Consortium agreement

for the

Collaborative On Fatigue Following Infection (COFFI)

1. Purpose of the agreement

The Collaborative on Fatigue Following Infection (COFFI) is an international scientific collaborative of post-infective cohort studies. The over-reaching aim of COFFI is to investigate factors influencing the development of long-term symptoms (in particular fatigue) following certain infectious diseases (such as glandular fever/infectious mononucleosis). Pooling of resources, data and biological samples from post-infective cohort studies across the world is a prerequisite for achieving this aim.

COFFI was initiated in June 2015. In September 2020, a more formal organization was established, with Akershus University Hospital (AHUS), Norway, as the hosting institution. Prof. Vegard Bruun Bratholm Wyller, Norway, was appointed to succeed Prof. Peter White, UK, as leader of COFFI by the other investigators in the collaborative.

This agreement regulates the responsibilities, roles and rights of the parties in the COFFI consortium.

2. Governance

The work within COFFI is organised around six different committees/groups:

2.1 Steering Committee (SC)

The Steering Committee (SC) comprises all Principal investigators (PIs) of included cohorts as well as the 2015 founders of COFFI (whether they lead a cohort with available data and/or specimens or not) – referred to as 'partners'. Each party is responsible for informing the chair about any changes in its representation or contact information. The SC is chaired by the leader of the COFFI collaborative, currently Prof. Vegard Bruun Bratholm Wyller.

Meetings (teleconferences) will be held at least quarterly in the first year and then at least twice annually and otherwise on an as-needed basis. Project managers and other key personnel involved in COFFI cohorts as well as representatives from the Member Group and Consumer Advisory Committee (CAC) (sections 2.3 and 2.44 below) may be invited to the meetings.

SC is responsible for the following tasks:

- Oversee and coordinate all research activity within the collaborative, including precepts for sharing of data and biological samples;
- Administer authorship and research publication development guidelines;
- Review and approve concept sheets for research projects within the COFFI collaborative;

- Review and approve grant applications related to the COFFI collaborative;
- Identify other post-infective cohort studies around the world that may be invited to the collaborative and make decisions regarding new members of the collaborative.

SC has a quorum when at least half of the partners are present or participate in the vote. Decisions are normally made by simple majority among participating partners. In matters regarding changes to a party's rights according to this agreement, decisions are made by a two-thirds majority.

New cohorts may be considered for inclusion in COFFI (and the PI as a partner joining the Steering Committee) upon the recommendation of an existing partner to the Steering Committee. The considerations for such inclusion are: the partner has a collaborative relationship with the existing COFFI partner, or has expressed willingness to participate in the activities of COFFI (having read this Consortium Agreement); and the cohort has the following characteristics:

- The cohort may include natural history studies (prospective, observational, case-control), or interventional studies with a control arm in which enrolment was based on a confirmed or probable acute infection and chronic fatigue was well characterised as a post-infective outcome.
- The acute infection at onset was either *confirmed* by a laboratory diagnosis (e.g., IgG seroconversion) *or* was a *probable* diagnosis of a specific acute infection based on a clinical syndrome (e.g., mononucleosis) or on a clinical syndrome within a high risk, epidemiological context (e.g., giardia outbreak) *and all of the following*;
- Data are available to characterise the post-infective illness at least at ≥6 months post onset;
- Validated self-report questionnaires that cover fatigue *and at least one* of the following symptom domains were used: pain, sleep, mood, cognitive difficulties, autonomic dysfunction and a measure of disability/functional impairment,
- Caseness for CFS (PIFS), CFS-like illness (diagnostic criteria applied but no formal medical, psychiatric or lab assessments) or CF (questionnaire only).

These cohort characteristics are best summarised by the cohort PI completing the COFFI Cohort Description Template (see Appendix A)

For approval of concept sheets for collaborative research projects (see further detail below), a unanimous decision of the SC should be sought. Also, the PI of each cohort retains the right to veto against data or specimens from their cohort being used in a specific research project as outlined in a concept sheet.

