# EXPLANATORY STATEMENT

**Practice Managers**

**Project: Project: Targeting Treatable Traits in COPD to Prevent Hospitalisations (TERRACOTTA) (Project ID: 28062)**


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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

**What does the research involve?**

Chronic obstructive pulmonary disease (COPD), a complex and heterogeneous disease, is the fourth leading cause of death worldwide and fifth in Australia. COPD was the top cause of preventable hospitalisations for chronic diseases in Australia in 2016-17. 'Treatable traits' (TTs) refers to individually assessing patients for a specified set of treatable problems, followed by the development and implementation of an individualised treatment programme. The aim of this research project is to evaluate the efficacy of a practice nurse-coordinated intervention - Targeting Treatable Traits in COPD to Prevent Hospitalisations (TERRACOTTA) – in the Australian primary care.

One or two nurses at each practice/clinic will be trained and employed on this project. The nurse will search the GP database/records and identify potential candidates for telephone interview based on their age, medical and medication history and lifestyle e.g. smoking. At the end of this

interview, those eligible/interested will be given an appointment for a face-to-face interview at the clinic. Written informed consent will be sought by the nurse during the face-to-face meeting, after provision of study information and opportunities for any questions. A questionnaire comprising previously validated scales will be used to collect the data. Smoking status will be confirmed using a handheld carbon monoxide breath test device. Spirometry will be performed to confirm the diagnosis of COPD and to check the lung function. The assessments and full interview for each participant will take up to half an hour. Depending on the group your clinic is allocated to, participants will receive educational materials or community-based care based on their multidimensional assessment from a team of health professionals. In both groups the practice nurse will be responsible for coordinating each participant's care. All participants are to be followed up at 6 and 12 months from baseline, where the measures are repeated.

Nurses in both groups will be provided training to identify and recruit eligible participants, carry out data collection and coordinate the care. Nurses in the intervention clinics will also receive training in multidimensional assessment of participants at baseline to characterise treatable traits (TTs) across pulmonary, extrapulmonary, and behavioural/risk factor domains and coordination of specific evidence-based interventions. Training on recruitment of eligible participants, data collection and coordination of care will last approximately two (2) hours. Multidimensional assessment to characterise treatable traits (TTs) across pulmonary, extrapulmonary, and behavioural/risk factor domains and coordination of specific evidence-based interventions will be an additional two (2) hours and offered only to those delivering the TERRACOTTA intervention.

In collaboration with GPs, trained nurses in the TERRACOTTA intervention clinics will coordinate mobile phone-based individualised risk reduction support, home-based pulmonary rehabilitation, home medication review by a pharmacist, written action plans for COPD management, smoking cessation support and referrals to other professionals. It is expected that this will take approximately one hour per participant.

**Why were you chosen for this research?**

General practice clinics have been identified in consultation with the Primary Health Networks and through our contacts in primary health networks. General practice clinics with at least 500 patients in their database and that have a practice nurse or are able to accommodate a practice nurse have been targeted. Your practice has been nominated as a potential site for recruitment of participants for this research project.

**Source of funding**

This project is funded by the GSK through the Investigator Sponsored Scheme (ISS) 2019.

**Consenting to participate in the project and withdrawing from the research**

Consenting to participate in this project involves issuing the researchers a permission letter outlining your interest in participating in the project. This letter should be on your organisation's letter head signed by an authorised person. The template for the permission letter is attached. Participation in any research project is voluntary and you may withdraw from further participation without being disadvantaged. Your decision to participate or participate and then withdraw will not have any implications on your organisation's relationship with the investigators or Monash University or the partner organisations. In case you withdraw from further participation in the project, we would like to use data already collected from your practice/patients.

**Possible benefits and risks to participants**

TERRACOTTA has the potential to improve respiratory health and thus reduce mortality, morbidity and healthcare costs; it can also improve the quality of life of patients with COPD and can make valuable contributions to 'Promoting and Maintaining Good Health' of Australians.

We do not foresee any risks to your organisation from participating in this project. Inconvenience and/or discomfort from participation in this project will be minimal. You may provide a room or private area for the nurse for conducting patient consultations at times convenient for the practice. The nurse will require access to the medical records of the participants to work with the General Practitioner to optimise their management of COPD and provide smoking cessation support.

**Payment**

Clinics will be paid according to group allocation. Intervention (TERRACOTTA) clinics will be paid $1000 per participant recruited and followed up. Control clinics will be paid $500 per participant recruited and followed up. In addition, clinics will be reimbursed staff time for training and administration of the project (up to $2,500 in control clinics and up to $5,000 in TERRACOTTA clinics). The project will also up-skill primary care health professionals to provide optimal care of COPD beyond the project.

**Confidentiality**

The practices or participants will not be named or identified in any report or publications resulting from the study. No potentially identifiable information will be included in any publications or presentations. Only group results will be published.

**Storage of data**

According to the University regulations, the data will be stored for 5 years and kept in a locked cupboard or filing cabinet at the clinic. An electronic copy of the data will also be stored in a password protected computer. The researchers involved in the study will only have access to de-identified data.

To dispose the information at the end of this period, all electronic copies of files will be permanently deleted; the hardcopies documents will be shredded and disposed placed in a confidential bin for destruction. Any identifiable information about the participants will be removed from the documents prior to disposal.

**Use of data for other purposes**

We may contact the patients for further follow-ups in the future. Separate consent will be sought for this purpose from each participant at the time of enrolment and will be subject to ethics approval being granted.

**Results**

A report summarising the findings will be submitted to each practice at the end of the project. The results of this project will be published in peer reviewed healthcare journals, which will also be forwarded to participating clinics.

**Complaints**

Should you have any concerns or complaints about the conduct of the project **(Project ID: 28062)**, you are welcome to contact the

Executive Officer, Monash University Human Research Ethics (MUHREC):
Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Building 3e; Research Office
Monash University VIC 3800
Tel: 03 9905 2052 Email: muhrec@monash.edu Fax: 03 9905 3831

Thank you,

**Johnson George**

(Insert letterhead of the organization giving permission)

PERMISSION LETTER

**Project: Targeting Treatable Traits in COPD to Prevent Hospitalisations (TERRACOTTA) (Project ID: 28062)**

Date

Dr Johnson George
Senior Lecturer
Centre for Medicine Use and Safety
Monash University (Parkville Campus)
381 Royal Parade, Parkville
VIC 3052, Australia

Dear Dr George,

Thank you for your request to recruit participants from (organization) for the above-named research.

I have read and understood the Explanatory Statement regarding the research project

**(Project ID: 28062 Targeting Treatable Traits in COPD to Prevent Hospitalisations [TERRACOTTA])**

) and hereby give permission for this research to be conducted.

We are aware that part of the practice nurse role will require specific training, accessing patient medical records recruitment of participants and coordination of care. We thus allow the practice nurse to access patient health information from our medical records on the agreement that patient confidentiality will be maintained and data will not be used for any other purpose. Only de-identified data will be shared with the researchers.

We look forward to collaborating with the research team.

Yours sincerely

(Signature of person granting permission)

(Name of person granting permission)

(Position of person granting permission)