

ADVISORY COMMITTEE CHARTER

Protocol Title:	SARS-CoV-2 Vaccination for COVID-19 Disease Safety Study (VAC4COVID Study)
Document date	22 nd February 2021
Sponsor	University of Dundee

VERSION 1.0

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1 Mission of the Advisory Committee

The mission of the VAC4COVID Advisory Committee (AC) is:

- to oversee the appropriate scientific and ethical conduct of the trial
- to advise on the conduct and analysis of the study
- to approve all publications and sub-studies

The Committee will fulfill its mission through meetings, teleconferences and e-mailings. The Advisory Committee will be made up of key study personnel, Sponsor representative invited experts, member(s) of the lay population and representatives (PIs) from other participating countries. The Advisory Committee will meet as frequently as required.

2 Members of the Advisory Committee

Composed of:

- Key members of the study team
- Other experts as deemed appropriate.
- Member(s) of the lay population
- PI or other delegated individuals from study teams in other participating countries as appropriate

There will also be observers present at meetings who will be invited as and when needed depending on the stage of the study and the issues which are to be discussed. They will be eligible to attend meetings but, will have no voting powers. Additionally, experts can also be invited to attend meetings as observers on the request of the Study Management Group.

The Advisory Committee will be composed of the following roles, and the membership detailed in a separate trial committee listing. Any changes will be noted in this document.

The AC will be composed of the following roles:

Role
Advisory Committee Chair
Chief Investigator
Country PIs (as appropriate)
MEMO Research Senior Research Manager
Experts in vaccine safety, epidemiology and pharmacoepidemiology as deemed appropriate
Lay person (at least one)
Study Statistician (at least one)
Sponsor representative (Observer status)
VAC4COVID Project Manager (Observer status)

All Members will approve the AC Charter before attending meetings.

3 Role of an Advisory Committee Member

It is intended that the Advisory Committee draws on the experiences, expertise, and insight of key individuals.

Advisory Committee members are not responsible for managing the day-to-day trial activities.

This means they:

- Provide a peer-review forum for the study.
- Facilitate the smooth running of the study.
- Raise awareness of the study amongst clinicians and relevant health care professionals.
- Provide scientific and technical advice when needed.
- Provide advice on how to maximise the recruitment of participants.
- Scientifically monitor the progress of the study on issues such as collection of data, cohort accrual rates, dropout rates etc.
- Provide advice on and discuss any queries and issues related to the study, for example sample size calculation, patient recruitment and questionnaires.
- Advise on how to meet the trial objectives.
- Balance conflicting priorities and resources to optimize study goals
- Approve publications and sub-studies related to the trial according to the Study Publications Policy

4 Advisory Committee Meetings

5.1 General

- The Advisory Committee will meet annually or as required to keep track of issues and the progress of the Trial.
- The Study Project Manager will organise and schedule the meetings.
- The chair of the Advisory Committee will review and approve the Agenda for Advisory Committee Meetings.
- An Advisory Committee meeting can be held with a quorum of voting members which is greater than 50%.

5.2 Meeting Schedule and Process

- At each meeting, the trial status will be reported to the members.

- Members will be circulated the agenda and any relevant documentation in advance of the meeting.

5.3 Decision Making and Voting


- The Advisory Committee can reach decisions through either consensus or voting.
- In the event of a tied vote the Chief Investigator will have the casting vote.

6 Intellectual Property

The study results will be presented at scientific meetings and will be submitted for one or more peer-reviewed publications at the discretion of the Advisory Committee. Any research papers produced over the course of the study will be approved by the Committee prior to publication.

Proposals for sub-studies will be presented to the Advisory Committee (either at meetings or by e-mailings). These will be approved by the Committee prior to commencement.

7. Charter Approval

Name	Signature	Date
Prof Lewis Richie Chair VAC4COVID Advisory Committee	Approval confirmed by email (See next sheet)	28-02-21
Prof Tom MacDonald Chief Investigator VAC4 COVID Study		25-02-21 (Approved verbally at VAC4COVID team meeting and recorded in minutes)

From: 'Lewis Ritchie' <l.d.ritchie@abdn.ac.uk>
Date: Sunday, 28 February 2021 at 18:45
To: "Wendy Saywood (Staff)" <W.Saywood@dundee.ac.uk>, Tom
<t.m.macdonald@dundee.ac.uk>
Cc: "Margaret Barton (Staff)" <m.barton@dundee.ac.uk>
Subject: Re: VAC4COVID Advisory Committee Charter for formal approval request

Dear Wendy

Content.

Best wishes and thanks
Lewis

From: Wendy Saywood (Staff) <W.Saywood@dundee.ac.uk>
Sent: 28 February 2021 12:59
To: Thomas MacDonald (Staff) <t.m.macdonald@dundee.ac.uk>; Ritchie, Lewis
<l.d.ritchie@abdn.ac.uk>
Cc: Margaret Barton (Staff) <m.barton@dundee.ac.uk>
Subject: Re: VAC4COVID Advisory Committee Charter for formal approval request

Dear Tom and Lewis

I know that the attached Advisory committee charter for the VAC4COVID study has been informally approved by both of you, but to tick all the boxes it does need to be signed off officially by both of you as CI and Chair of Committee respectively.

As such, please can you confirm by email that you approve this version of the charter (version 1.0, 22-02-21)? Or if its easier print the approvals page, sign and scan the page back to me.

Once formally approved it can then be sent officially to the potential members of the Committee so that they can too can confirm they are happy to participate in line with the document.

Thanks in advance
Best wishes
Wendy

Wendy Saywood
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<https://www.vac4covid.com/>