2.2 Executive Committee (EC)

The Executive Committee (EC) comprises the head and deputy head of the collaborative, as well as a data manager, a biorepository manager, and an administrative assistant at the host institution (AHUS, cf. section 7 below).

EC will meet monthly.

EC is responsible for the following tasks:

- Daily running of the collaborative

- Communication with public stakeholders, such as politicians, policy-makers, journalists and patients' organizations
- Organize regular meetings with the Consumer Advisory Committee (section 2.4. below)

The tasks of the different EC roles are outlined in section 4 below.

2.3 Members group (MG)

COFFI members include scientists who are generally interested in post-infective fatigue research but do not lead or run a post-infective cohort study themselves. Members are nominated by COFFI Partners and membership is granted by the EC. COFFI members may be invited to join Project Working Groups (section 2.5) as well as participate in general scientific and strategic discussions within the collaborative.

2.4 Consumer Advisory Committee (CAC)

The Consumer Advisory Committee (CAC) comprises lay individuals who have first-hand experience with post-infective fatigue or chronic fatigue syndrome, either as sufferers themselves, or as next-of-kin.

CAC will meet with the EC twice annually.

CAC will provide comments and perspective on all parts of the research conducted within the collaborative, such as prioritization among projects and concept sheets, as well as publication and dissemination of results. However, the CAC exerts an advisory role only.

2.5 Project Working Groups (PWGs)

The Consortium will form Project Working Groups (PWGs). These are *ad hoc* groups arranged around one research aim that may be investigated within the COFFI collaborative.

A PWG should always include one PI or lead co-investigator. Additional group members are freely assembled as needed.

Further practical routines, meeting frequencies, etc., are decided by the group themselves.

The group should submit a research idea with a *concept sheet* (cf. Appendix C) to the SC for review and approval before the group may proceed with data analyses based on the common COFFI database and/or biobank. Comment from the CAC may be obtained before final decision in the SC.

The PWGs are responsible for drafting scientific abstracts and papers based on approved concepts sheets, and publication and dissemination of results. Authorship is granted according to guidelines as outlined in section 9 below and Appendix B, and agreed to by the PWG.

All activity in the PWGs should be reported twice annually to the EC.

2.6 Scientific Advisory Board (SAB)

The Scientific Advisory Board (SAB) is appointed by the SC, and should consist of distinguished researchers in the field who are not otherwise affiliated with the COFFI collaborative or single COFFI cohorts. The SAB should meet with the SC at least annually to advise on strategic plans. In the case of unresolvable disputes, the SAB should undertake arbitration and conciliation (cf. point 12 below)

3. Tasks of the EC members

3.1 Head and deputy head of the Collaborative

- Chair the EC and SC meetings
- Initiate and encourage research within the COFFI collaborative, especially multidisciplinary collaboration
- Foster research grant applications
- Supervise local PhD and postdoctoral fellows affiliated with COFFI

3.2 Data manager

- Communication with PIs/data managers of single COFFI cohorts
- Develop a common database for all included COFFI cohorts; facilitate data merge
- Facilitate grant applications based on the COFFI collaborative
- Develop and update COFFI website
- Facilitate data and sample access for PWGs as needed
- Oversee that COFFI research projects are conducted within accepted norms, as well as the guidelines agreed upon by the collaborative partner themselves
- Report operations, progress and milestones regularly to the SC and on the COFFI website
- Facilitate the integration of new COFFI members (as decided by the SC).

3.3 Specimen manager

- Communication with PIs/specimen managers of single COFFI cohorts
- Develop a common biobank for all relevant COFFI cohorts (either virtually or physically)
- Facilitate shipping of specimens across study sites according to material transfer agreements
- Oversee quality requirements for all shipping, storage and further analyses of biological specimen
- Develop laboratory analysis protocols as needed (as implicated from concept sheets); oversee laboratory analyses conducted on specimens in the common biobank
- Facilitate integration of biological specimens from new COFFI cohorts (as decided by the SC).

