



Manual of Operations (MOP)

Section 23. Results To Participants

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23.1 OVERVIEW

The primary outcome of the D2d study will be presented publicly at the American Diabetes Association (ADA) conference on Friday, June 7th, 2019 (11:30 am to 12:30 pm PT). A simultaneous publication in a major medical journal is planned. All participants will receive a letter that summarizes the D2d study results. The timing should be such that participants receive the letter the same day the results are announced at the ADA.

Prior to public announcement of the results, all site investigators and staff must maintain strict confidentiality of the results; for this reason, the results letter will not be made available any earlier than necessary.

23.2 TIMELINE OF D2d STUDY RESULTS ANNOUNCEMENT PROCESS

1. The CC and the Public Relations offices of Tufts Medical Center and NIDDK and will work together to develop the press release.
2. Based on the press release, the CC will prepare the “*D2d results letter to participant*” and submit to the Tufts Medical Center IRB for review and approval (mid May). When the final version of the result letter for participant is available, the CC will send each site the D2d results letter along with the Tufts Medical Center IRB approval letter and the press release. The local IRBs only need to review the results letter to participants and will be expected to do so rapidly so that the site coordinator can send out the letter to participants in a timely fashion.
3. The D2d results letter will be mailed out to all participants on Thursday, June 6th, 2019, one day before the public presentation of the study results on Friday, June 7th, 2019.
4. At the conclusion of the ADA presentation, the results will be posted online at d2dstudy.org (the link will be provided in the letter to participants).
5. The Press Release will become available to the media prior to Friday, June 7th, 2019, but with an embargo until 12:30 pm Friday, June 7th, 2019.

23.3 COMMUNICATING D2d STUDY RESULTS TO PARTICIPANTS

The CC will send sites the “D2d results letter to participant” (Appendix 1) to submit to the local IRB and mail to participants upon IRB approval, but no earlier than the date specified above. The CC will instruct site staff to:

1. Mail “D2d results letter to participant” (Appendix 1). The letter should be sent to all participants who did not withdraw participation. The letter will:
 - Summarize the D2d study results
 - Include the registry information and where to find updates on a potential future study

NOTE: If you have extra Registry cards and return envelopes that you can include for participants who have not yet registered, please be sure to write each participant ID on the registry card prior to mailing

2. Work with the site Investigator and site public relations department to organize a press release using the “D2d Press Release template” (Appendix 2). Sites may add the local contact information to this template but cannot change the text to ensure consistency across all D2d related media publications.

If the primary site coordinator is unavailable at your site, it is the Investigator’s responsibility to ensure that all letters are mailed out to participants. The D2d Steering Committee has determined that participants should receive the overall study results as soon as they are made public; therefore the tight timeline described above must be adhered to.

***Please note:** The results that are described in the “D2d Results letter to participant” should remain strictly confidential until publication/presentation. Please do not share or discuss the results with other staff members at your site until after the ADA presentation.

23.4 APPENDICES

Appendix 1 D2d results letter to participant

Appendix 2 D2d press release template [pending]