Agreement

between

Oslo University Hospital

and

Sumandeep Vidyapeeth Deemed to be University

Regarding the research project:

Development of an international questionnaire to assess patient-reported quality of life related to COVID-19 disease, the Oslo COVID-19 Quality of Life Questionnaire (QLQ) - ## ©

Phase III of questionnaire development

Oslo University Hospital and Sumandeep Vidyapeeth Deemed to be University may be referred to herein individually as a "Party" or collectively as the "Parties."

1. Purpose

This agreement formalizes the collaborative work initiated by Oslo University Hospital (Cecilie Delphin Amdal (PI) and Kristin Bjordal) and the EORTC (Andrew Bottomely) in March 2020. No money has been involved before now (Table 1).

This agreement is an update of previous agreements between the partners that regulates the responsibilities of the involved Parties. Some partners have been involved from the start of the project; others have joined in phase III (Table 1, appendix 1). The agreement includes the roles and the rights of the Parties, regarding the implementation of research projects in accordance with the research protocol. A copy of the REC approval (Regional Ethical Committee in Norway) is included in this agreement.

This agreement shall ensure that the study is 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 study that falls within their own institution, and that this is done in accordance with relevant legislation and based upon formal approval.

2. Contact information

Name of the Principal Investigator (CI): Cecilie Delphin Amdal, Oslo University Hospital HF

Contact information: P. box 4953 Nydalen, NO-0424 Oslo. E-mail: cecia@ous-hf.no.

Phone:+47 1517199

Local responsible national partner: Ghanshyam Parmar, Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University

Attested CTC

30/11/2023

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

SUMANDEEP VIDYAPEETH

Contact information: Piparia, Waghodia, Vadodara-391760, Gujarat, India. Mobile: +919825963050,
E-mail: ghanshyamparmar.dop@sumandeepvidyapeethdu.edu.in, ghanstaurus22@gmail.com

3. Principalinvestigator's responsibilities(CecilieDelphinAmdal)

The principal investigator has the responsibility for overseeing the project. The chief investigator is also responsible for fulfilling the conditions in this agreement.

The principal investigator has the responsibility for making sure that the national responsible partners within the project, has access to the latest version of the study protocol, consent forms and other important documentation and approvals.

The principal investigator must facilitate a good organization and flow of information between the participating institutions via the national responsible partners. Project meetings at regular intervals will be arranged as considered necessary.

4. The responsibilities of the national partner

The national responsible partner has the responsibility for overseeing the project within the affiliated institutions in their country and make sure that the study is conducted within this agreement, including the appendix. The national responsible partner also has a responsibility of abiding by local internal routines within their country and institutions involved. The national responsible partner is required to report any discrepancies to the Principal investigator.

5. Data management and data access

Personal data collected for the purpose of the Study shall be processed in accordance with all relevant rules and regulations, decisions by public bodies, the Study protocol, this Agreement, as well as the informed consent of the research subjects to the extent that the Study relies upon participant consent.

The data is stored in a Ledidi © (https://www.ledidi.com/)which satisfies the necessary security requirements and privacy policy requirements including GDPR (https://www.ledidi.com/security/). OUH is the coordinating centre for the project, and coded information from all participants will be stored and coordinated here. Coded data will be shared with the EORTC Quality of Life Department for collaboration on the analyses.For the purpose of this study, within the Ledidi system ©, an active link is forwarded to the patients' smartphones or tables to facilitate data collection in patients in isolation/quarantine and to minimize missing data.

The Parties are responsible for ensuring that all processing of research data thatwill takes place in their own institution is carried out in accordance with the purpose, legal basis for processing, REK approval with associated approved research protocol, and other applicable regulations, including the GDPR.At the end of the project period, each of the Parties has an independent responsibility for ensuring that research data in their possession under this Collaboration Agreement, are handled in accordance with the legal basis for processing, REK approval with the associated approved research protocol, and other applicable regulations, including the Privacy Regulation.