3.4 Administrative assistant

- Facilitate communications, teleconferences, circulate concept sheets
- Arrange travels, meetings, research seminars, etc.
- Administer budget, accounting, etc.
- Administer the COFFI website.
- Administer archiving, report on meetings

4. Admittance of new consortium partners and members

The SC will make decisions on admittance of new consortium partners (i.e., included in the SC) as well as members (i.e., included in the MG). All present partners must approve of the inclusion of new partners.

If inclusion is unanimously decided by the SC, the new partner is admitted by signing the consortium agreement. An entry agreement will be included as an annex to the consortium agreement.

Following inclusion in the consortium, the new partner is entitled to join the SC.

5. Responsibilities

The parties agree that projects will be conducted and documented in accordance with relevant legislation and recognized ethical norms for good and reliable research.

The parties have an independent responsibility for organizing and executing the part of the project that falls within their own institution, and ensuring that this is done in accordance with relevant legislation and based upon formal ethics and governance approvals.

6. Construction and administration of a joint data centre

An overarching aim of the COFFI consortium is to collate clinical data and biological specimens from the participating cohorts into a joint data center. Akershus University Hospital, Norway, will be the host and administrator of this joint data centre on behalf of the consortium. Future cohorts included in the COFFI consortium as well as future results that are generated from projects conducted within the COFFI framework will be included in the joint data center.

The joint data center will consist of three parts:

a) A clinical database, based on the platform Services for Sensitive Data (TSD) at the University of Oslo (https://www.uio.no/english/services/it/research/sensitive-data/index.html). This database will be established using data variables agreed upon by the SC and collated in a central database. The merged COFFI database will be made accessible via a password protected web-based interface to all cohort PIs.

b) A database of available biological specimens, also based on the TSD platform.

c) A biorepository of the actual biological specimens from each cohort. A joint biorepository will be hosted by the Epigen Research Laboratory at the Akershus University Hospital, Norway.

While these three points are considered the preferred strategy for data and specimen sharing, it is acknowledged that it may not apply to all cohorts. For instance, with regard to data sharing one approach may be to sharing of an agreed de-identified (coded) ‘minimal’ dataset with additional data available on request. This option would necessitate ongoing support from each investigator to meet data sharing requests. Similarly, with regard to specimen sharing,

shipping of biological specimens might be constrained by national policies, as well as ethical approval and limited patient consent in some of the participating cohorts. In that case, the actual biological specimens will be stored by the primary institutions, and standard operating procedures for consistent assaying of samples will be developed to ensure comparable results across laboratories. As a general rule, cohorts will be welcomed in the Collaborative even if they are not able to adhere fully to the joint data center principles as outlined above.

Data and biological material will be made available on request from consortium members for further research generated by PWG's following acceptance of a concept sheet. The project manager at the host institution will, under the lead of Prof. Vegard Bruun Bratholm Wyller or the future leader of COFFI, make recommendations on how to distribute the biological material among the consortium members, to ensure high quality studies and oversee adherence to ethical and formal regulations (cf. point 8). Any disputes arising from the availability of material will be decided by the SC.

Despite construction of a joint data center, the PI of each cohort remains fully responsible for their own data, and may veto the use of data for specific projects or purposes. Biological specimens that are shipped to a joint data center will be returned at the PIs request.

7. Data management and data access

The parties have a joint responsibility to protect personal data from unlawful processing or disclosure. Each party is responsible for the management and processing of personal data and biological material that is performed within or under the control of their own institution. The parties will ensure that all persons who are given access to personal data are familiar with and subject to the provisions of this agreement, approvals and relevant legislation.

The parties are required to ensure that inclusion, processing, storage and destruction of personal data is performed in accordance with the local regulations in the country from which study patients were included.

Further processing of personal data and biological material collated in the joint data centre will be subject to the provisions of the General Data Protection Regulation (GDPR, EU regulation 679/2016, https://gdpr-info.eu/) and Norwegian law. A Data Protection Impact Assessment (DPIA) for the collation, storage and use of collated data has been performed in accordance with Article 35 of the GDPR.

