

RE: Recruitment of pre-menopausal females to the favipiravir arm of Principle

PRINCIPLE Study <principle@phc.ox.ac.uk>

Thu 10/7/2021 12:25

To: Hannah Swayze <hannah.swayze@phc.ox.ac.uk>

Dear Investigator,

RE: recruiting of pre-menopausal females to the favipiravir arm of Principle

The MHRA have requested that the PRINCIPLE trial includes a 'highly sensitive pregnancy test' as part of the screening procedures in Women of childbearing potential who will be receiving potentially teratogenic medicinal products – favipiravir.

We are currently developing a process for having this in place and until then, we are temporarily excluding anyone who answers 'Yes' to the screening questions 'Are you a pre-menopausal female that is capable of becoming pregnant' or 'Do you have a female sexual partner who is pre-menopausal and capable of becoming pregnant'.

The online screening form is currently being updated to exclude these participants.

We will be in touch again when screening has re-opened to all aged 18 and over and update you as to the system.

Many thanks for your continued help and support with the PRINCIPLE Trial,

Sincerely,

The PRINCIPLE Trial Team