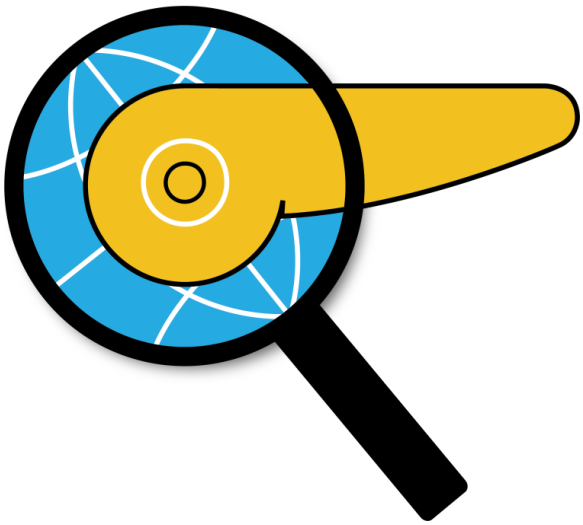

Consortium Agreement of the CAPS Consortium

RULES for PUBLICATION, AUTHORSHIP, and OWNERSHIP of DATA

Introduction

Various centers around the world are currently investigating the feasibility and yield of screening and surveillance for pancreatic cancer in high-risk individuals.
Evidence is beginning to accumulate that surveillance may lead to the early detection of non-invasive precursor lesions and asymptomatic early stage pancreatic cancer. Ultimately, the goal of surveillance is to reduce mortality in these high-risk individuals.

Many research questions need to be answered to confirm the feasibility and yield of screening and surveillance in high-risk individuals and to develop evidence-based screening protocols. For this, large cohorts are needed, but the numbers of screened high-risk individuals in each separate screening facility are too small. The 'CAncer of the Pancreas Screening' (CAPS) consortium is a unique collaboration, created in 2010 to pool data from different centers. It organizes and facilitates research on surveillance for pancreatic cancer in high-risk individuals on a global scale.

The key characteristics of the CAPS consortium are

- No internal competition but collaboration based on trust
- Joint discussions of study protocols
- An open, approachable atmosphere of communication
  A multidisciplinary collaboration

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

1. Structure of the consortium

a. The CAPS consortium is composed of:
   i. A steering committee
   ii. Collaborating parties
   iii. Principal investigators of participating centers

2. Membership

a. To be a collaborating party, participation in CAPS activities is required including active registration of high risk individuals in the prospective CAPS database.
b. All collaborating parties will be listed on the website (www.CAPS-registry.com) .
c. All interested parties can register with the steering committee of the CAPS consortium and will then be evaluated for eligibility to be a collaborating party in the CAPS consortium.
d. There is no formal membership.

3. Steering committee

a. The steering committee commits itself to use the below rules on study proposals, ownership of data, authorship, publications and grants, to ensure that reasonable expectations of the collaborating parties are met.
b. The steering committee will be composed of a chairman, a vice-chairman and four collaborating parties who actively participated in CAPS activities.
c. The chairman and vice-chairman will be from the Erasmus MC University Medical Center Rotterdam and the Johns Hopkins University School of Medicine. The chairman and vice-chairman will alternate positions every 2 years.
d. Collaborating parties can apply for a position in the steering committee, provided they actively participated in CAPS activities including active registration of high risk individuals in the prospective CAPS database. The four collaborators to be seated in the steering committee will be elected by all other collaborating parties for a term of 2 years.
e. The chairman has the following tasks:
   i. Chairing CAPS meetings
   ii. Spokesman for the outside world
   iii. Liaising with patient and professional associations
   iv. Coordinate requesting non-study-related grants for the benefit of the CAPS Consortium (e.g. unrestricted grants)
   v. Coordinate rising issues
   vi. Send an annual report with scientific output, current projects and financial situation
   vii. The vice-chairman is the previous chairman and replaces the chairman in his or her absence

4. Meetings

a. The CAPS consortium meets at least once a year during the international Digestive Disease Week. Information on the date and location of the meeting will be sent well in advance.
b. Communication in between meetings will take place through the CAPS website, Skype/WebEX-calls or via other social media.

5. Study proposals

a. All collaborating parties that have actively participated in CAPS activities can submit study proposals to the steering committee. This study proposal should be described concisely (e.g. 2 pages) and should include background, study hypothesis, target population, and research methods.
b. After the steering committee has assessed the feasibility of this proposal within the CAPS consortium (patient data, scientific value, financing, logistics, target population), the study proposal will be discussed with all collaborating parties, reviewing desirability and feasibility (logistical, financial). All costs and efforts related to the proposed study are at the expense of the proposing center, unless agreed otherwise.
c. After discussion of the study proposal by the collaborating parties, the collaborating parties will then be asked to indicate if they consent to make their entered data available to the submitter of the study proposal. See also section 6d. on ownership of data.