Akershus University Hospital will take the role as controller for de-identified and coded personal data and biological material submitted to the joint data centre, and make sure that storage of, and access to, data and material is conducted according to the GDPR.

When given access to data or material from the joint data centre, each party will establish and maintain an overview of all data and processing or, where relevant, a record of its own processing activities in accordance with Article 30 of the General Data Protection Regulation, and take all reasonable measures to ensure that individual-level data is accurate and updated regularly. Each party will also establish routines to erase information which is no longer needed in accordance with established routines and guidelines.

The parties agree to establish and comply with all necessary technical and organisational measures considering continued confidentiality, integrity, accessibility and robustness in the processing of personal health data to ensure satisfactory information security in accordance with the provisions of data protection legislation, and to establish necessary systems and routines to safeguard information security and follow up breaches following the unlikely event of a data breach.

At the end of a study the parties have an independent obligation to insure that personal data is stored or destroyed in accordance with the approved protocol.

8. Publication

The Parties shall secure transparency regarding the research. All significant project results shall be published.

Authorship and research publication development guidelines are included as Appendix B.

9. Background

Background means all information, ideas, methods, solutions, devices, materials, data etc. necessary for conducting a project generated outside COFFI, irrespective of whether they are or can be protected by intellectual property rights.

Ownership comprises law of properties, patents, patent applications, inventions, copyrights and other intellectual property rights.

The ownership of the background shall not be affected by this agreement. If another party's background is needed for project results, the parties may agree on collaboration. A party shall, however, not be obliged to collaborate with other COFFI members.

10. Ownership and utilisation of project results

Project results comprise all the results, information, ideas, methods, solutions, devices, materials, data etc. arising from a project, irrespective of whether they are or can be protected by intellectual property rights.

Project results shall belong to the party who has created, invented or generated it. Results created or generated jointly by > 1 party shall belong jointly to those parties.

Regardless of ownership, each party shall have a royalty-free user right to project results for non-commercial research and teaching purposes.

Each party has the right to commercialise its own project results. If the results have been obtained in collaboration between two or more consortium members, the specifics concerning distribution of rights among the parties, securing of intellectual property rights, the commercial purpose and the compensation shall be regulated in a separate agreement among the contributing institutions.

Any party who wants to commercialise project results by applying for a patent may ask to postpone publication for a maximum of 90 days.

11. Confidentiality

Confidential information is all information, including but not limited to any knowledge, trade secrets, scientific material, data, drawings, samples, specifications, devices, demonstrations, information concerning the structure, design and code of software, know-how and other materials of whatever description whether or not subject to or protected by copyright, patent, trademark, registered or unregistered or otherwise, that is disclosed or communicated in writing, orally or in electric form or that has otherwise become known to a party in connection with collaboration within the consortium.

Each party shall keep confidential information disclosed or communicated to it, directly or indirectly, in strict confidence and shall not use confidential information for any purpose other than is necessary for the conduct of the project(s). The obligation for confidentiality shall not apply if the confidential information:

a) was at the time of receipt published or otherwise generally available to the public;
b) has after receipt by the receiving party been published or become generally available to the public other than through an act or omission on the part of the receiving party;
c) was already in the possession of the receiving party without any restriction on disclosure;
d) was rightfully acquired from a third party without any agreement to confidentiality;
e) was developed independently by the receiving party; or
f) is required to be disclosed by applicable law or court order.

12. Disputes

Parties shall attempt, in good faith, to resolve through negotiations any controversy, claim, or dispute arising out of this agreement. In the event that negotiations are not successful, the controversy, claim, or dispute shall be discussed by the Steering Committee. If an acceptable solution is not found by the Steering Committee itself, the Scientific Advisory Board will be asked to act as an independent arbitration and conciliation group.

13. Duration

This agreement shall commence on the date of the last signature below and will run for 10 years. The parties may extend the term of the agreement by written consent.

