the PACYFIC study remain property of the participating center that collected the data and/or tissue. By participating in the PACYFIC study, the participating center agrees to the use of this material as is described in the PACYFIC study protocol and this Consortium Agreement.

II. Authorship, acknowledgement, and financial support and sponsorship

The following rules related to a) authorship, b) acknowledgements and c) sponsors of the PACYFIC project, based on the 1991 guidelines of the International Committee of Medical Editors (1), modified by a *New English Journal of Medicine* editorial and correspondence (2), and a *Lancet* editorial (3), apply to the PACYFIC publication policy.

1. Authorship rules

Categories of articles that will be generated:

a) General papers: these include clinical and biological data, generated by the PACYFIC study group on the full series (or a subset) of patients, addressing the primary and major secondary endpoints of the primary PACYFIC study protocol (appendix 2).

b) Side study papers: studies that do not concern the primary study protocol and focus on a specific research question and/or a defined subset of samples from the PACYFIC study. Each PACIFYC group study member may propose a side study. The protocol of such a study needs to be discussed and approved by the PACYFIC steering committee.

a) Rules for all papers;

Authorship credit will be based on the Recommendations of the International Committee of Medical Journal Editors (ICMJE, www.icmje.org). The criteria for authorship are defined as:

1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data.
2. Drafting the article or revising it critically for important intellectual content.
3. Final approval of the version to be published.

Eligible authors should meet conditions 1, 2, and 3. Every article author list will finish with 'the PACYFIC study group', which will be specified (depending on the publication rules of the journal) as follows; Coordinating center: four participants with their affiliation, Members of Steering Committee with affiliation, Study contributors and collaborators with affiliation, Principal investigators of those participating centers who acquired the data used for the manuscript, with affiliation, Industrial Partners: one per group, with affiliation.

b) Rules for papers pertaining the primary research protocol;

The first and last author will come from the coordinating center (Erasmus MC Rotterdam, the Netherlands). Participants from collaborating centers will be listed according to the number of patients they have included; 50 patients results in one author citation, 100 or more in two. If a journal limits the number of authors, those collaborators who provided the most substantial contribution, as mentioned in the 3 criteria above, will have priority. Subsequently, if possible, a single author per collaborating center will be listed, according to the rules mentioned above, or, if further limitation is necessary, the absolute number of included patients will determine priority. Whenever possible, a journal will be chosen that allows to give a list of PACYFIC study group collaborators that results in a PubMed citation.

c) Rules for side study papers:

Authorship rules will be based on the Recommendations of the International Committee of Medical Journal Editors, as mentioned above. Only members of the PACYFIC study group that have actually contributed to a particular side study (either by executing the study, or assembling data) may be mentioned as authors of that study. Their order will be determined by the steering committee, based on their respective contributions. Whenever possible, a journal will be chosen that allows to give a list of PACYFIC study group collaborators that results in a PubMed citation.

1. Acknowledgements:

a) Acknowledgements in manuscripts

Persons, who have made special intellectual or technical contributions to the study, but whose contributions do not justify authorship, should be acknowledged by name. Also, their function or contribution will be described – for example: 'scientific adviser', critical review of study proposal, 'data collection', 'participation in clinical trial', 'general support'. Such persons should have approved the final version or must have given their permission to be named. Acknowledgements are made at the end of the article.

b) Acknowledgements on the PACYFIC website

The PACYFIC study website (**www.pacyfic.net**) contains all relevant study information for both professionals (participants) and patients. Every member of the PACYFIC study group will be listed as a participant on this website, with affiliation.

2. Financial support and sponsorship:

Financial support and technical help should be acknowledged, separately from acknowledgment of contributions. Acknowledgements are made at the end of the article.

Signature page

This Consortium Agreement, named 'Consortium Agreement of The PACYFIC study group; Rules for publications, authorship, and ownership of data', was approved by;

Name:_____

Signature:_____ Date:_____

References

- International Committee of Medical Journal Editors. Style matters: Uniform requirements for manuscripts submitted to biomedical journals. BMJ 1991;302:338-41.
- Kassirer JP, Angel M. On authorship and acknowledgments. N Engl J Med 1991;325:1510-2 and 1992; 326: 1084-8 (correspondence).
- Olivir MF. Al or the anonymity of authorship. Lancet 1995;345:668.