Clinical Research Protections
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Institutional Review Board
Notification of Continuation Approval

Date: June 16, 2020

To: Trilokesh Kidambi, M.D, Principal Investigator
City of Hope - Department of Medicine

From: Milda Plioplys, Director
Clinical Research Protections

COH Protocol # /Ref #: 18321 / 191676

Protocol Title: Safety of endoscopy in patients with suspected graft versus host disease after stem cell transplant

Regulatory Sponsor:

Sponsor #:

Type of Review: Expedited Review under 45 CFR 46.110(b) and/or 21 CFR 56.110(b) Category 5

Action Date: 06/15/2020
Action: APPROVED

Expiration Date: 06/14/2021

This protocol has been reviewed and approved by the City of Hope (COH) Institutional Review Board (IRB). Conditions set by the IRB, if any, for approval of this protocol have been met and the criteria for IRB approval set forth at 45 CFR 46.111 and/or 21 CFR 56.111 have been satisfied.

Please note the following:

This protocol is open to analysis of previously collected data only.

As Principal Investigator, you are responsible for the following:

1. Submission via IRIS of any and all changes to this protocol (e.g., protocol, recruitment materials, consent form, study completion) to the IRB for review and approval before the change can be implemented, except where necessary to eliminate apparent immediate hazards to the participant(s). Changes made to eliminate apparent immediate hazards to participants must be reported to the IRB via IRIS within 24 hours.
2. Submission via IRIS of any and all serious adverse event(s) that occur during the course of this protocol in accordance with the IRB's policy on adverse event reporting.
3. Submission via IRIS of any and all unanticipated problems involving risks to participants or others.

4. Use of only IRB approved copies of the protocol, consent form(s), questionnaire(s), letter(s), and advertisement(s) in your research. Do not use expired consent forms.
5. Informing all investigators listed on the protocol of changes, adverse events, and unanticipated problems.
6. Submission via iRIS to the IRB of any action by the sponsor, funding agency or FDA, including warnings, suspension or termination of your participation in this trial.
7. For studies which continue beyond one year, submitting a request via iRIS to the IRB for continuing review and re-approval of the research project prior to expiration of the IRB's approval period.
8. If this study is completed or otherwise ends before completion within the approval period, you are required to submit a Study Closure form in iRIS. The study is considered completed when:
    a. Investigators will not contact subject for further information related to this project.
    b. Access to subject health care records and use of individually identifiable information are no longer required for information related to this project.
    c. All IRB requests for information have been completed and no longer require an investigator response.

If you have questions or concerns about this submission, please contact Diana Ontiveros or IRBeSubmit@coh.org.