A party may be excluded from the consortium by the Steering Committee within 30 days if that party is in material breach or not capable of fulfilling its obligations under this agreement.

A party may terminate its participation upon 6 months' written notification to the Steering Committee Chair, thereby waiving its rights and being released from its duties according to this agreement.

Following expiry or termination, sections 8, 11 and 12 will continue to be valid between the parties.

14. Signatures

A signature from a PI or lead-co-PI of a post-infective cohort study (or a COFFI founding partner who does not currently lead a cohort with data and/or specimens) confirms

partnership in the COFFI consortium under the conditions specified in the present agreement. Signatures are provided on separate sheets of paper, for the sake of convenience.

Each party keeps one copy of the agreement and one copy of the signature sheet (Appendix E and Appendix F).

Appendices:

A: Cohort Description Template
B: Authorship and research publication development guidelines
C: Concept sheet template
D: Note on key concepts, measures and definitions
E: Signature sheet template for PI of post-infective cohort study
F. Signature sheet template for 2015 COFFI founding partner

Appendix A

Cohort description template

Cohort description template for studies involved in Collaborative On Fatigue Following Infection

This document is designed to provide a cohort description summary to facilitate data sharing for the Collaborative On Fatigue Following Infection (COFFI).

The text in blue provide suggestions or instructions on the information to be completed in each section. Please enter your answers in the grey text box provided. Some of the information below has been pre-populated for your cohort - please check this information is correct and make any appropriate edits.

Study details

Study or cohort name (and acronym if applicable):
Principle investigator (PI):
Institution (include country):
Clinical Trials number or similar:

1. Status of cohort

Year of first enrolment:
Year of last enrolment: Please select status of study
Year of last follow-up visit Please select status of study

2. Study overview

2.1. Primary objectives of study/cohort:

Primary aim/s or objective/s of the cohort include specific infection/s that was studied.
Insert text:

2.2. Study design(s):

Indicate study design (e.g. Prospective observational, case-control, cross-sectional). If your study has multiple designs (e.g. prospective cohort which is followed by an intervention) – please provide a brief description of each.
Insert text:

2.3. Setting:

Regions/areas and country where study was conducted.
Insert text:

2.4. Population/participants:

Indicate the enrolment sample size (separated by infection type e.g. number of EBV, number other mononucleosis).
Enrolment sample size:

2.4.1. Indicate the drop-out rate (percentage of enrolment sample), including withdrawal and lost to follow up at the following timepoints:

a. 6 month; *percentage of enrolment sample*

b. 12 month; *percentage of enrolment sample*
c. Other time point/s: (please specify)

2.4.2. Did you include a comparison group? Please select

2.4.3. If Yes, select which of the following apply and indicate the sample size:

☐ Healthy control; *enter sample size*
☐ Alternative infection; *enter sample size*
☐ Family member; *enter sample size*
☐ Other (please specify):

2.5. Case recruitment

Select the check boxes that apply.

2.5.1. Potential participant identification methods:

☐ Pathology laboratories
☐ Other (specify):

2.5.2. Recruitment site(s):

☐ Population level recruitment (e.g. national registry)
☐ General practice/primary care clinics
☐ Tertiary hospitals
☐ Other (specify e.g. school):

2.6. Eligibility criteria:

Provide summary of inclusion and exclusion criteria for study.
Inclusion criteria:

Exclusion criteria:

2.7. Method of diagnosis of acute infection

Specify the diagnostic test/s e.g. Monospot, EBV IgM, EBV acute and convalescent IgG.

Insert text:

2.8. Study assessment timepoints

- Baseline: Provide a summary of the baseline assessment timepoint e.g. within x weeks of symptom onset after presentation to family doctor and serological diagnosis of acute EBV.
  Insert text:

- Follow-up timepoints: Provide brief summary of follow-up timepoints e.g. patients were reassessed at 3, 6 and 9 months post-baseline.
  Insert text:

2.9. Overview of data collection

Please note this is a summary only. We will ask for further details subsequently. Select the check boxes that apply.

