**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:

Year of last follow-up visit

1. **Study overview**
	1. **Primary objectives of study/cohort:**

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

Insert text:

* 1. **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:

* 1. **Setting:**

Regions/areas and country where study was conducted.

Insert text:

* 1. **Population/participants:**

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

Enrolment sample size:

* + 1. **Indicate the drop-out rate (percentage of enrolment sample), including withdrawal and lost to follow up at the following timepoints:**
1. 6 month; *percentage of enrolment sample*
2. 12 month; *percentage of enrolment sample*
3. Other time point/s: (please specify)
	* 1. **Did you include a comparison group?**
		2. **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):

* 1. **Case recruitment**

Select the check boxes that apply.

* + 1. **Potential participant identification** **methods:**

[ ]  Pathology laboratories

[ ]  Other (specify):

* + 1. **Recruitment site(s):**

[ ]  Population level recruitment (e.g. national registry)

[ ]  General practice/primary care clinics

[ ]  Tertiary hospitals

[ ]  Other (specify e.g. school):

* 1. **Eligibility criteria:**

Provide summary of inclusion and exclusion criteria for study.

Inclusion criteria:

Exclusion criteria:

* 1. **Method of diagnosis of acute infection**

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

Insert text:

* 1. **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:

* 1. **Overview of data collection**

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

* + 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)

* + 1. **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)

* + 1. 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)

* + 1. Other illness characteristics assessed objectively

[ ]  Autonomic function
[ ]  Actigraphy/Accelerometry

[ ]  Neurocognitive performance

[ ]  Neuroimaging (please specify)

[ ]  Other (please specify)

* 1. **Timing and definition of fatigue state applied.**
		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)

* + 1. **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:

* + 1. **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:

* 1. **Were specimens collected?**

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

* + 1. **If yes, are they still in storage?**
		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):

1. **Summary of key findings**

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

Insert text:

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

. If yes, name and email

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

. If yes, name and email

1. **Publications arising from study/cohort**
	1. **Primary outcomes manuscripts**
2. 1. **Other manuscripts**
3.