6. Ownership of data and biological samples

a. Participating parties will be asked to record study data in an online Case Record Form (eCRF). Data will be stored in a secured database, managed by the Erasmus MC University Medical Center Rotterdam, The Netherlands. Access to the database by the Parties shall be subject to the authorization of the Steering Committee, provided however that Parties shall at all times have access to their own 'Background Data' (see 6.d) and are allowed to use such at their sole discretion.
b. Parties agree to comply with all relevant laws and regulations of the EU, if directly applicable or of direct effect, and all relevant laws and regulations and with all relevant guidance relating to personal data protection and Privacy Laws.
c. Parties agree that each Party is responsible for ensuring that the respective subjects have given full informed consent, if applicable, for, including but not limited to, provision, use and analysis for purposes under this Agreement.
d. All Background Data (meaning "*set of (raw) data collected by a Party, created prior to this Agreement*") collected in the central database of the CAPS Consortium shall be owned by the Party that created such data. The Parties agree that Background Data shall be available through the database to the other Parties for projects which may create new Foreground Datasets (meaning "*all data, information and/or reports generated through a project in the field by, or on behalf of, a Party and/or Parties*").

e. All Foreground Data will be owned by the Party and/or Parties that creates such. The Parties agree that all Foreground Data, will be made available to the other Parties for research purposes.
f. Use of any type of data from a collaborating party for a CAPS study project is only allowed after explicit consent by that party (in accordance with section 5c. above) and results in co-authorship for that study, provided a substantial involvement in the preparation of the study protocol and/or manuscript (see also paragraph 7 on authorship rules).
g. Human samples collected will be stored locally. If local facilities are not sufficient, samples may be sent to the Erasmus MC University Medical Center Rotterdam, The Netherlands, or to the Johns Hopkins University School of Medicine, Baltimore, United States of America.
h. Each Party shall use best efforts to ensure the accuracy of any data and/Background Data that it places into the database, or data and other information and/or materials that it supplies to the coordinator hereunder and promptly to correct any error therein of which it is notified.
i. The Parties shall always seek to maintain the integrity of the Foreground and Background Data and to enhance the long term and collective value of the database. Each Party undertakes not to publish any Foreground Data developed by the other Parties without written consent of the Steering Committee.

7. Intellectual Property

a. All Background Intellectual Property (meaning “any inventions, designs, information, know-how, specifications, formulae, data, processes, methods, techniques, and other technology, other than intellectual property, used in, or disclosed in connection with the performance of, a project and the intellectual property rights therein that exist at the time of execution of this Agreement, or that is generated by the relevant Party outside the a Project.) belonging to one Party is and shall remain the exclusive property owning it. Each Party shall make available to the other Parties such Background Intellectual Property to the extend it is necessary in order to enable the other Parties to make use of the data in a project.
b. The rights to Foreground Data of a project performed under this Agreement will vest in the Party and/or Parties who generates such Foreground Data. CAPS may use such Foreground Data for research and educational purposes only.
c. In the event intellectual property arises out of a project, ownership shall follow inventorship. CAPS however, shall be allowed to use such intellectual property for non-commercial research and educational purposes.

8. Authorship rules

a. Authorship credit will be based on the Recommendations of the International Committee of Medical Journal Editors (ICMJE, www.icmje.org), see Appendix 1. The criteria for authorship are defined as:
   i. Substantial contributions to the conception or design of the work; or the acquisition analysis, or interpretation of data for the work.
   ii. Drafting the work or revising it critically for important intellectual content.
   iii. Final approval of the version to be published.
   iv. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
   v. All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors.

b. The submitter of a research proposal can assign the first two and the last author of the manuscript, taking into account scientific input and involvement in the end result, and also taking into account inter-institutional efforts. Publication with a first, second and last author from different collaborating centers is encouraged. All other collaborating parties will be listed according to the number of patients they have included.

c. Each participating center can assign co-author(s) depending on the number of patients provided. The number will be determined for each separate study protocol.

d. All other collaborating parties are included under ‘collaborators’ at the end of the article. Whenever possible, a journal will be chosen that allows to give a list of the CAPS consortium study group collaborators that results in a PubMed citation.

9. Publications / abstracts

a. For all publications and abstracts co-authors will be given ample time for feedback and discussion before submitting to a congress or journal.

b. All co-authors receive a stated maximum days to correct the publication or abstract. If a co-author does not respond within the time set, he/she is considered to be in approval of the manuscript or abstract.