2.9.1. Data collection method (further information below in 2.9.2, 2.9.3, 2.9.4)

☐ Questionnaires
☐ Interview (e.g. semi-structured, qualitative, structured)
☐ Objective assessments (e.g. actigraphy, cognitive performance)

2.9.2. Symptom domains assessed by interview or by questionnaires

☐ Fatigue
☐ Anxiety
☐ Depression
☐ Pain
☐ Sleep
☐ Gastrointestinal symptoms
☐ Neurocognitive symptoms
☐ Post-exertional exacerbation/malaise
☐ Autonomic symptoms
☐ Other (please specify)

2.9.3. Other topics assessed by interview or questionnaire

☐ Personality
☐ Disability
☐ Quality of life
☐ Social support
☐ Health care utilization
☐ Illness behaviour/perspectives
☐ Activity
☐ Occupational status (work/study)
☐ Other (please specify)

2.9.4. Other illness characteristics assessed objectively

☐ Autonomic function
☐ Actigraphy/Accelerometry
☐ Neurocognitive performance
☐ Neuroimaging (please specify)
☐ Other (please specify)

2.10. Timing and definition of fatigue state applied.

2.10.1. Caseness

Select the check boxes that apply.

☐ Caseness for prolonged fatigue (at least one month)
☐ Caseness for chronic fatigue (at least six months)
☐ Caseness for chronic fatigue syndrome (prolonged and disabling fatigue lasting at least six months, unexplained by other medical or psychological conditions)

2.10.2. Timing

If caseness for a chronic fatigue syndrome was designated more than 6 months following acute infection, please indicate when this occurred (e.g. 12 months post-acute infection onset).

Insert text:

2.10.3. Diagnostic criteria of CFS

Indicate which diagnostic criteria of CFS was applied (e.g. Fukuda, Oxford). Select the check boxes that apply.

☐ Centers for Disease Control (CDC)/ Fukuda criteria
☐ Oxford criteria
☐ Canadian Consensus Criteria (2003)
☐ International Consensus Criteria (ICC) (2011)
☐ Institute of Medicine (IOM, 2015)
Comment:

2.11. Were specimens collected? Please select

Please note this is a summary only. We will ask for further details subsequently.

2.11.1. If yes, are they <u>still</u> in storage? Please select

2.11.2. Which of the following do you have in storage?

Select the check boxes that apply.

☐ Serum
☐ Plasma
☐ Peripheral blood mononuclear cell (PBMCs), a subgroup
☐ Genomic DNA (or whole blood)
☐ Other (please specify):

3. Summary of key findings

Suggestion: key findings may be copied from manuscript abstract or COFFI paper.

Insert text:

4. Is there a data manager who could assist in sharing information and data?

Please select. If yes, name and email

5. Is there a biobank manager who could assist in sharing specimens?

Please select. If yes, name and email

6. Publications arising from study/cohort

6.1. Primary outcomes manuscripts

1.

6.2. Other manuscripts

1.

Appendix B

Authorship and research publication development guidelines

The potentially large number of contributors to COFFI require a-priori guidelines regarding authorship and publication. The present guidelines adhere to the guidelines from the International Committee of Medical Journal Editors (ICMJE, the Vancouver declaration).

Scientific abstracts and papers will be produced within the PWGs (as outlined above). The process starts with the assembly of a PWG and completion of a "concept sheet" (cf. Appendix C). The concept sheet should outline the aim of the specific investigation, the data/variables that are to be used, the planned statistical analyses, etc. After completion, the concept sheet is submitted to the SC. The SC may consult the CAC for general advices on the concepts sheets before making a final decision. The PWG should receive a decision from the SC no later than 4 weeks after submission of the concept sheet. The EC should assist the PWG with necessary practical issues, such as access to relevant data. The final version of a scientific paper should be submitted to a scientific journal no later than one year after final data analysis is completed.

