

Adalimumab in Juvenile Idiopathic Arthritis-associated Uveitis Stopping Trial (ADJUST)

ADJUST PPM #10

21 July 2021

TO: ADJUST Co-investigators and Lead Coordinators

RE: ADJUST PPM #10: Protocol v1.4 and updated informed consent/assent forms

The ADJUST Protocol has been revised and approved by the DSMC, the UCSF IRB, and UK MHRA. Attached, are all the documents that include these revisions. The ADJUST MOP has been updated to reflect these changes as well. Please note the following modifications:

1. For screening and follow-up, the frequency of lab collection is now customized for patients on antimetabolites vs. on adalimumab only. The screening lab requirement will be expanded to within 180 days prior to enrollment for patients not on antimetabolites. The requirement remains 90 days if a patient is on a concurrent antimetabolite. Following enrollment, lab frequency will be decreased to every six months for those not on antimetabolites and stay at every three months for those on antimetabolites. This change is consistent with standard-of-care laboratory monitoring and reduce the burden for our patients.
2. We removed the inclusion criteria of a recent tuberculosis (TB) test and now require that a TB test be conducted at baseline, if not collected in the last 12 months. Indeterminate test results should yield follow-up testing, and patients who test positive should receive appropriate medical care.

US clinics, please submit the UCSF IRB Outcome Letter, updated protocol, and the stamped informed consent and assent forms to your local IRB. We will provide the localized stamped forms to each site in a follow-up email, and they are also available for download on the website.

UK clinics, we will provide approved Amendment #13 packet and the localized forms to each site in a follow-up email. Please note, this amendment was determined to be non-substantial, so it did not receive full committee review. Please submit the updated protocol, consents, and approved Amendment #13 packet to your local R&D department.

For Australian clinics (other than RCH), please await the approval letter from HREC, which RCH is submitting this week. Upon approval from HREC, we will circulate for submission to your local R&D department.

If you have any questions regarding this PPM or the updated documents, please contact Kathryn Dudum (Kathryn.dudum@ucsf.edu; 415-476-6687). As always, our Coordinating Center team is available to support you: Elia Rubio (elia.rubio@ucsf.edu; 415-476-3099), Jason Richards (jason.richards@ucsf.edu; 415-514-9412).

Thank you,

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Attachments:

Summary of Changes v1.4
ADJUST Protocol v1.4_tracked
ADJUST Protocol v1.4
ADJUST MOP v1.4
UCSF IRB Outcome Letter for ADJUST Protocol v1.4
IRAS 259372 - Amendment 13 Packet