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PERSONAL AND CONFIDENTIAL
Via Email and Regular Mail

January 19, 2021

We have received numerous email communications from you. I am aware that you have not been satisfied with our response to your questions about the clinical trial in which you are currently enrolled. Please allow me to respond on behalf of your Jefferson study team.

I would like to be clear that we have provided you with accurate information and have communicated with the sponsor, Galmed about your requests throughout your participation in the clinical trial. In response to your recent requests, we have confirmed with Galmed that in order to continue in the clinical trial you will need to participate in the next study visit by coming to the office in person to complete the required study procedures, as per the study protocol. For this requirement you will need to undergo: an EKG, a blood draw for study labwork, a physical exam and assessment, and a study medication review. You will need to bring your study medication and empty bottles to the visit. We are unable to waive this study requirement. As we have discussed with you, this study visit needs to be completed during the time period stated in the study protocol. Please let us remind you that January 25th is last possible date for you to come in for this study visit in order to be compliant with the protocol and remain in the study.

We appreciate that you are hesitant to come in person to Jefferson for the study visit. We understand your concerns about COVID-19 and have taken numerous precautions for your safety. Staff attending to you will be wearing personal protective equipment including masks. In addition, we are willing to make other reasonable accommodations to keep you safe during this visit. These accommodations include: you will text us when you arrive at Jefferson in the downstairs lobby ; we will meet you at the elevator and take you directly into a patient room avoiding any public areas; we will limit the number of study staff meeting with you, and we will have the same staff member that you requested draw your blood. We are not able to accommodate your request for a COVID-19 vaccination. As your study team, we are unable to provide you with COVID-19 vaccination. The COVID-19 vaccination is not a study requirement and

we do not have access to this vaccine for study subject administration. We recommend that you speak with your primary care doctor about receiving the vaccine.

As a reminder, you voluntarily consented to be in this clinical trial. The fact that this clinical trial has a placebo group was clearly explained to you at the time of your informed consent. Because this clinical trial has a placebo group, you were aware that you may not be getting the study drug, but may receive the placebo. In addition, we have told you on numerous occasions that we at Jefferson do not know whether you are receiving the study drug or the placebo and we are not permitted to learn this given the study design.

We also know you are very interested in the study amendment. The amendment of the current protocol is still in being developed by Galmed and will not affect your current study procedures/protocol requirements.

Moreover, at the time of your consent, you were made aware that being in the clinical trial was not the same as treatment. Treatment is designed to specifically benefit an individual patient, whereas a clinical trial is designed primarily to obtain data from a group of individuals. We value your participation in the clinical trial to further science while recognizing that you may not benefit from your participation. Until the clinical trial is concluded, we have no way of knowing whether the study drug is any more effective than the placebo.

We understand if you elect not to attend the study visit. Your wellbeing is our priority and we want you to consider your comfort level and safety first. However, if you decide not to make the required in-person study visit by January 25th, you will be removed from the clinical trial, since this will constitute a definitive deviation from the protocol. We have tried our best to accommodate your requests, but cannot change the clinical trial protocol, including the type of study visits that are required.

Please be advised that ending your participation in the trial will not affect your status as a Jefferson patient, and there is no penalty to you for withdrawing.

I am sorry to learn of your mental anguish that you have indicated you are experiencing because of your participation in this clinical trial. There will be promising treatments in the future for NASH and you will be able to consider them with your physician.

Please also know that I am aware that you have communicated with various leaders at Jefferson about your concerns related to your participation in this clinical trial. On behalf of Jefferson, we thank you for sharing your concerns and want you to know that we take our study subject's comments very seriously. Jefferson is committed to maintaining good research practices. In response to concerns like the ones you have expressed, Jefferson is continually reviewing and enhancing its practices.

In addition, we thank you for sharing with us your communication with the IRB of record, WIRB, with us. We will follow up with WIRB to address your concerns.

To ensure the most effective communication, please direct all further communications regarding the study directly to me, the primary investigator of the study. I will share the needed information with the rest of your study team.

Sincerely,

[redacted]

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