

Hello ENSEMBLE participant!

As you've no doubt seen, the FDA Vaccines Advisory Panel unanimously approved Johnson & Johnson's Emergency Use Authorization (EUA) request on Saturday, 27 February. There are a few upcoming changes to the way we run the study soon.

What does this mean for me?

Certain subjects have already been "unblinded," that is, told whether they received the investigational vaccine or a placebo with no vaccine in it. At the moment, we on the study team are only allowed to unblind subjects who are already eligible to receive an EUA COVID-19 vaccine through their state of residence or their workplace and have not already received an EUA COVID-19 vaccine.

However, this will be changing very soon. Once the upcoming protocol amendment is approved, we will be able to unblind all of our research subjects, and we will be offering the investigational vaccine to subjects who were randomly assigned to the placebo group. Please note that this amendment has not yet been approved, so unblinding requests from subjects who are not otherwise eligible for an EUA COVID-19 vaccine will not be processed until the amendment is approved. We anticipate the approval to come through sometime this week, and we will be sending out another mass e-mail to everyone once we know more.

Can I stay in the study even after I get the J&J COVID-19 vaccine from you (or if I got the vaccine back in November/December)?

Yes! All of our subjects are encouraged to remain in the study through the follow-up period. Will I get a letter or card documenting that I was vaccinated?

We have a temporary letter that can document your vaccination status, but it does not contain information about the EUA. We ask that if you do not require documentation for work or travel please wait until we have more information.

How will I find out when I'll be getting vaccinated?

We will be vaccinating our subjects roughly in the same order as the Massachusetts roll-out plan. That is, high-risk populations and elderly subjects first, then older adults and subjects with 2+ comorbidities, and so on. We will reach out to you when we are vaccinating your group. We kindly ask for your patience while we work our way through the list to contact everyone.

Can I get another COVID-19 vaccine, even if I've received the J&J COVID-19 vaccine?

Because there is no information regarding the use of multiple COVID-19 vaccines, we are discouraging subjects from receiving another EUA COVID-19 vaccine if they receive the J&J vaccine. Likewise, subjects who have already received an EUA COVID-19 vaccine will not be eligible to receive the J&J vaccine through this study.