The PWGs are responsible for inviting "relevant investigators" to participate in authorship of scientific abstracts and papers. "Relevant investigators" are the PI's and co-investigators from cohorts providing data that are included in a particular paper/abstract, as well as investigators outside the COFFI collaborative assembled by the PWG on an *ad hoc* basis. Authorship requires (all three conditions must be met):

a) Substantial contributions to conception and design, acquisition of data, *or* analysis and interpretation of data;
b) Drafting the article *or* revising it critically for important intellectual content; and
c) Final approval of the version to be published.

All "relevant investigators" shall be eligible as authors, but it is assumed that, as a matter of practice, each will be judicious in requesting authorship and will waive rights to authorship on articles for which their contributions or interests are marginal. The phrase "… on behalf of the COFFI collaborative" must be added to all papers arising from the collaborative with the PIs of each cohort listed in Acknowledgements.

Investigators who leave a PWG may deserve authorship on later papers because of their contribution to the design of the project early on. Investigators who join a PWG after it has begun working on a project may deserve authorship on subsequent papers. Conflicts regarding authorship that is not resolved within a PWG are to be conveyed to the SC which will make a final decision.

First authorship should be granted to the person originating and/or making the greatest scientific contribution to the particular paper. He or she will take the lead in producing the paper, and thus do most of the drafting. The first author generally should be the one who drafts the concept sheet and takes responsibility for communicating the direction of the paper (e.g., detailed outline, manuscript draft, etc.) with all co-authors throughout the writing process. Prior to submission, the first author is required to circulate a full complete draft of the manuscript for comment and feedback. The senior author will generally be granted to the PI of the cohort or laboratory leading the paper (usually that of the first author)

An acknowledgements section in each manuscript submitted from the COFFI collaborative and should include:

a) The PIs and institutional affiliations for all cohorts used in the particular study.
b) Project staff (who do not qualify for authorship)
c) Funding sources
d) Contributions from the CAC, if any

The guideline outlined here does not preclude any PI or co-investigator from publishing results based on the specific cohort of which they are affiliated.

Consistent terminology across COFFI research products is beneficial. Therefore, all authors of COFFI papers should comply with key concepts and measures as defined by the SC (cf. Appendix D)

Whenever a PWG succeeds in having a scientific paper accepted for publication, they are expected to publicize and disseminate the results to a broader audience. A plan for dissemination should be outlined in the concept sheet.

Appendix C

Concept sheet template

Project title	**Date:**
Investigators and affiliations	**Contact information for lead investigator (Cell phone, email)**
Background/rationale:	
Primary and secondary aims and hypotheses:	
Design	
Included subjects	
Data request	
Specimen request	
Statistical analysis plan and power estimate	
Anticipated results	
Dissemination plan	
Timeline	
Comments from the Consumer Advisory Committee	
Comments from the Steering Committee	

Appendix D

Note on key concepts, measures and definitions

In order to advance the field and for research to be generalizable, it is desirable to use standardized case definitions and for different groups to utilize the same and best studied tools. The case definitions of CFS used should be reported in all publications. Also, a prioritized task of the SC will be to develop a detailed list of Common Data Elements to be used in COFFI publications, analogous to the US National Institute of Neurological Disorders (NINDS) (see https://www.commondataelements.ninds.nih.gov/crf-library - search term “myalgic encephalomyelitis/chronic fatigue syndrome”)

Appendix E

Signature sheet template – PI of post-infective cohort

I hereby confirm that the <name of cohort> is participating in the COFFI collaborative under the conditions specified in the “Consortium agreement for the Collaborative On Fatigue Following Infection (COFFI)”

Date:

_____

<Responsible person>

<Title>

<Institution>

<Contact information>

Appendix F

Signature sheet template – 2015 COFFI founding partner

I hereby confirm my participation in the COFFI collaborative under the conditions specified in the “Consortium agreement for the Collaborative On Fatigue Following Infection (COFFI)”

Date:

_____

<Name>

<Title>

<Institution>

<Contact information>