10. Grants and gifts

a. Grant applications in which the CAPS Consortium is mentioned can only be submitted after consultation with and approval by the steering committee.

b. Grant money and philanthropic gifts that are not tied to a specific study proposal will be managed by the steering committee.

c. Grant money and philanthropic gifts that are bound to a specific study proposal or member of the CAPS consortium will be managed by the submitter who has received the grant or gift.

11. Term, withdrawals and termination

a. This Agreement shall become effective from the date set out on page 14 ("**Effective Date**") and shall continue in effect for five years from the Effective Date.
b. On termination of this Agreement the Party terminating the Agreement shall continue to allow the other Parties access to their Foreground and Background Data for the project, but its access rights to the database shall cease; and furthermore, shall have no further obligations to submit any data upon the Effective Date of the termination of its participation.
c. If any Party shall commit any material breach of or be in default of any of the terms or conditions of this Agreement, and shall fail to remedy such default or breach within ninety (90) days after the receipt of written notice from the Steering Committee, the other Parties may, at their option cease to permit access to their Background and Foreground Data. If such breach is substantial and is not remedied within that period or is not capable of remedy, the Steering Committee may furthermore declare the Party to be in default and to decide on the consequences thereof.

12. Liabilities

a. Each Party undertakes to use its reasonable efforts and perform its work under this Agreement and is carried out in good faith and in accordance with scientific principles and standards. Parties make no representation or warranty that any Background Intellectual Property, results or intellectual property will be fit for any particular purpose, and accepts no responsibility for any use which may be made of any Background Intellectual Property or intellectual property by the other Parties arising from its work on the project or otherwise supplied to or to which a Party gains access.
b. Parties shall not be held liable for any damages, dispute or injury arising during the undertaking of activities under this Agreement unless caused by the gross negligence of that Party.

13. General

a. In the performance of all activities hereunder each Party shall be deemed to be, and shall be, independent contractors. Nothing in this Agreement shall create or be deemed to create a partnership or to have created the relationship of principal and agent.
b. None of the Parties are authorised to act as an agent for the other for any purpose and shall not on behalf of any other enter into any contract, warranty, or representation as to any matter. None of the Parties shall be bound by the acts or conduct of another.
c. This Agreement shall not be assigned by any Party without the prior written consent of the other Parties hereto.
d. Any agreement to amend the terms of this Agreement in any way shall be valid only if the change is made in writing and approved by mutual agreement of authorised representatives of the Parties hereto.

e. If the whole or any part of any provision of this Agreement is void or unenforceable in any jurisdiction, the other provisions of this Agreement, and the rest of the void or unenforceable provision, will continue in force in that jurisdiction, and the validity and enforceability of that provision in any other jurisdiction will not be affected.
f. Nothing in this contract confers or purports to confer on any third party any right to enforce any term of this contract.
g. This Agreement and all questions of construction, validity and performance under this Agreement shall be governed by the Laws of the Netherlands and shall be subject to the exclusive jurisdiction of the Court of Rotterdam.
h. This Agreement represents the entire agreement between the Parties hereto relating to the subject matter hereof and supersedes and replaces any oral or written communications heretofore made between the Parties relating to the said subject matter.
i. This Agreement may be executed in any number of counterparts, and by the Parties on separate counterparts, each of which so executed and delivered shall constitute an original but all the counterparts shall together constitute one and the same instrument.

Appendix 1: ICMJE criteria for authorship

Reference: ICMJE.org [homepage on the internet]. International Committee of Medical Journal Editors. [Cited 31 October 2016]. Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

1. Why Authorship Matters
Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and accountability for published work. The following recommendations are intended to ensure that contributors who have made substantive intellectual contributions to a paper are given credit as authors, but also that contributors credited as authors understand their role in taking responsibility and being accountable for what is published.
Because authorship does not communicate what contributions qualified an individual to be an author, some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy. Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship. The ICMJE has thus developed criteria for authorship that can be used by all journals, including those that distinguish authors from other contributors.

2. Who is an author?
The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors. All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged—see Section II.A.3 below. These authorship criteria are intended to preserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses. It is the collective responsibility of the authors, not the journal to which the work is submitted, to determine that all people named as authors meet all four criteria; it is not the role of journal editors to determine who qualifies or does not qualify for authorship or to arbitrate authorship conflicts. If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed, not the journal editor, should be asked to investigate. If authors request removal or addition of an author after manuscript submission or publication, journal editors should seek an explanation and signed statement of agreement for the requested change from all listed authors and from the author to be removed or added.

The corresponding author is the one individual who takes primary responsibility for communication with the journal during the manuscript submission, peer review, and publication process, and typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and gathering conflict of interest forms and statements, are properly completed, although these duties may be delegated to one or more coauthors. The corresponding author should be available throughout the submission and peer review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication. Although the corresponding author has primary responsibility for correspondence with the journal, the ICMJE recommends that editors send copies of all correspondence to all listed authors.

