

ALLIANCE FOUNDATION TRIALS, LLC

AFT SDC at Mayo Notice - Temporary RAVE data entry instructions for Biospecimens on AFT trials

Dear AFT Investigators, Site staff, Monitors, Partners and Colleagues,

The AFT SDC at Mayo has provided the below instructions due to limited operations of the AFT Biospecimen Repository (BioMS) and other biospecimen repositories. Please refer to the [AFT BioMS public page](#) for up to date information.

The following instructions should be used when entering specimen collection and submission information on any RAVE Specimen Submission form for AFT trials:

1. If a biospecimen was collected and shipped per protocol, enter data as it would typically be recorded.

2a. If a biospecimen was NOT collected due to patient or physician decision related to COVID-19 enter data as follows:

Was specimen submitted?	No
If no, why was specimen not submitted?	Patient unable to submit sample

2b. Additionally, document the missing sample on the Deviations form as follows

Type of deviation	Other
Description of deviation	Missed collection was due to COVID-19

3. If a biospecimen was NOT collected or submitted due to a Biospecimen Repository closure or limit of operations enter data as follows:

Was specimen submitted?	No
If no, why was specimen not submitted?	Other
If not submitted for another reason, please specify	specimen not submitted due to a COVID-19 related biospecimen repository closure

IMPORTANT NOTE: If the specimen could be submitted to the repository at a later date, you MUST go back into the appropriate specimen submission form and update the information to reflect the shipment.

NEW COVID-19 FORM

Over the next several weeks, you may notice the addition of a new COVID-19 form for each of your patients at the subject level in Rave. *This form will be used to document the following:*

- * a participant's COVID-19 testing history
- * missed and delayed visits
- * treatment discontinuation
- * study discontinuation due to COVID-19

Additional instructions on the use of this form will be distributed closer to the time of implementation. In the meantime, please continue documenting any COVID-19 related deviations, including missed or

canceled visits, on the Deviation form.

If you have any questions about the specimen submission form data entry or the new COVID-19 form, please contact your study Data Manager.

Thank you,

Daniel G Jones, MSN RN
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Alliance Foundation Trials, LLC

AFT BioMS Public Web page:

<https://cbmiapps.wustl.edu/confluence/display/COVID19+Updates+AFT+Biorepository+Closures>

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