If one of the Parties becomes aware of a breach of the security of personal data as defined in Art. 4 No. 12 of the GDPR, that Party must immediately inform the other Party. The Parties agree to cooperate to ensure that breaches of personal data security are followed up and that the notification obligation in Art. 33 and 34 in GDPR are taken care of.

Attested CTC

30/11/2023

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

SUMANDEEP VIDYAPEETH

7. Finances

Phase I and Phase II of the project has been based on voluntary work by the parties and available local funding and support within the participating institutions. Some funding for Phase I and Phase II will be sought.

For Phase III, Euro 2.000 per country will be payed to each participating country thathas completed recruitment of the planned 30 patients in phase IIIB. Euro 300 will be provided for those who recruit at least 5 patients for the test-retest. The money will be payed to the institutional account of the national responsible partner Dr. Ghanshyam Parmar.

Distribution of money between collaborators within each country will be decided locally.

8. Publication

All authors must fulfil the criteria in the Vancouver convention. In general, each country will have one co-author. In countries with 30 included patients, with more than one collaborator, an additional co-authorship is offered based on discussion with the PI. The PI for the test-re-test will have one additional co-authorship.

The Parties involved in this agreement shall secure openness regarding the research project. Both positive and negative research results from the study must be published.

Unless otherwise is stated, the Parties have the right to publish results from data collected within their institution after the main paper is published.

The PI (CDA) should be informed of plans for local publications, invited to be involved and offered co-authorship provided that the Vancouver criteria are fulfilled.

9. Ownership of the research results

Results are owned by the Party that generates them.

The Parties own results jointly if they have jointly generated them and it is not possible to establish the respective contribution of each Party, or separate them for the purpose of applying for, obtaining or maintaining their protection.

The Oslo University Hospital has the copyright to the questionnaire, but it will be made available for all users in the medical society (academic and pharma studies) worldwide without any fee.

The results from this study will be published in international peer-reviewed journals with Open Access and presented at international conferences.

10. Processing of discrepancies

Adverse medical events: Not applicable

11. Duration and survival clauses

This agreement is valid from the date of the last signature, and the duration of the agreement runs until the research study has ended. After the study end date – sections 8 and 9 in this agreement are still valid between the involved Parties.

Attested CTC

30/11/2023

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

SUMANDEEP VIDYAPEETH

12. Legal matters

The involved Parties rights and obligations in this agreement are based upon Norwegian law.Any legal disputes from this agreement will be settled in court. Oslo District Court is set as the legal venue.

13. Signature

This agreement is signed on 2 –two- copies, and each Party keeps 1 –one- copy.

On behalf of Oslo University Hospital

Cecilie Delphin Amdal

On behalf of Sumandeep Vidyapeeth
Deemed to be University

20/06/22.

Dr. Chandramani More
Registrar, Sumandeep Vidyapeeth
Deemed to be University

Attested CTC

30/11/2023

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

Appendix 1:

Table 1 Overview countries and partners involved

	Country	Partner/institution	Role
1	**Austria**	Bernhard Holzner/ Medical University of Innsbruck	**National responsible partner** Involved from start, phase I-III, planning, discussions, analyses, co-author Paper I-III Recruitment of patients phase I and IIIA and B
2	**Belgium**	Andrew Bottomley, EORTC Quality of Life Department (QLD)	**National responsible partner** Project management from start, phase I-III, planning, discussions, analyses, writing committee, co-author
3		Madeline Pe, EORTC QLD	Involved from start, protocol, phase I, statistical analyses, writing committee. co-author
4		DagmaraKulis, EORTC QLD	Involved from start, phase I-III, planning, discussions, analyses Main responsible phase II and coordinating translations, writing committee, co-author
5		Claire Piccinin, EORTC QLD	Involved from start, phase I-III, planning, discussions, writing committee, co-author
6	**Croatia**	GraciaDekanić Clinical Hospital Centre Rijeka	**National responsible partner** Involved Phase III, discussions, analyses, co-author paper III. Recruitment of patients phase IIA and IIIB
7	**Germany**	Susanne Singer University Medical Centre of Johannes Gutenberg University Mainz	**National responsible partner** Involved from start,phase I-III, planning, discussions, analyses, co-author. Responsible test-retest substudy
8		Kathy Taylor University Medical Centre of Johannes Gutenberg University Mainz	Actively involved phase I-II, planning, discussions, analyses, co-author Part of local German group
9		Melanie Schranz University Medical Centre of Johannes Gutenberg University Mainz	Involved phase I and II. Part of local German group, co-author paper II
10		Nicola Riccetti, AziendaUnitàSanitaria Locale (USL)	Involved phase I and II. Part of local German group, co-author paper II
11		Oliver Bayer University Medical Centre of Johannes Gutenberg University Mainz	Part of local German group. Discussion, co-author paper III, responsible recruitment patients phase IIIA and IIIB.
12	**Ghana**	Lambert TettehAppiah KomfoAnokye Teaching Hospital	**National responsible partner** Actively involved phase IIIA and B. Co-author paper III Responsible recruitment patients.
13	**India**	Ghansyam Parmar Sumandeep Vidyapeeth	**National responsible partner** Actively involved phase IIIA and B. Co-author paper III. Responsible recruitment patients phase III.
14	**Norway**	CecilieDelphinAmdal Oslo University Hospital	**National responsible partner** Principal investigator, project management

Attested CTC

30/11/2023

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

			responsible all phases and all parts of the project from start
15		Kristin Bjordal Oslo University Hospital University of Oslo	Senior researcher, project management. Involved all parts of the project.
16		Ragnhild S Falk Oslo University Hospital University of Oslo	Involved from start, protocol, phase I-III, statistical analyses, writing committee, co-author.
17		Kristin Hofsø Oslo University Hospital Lovisenberg diakonale høyskole	Involved from start, phase I-III, planning, discussions, analyses, co-author Paper I-III Recruitment of patients phase I and IIIA and B
18		Eirik Buanes, Helse Bergen, Haukland Sykehus HF	nvolved phase IIIB, Co-author paper III. Responsible recruitment patients phase III.
19	**Palestine**	Niveen M Abu Rmeileh, Institute of Community and Public Health, Birzeit University	**National responsible partner** Involved phase IIIA and B. Co-author paper III. Responsible recruitment patients phase III.
20	**Spain**	Juan Ignacio Arraras, Servicio de Navarro de Salud	**National responsible partner** Involved from start, phase I-III, planning, discussions, analyses, co-author Paper I-III Recruitment patients phase I and IIIA and B
21	**Sweden**	PernillaSahlstrand Johnson, Skåne University Hospital	**National responsible partner** Actively involved phase IIIA and B. Co-author paper III. Responsible recruitment patients phase III.
22	**The Philippines**	Melissa Mariano, University of the East Ramon Magsaysay Memorial Medical Center	**National responsible partner** Involved from start, phase I-III, planning, discussions, analyses, co-author Paper I-III Recruitment of patients phase I and IIIA and B
23		James H Barte, University of the East Ramon Magsaysay Memorial Medical Center	Local filipinogroup. Phase I. Co-author, paper II. Recruitment of patients phase I
24		Ma Victoria Fernandez, University of the East Ramon Magsaysay Memorial Medical Center	Local filipino group.. Recruitment of patients phase IIIA
25	**UK**	Anne Sophie Darlington, University of Southampton	**National responsible partner** Involved from start, phase I-III, planning, discussions, analyses, co-author
26		Sally Wheelwright, University of Southampton	Involved from start, phase I-III, planning, discussions, analyses, co-author
27		Samantha Sodergren, University of Southampton	Part of local UK groupInvolved Phase III, discussions, analyses, co-author paper III. Recruitment of patients phase IIIA and IIIB

Attested CTC

30/11/2023

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

SUMANDEEP VIDYAPEETH