When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication. All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete conflict-of-interest disclosure forms.

Some large multi-author groups designate authorship by a group name, with or without the names of individuals. When submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists, and clearly identify the group members who can take credit and responsibility for the work as authors. The byline of the article identifies who is directly responsible for the manuscript, and MEDLINE lists as authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators.

3. Non-Author Contributors
Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").

Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals.

Appendix 2: Participating centers and principal investigators (in alphabetical order)

Academic Medical Center Amsterdam	P. Fockens, J.E. Van Hooft
AOUI University Hospital of Verona	G. Malleo, S. Paiella
Aristotle University of Thessaloniki	O. Ioannidis, K. Tsalis
Banner University Tucson	H. Gavini
Beaujon Hospital	P. Lévy, P. Ruszniewski, V. Rebours
Champalimaud Foundation	R. Rio Tinto
CHU-Lyon (Hospices Civils de Lyon)	J.C. Saurin
Cliniques Universitaires Saint-Luc	P. Deprez, I. Borbath
Columbia University Medical Center	F. Kastrinos
Creighton University's Hereditary Cancer Center	H. Lynch
Dana Farber Cancer institute	S. Syngal, J. Saltzman
Erasmus University Medical Center	M.J. Bruno, D.L. Cahen, J.W. Poley
Gastroenterology Consultants	M. Catalano
Hospices Civils de Lyon	J.C. Saurin
Hospital of the University of Pennsylvania	A. Rustgi, M. DeMarshall
Indiana University Purdue University Indianapolis	E. Ceppa
Institut Paoli-Calmettes	M. Giovannini
Institutô do Câncer do Estado de São Pauo (ICESP)	F. Maluf Filho
Jefferson Medical Center	H. Lavu, C. Yeo, T. Yeo
The Johns Hopkins Hospital	M.I. Canto, M.G Goggins, P. Saxena, E. Shin, A.M. Lennon, R. Hruban
Karolinska Institutet	M. Del Chiaro
Kyoto University Hospital	K. Takaori
Maria Sklodowska-Curie Memorial Cancer Center	M. Polkowski
Mayo Clinic Florida	M. Wallace
Mayo Clinic Rochester	M. Raimondo, M. Levy, M. Topazian
Medical College of Wisconsin	J. Geurts, S. Tsai, C. Barnes
Medical University of South Carolina	J. Romagnuolo
Medical University Vienna	A. Puspok
Memorial Sloan-Kettering	H. Gerdes, R. Kurtz
Mount Sinai Hospital	A. Lucas
Ohio State University Wexner Medical Center	D. Conwell, P. Hart, S. Krishna, S. Eldika
Osaka Medical Center	R. Ashida

Pancreatic Cancer Action Network	L. Rahib
Rambam Health Care Campus	E. Half, E. Hasnis, J. Lachter
Royal Prince Alfred Hospital	P. Saxena, A. Kaffes
San Raffaele Hospital	P. Giorgio Arcidiacono
St. Vincent's Hospital	D. Williams, A. Stoita
SUNY Downstate Medical Center	F. Gress
Teikyo University Hospital	K. Wada
UC San Diego Medical Center	T. Savides, G. Anand
University Hospital Hamburg-Eppendorf	T. Rösch
University Hospital of Brno	P. Dite
University Hospital Santiago de Compostella	J. Iglesias Garcia
University Hospitals Cleveland Medical Center	A. Chak
University Medical Center Groningen	H.M. Van Dullemen
University Medical Center Utrecht	M.G.E.M. Ausems, F.P. Vleggaar
University of Alabama Medical Center	J. Ramesh
University of California Irvine	K. Chang
University of Colorado Denver Hospital	R. Schulick, C. Meguid, A. Paniccia, B. Brauer, S. Edmundowicz
University of Michigan Medical Center	E. Stoffel, R. Kwon
University of Nebraska Medical Center	A. Sasson
University of Pittsburgh Medical Center	D. Whitcomb, R. Brand
University of Southern California Medical Center	A. Sahakian
University of Texas MD Anderson Cancer Center	M. Bhutani, J. Lee
University of Washington	T. Brentnall
Waikato Hospital	F. Weilert
Washington University Medical Center	D. Early, T. Hollander
Western General Hospital	I. Penman
Westmead Hospital / Westwood Medical Center	V. Kwan
Yale Medicine	J. Farrell
Yonsei University College of Medicine	H. Seung Lee, S. Hoon Lee

Appendix 3: Signature page

This consortium agreement, named

'Consortium Agreement of the CAPS consortium; rules for publications, authorship, and ownership of data'

was approved by:

Name: _____

Institution: _____

Signature: _____ Date: _____