

### APPROVAL

<b>Principal Investigator:</b>	Katherine Kutney
<b>Title:</b>	Hepatic steatosis in patients with cystic fibrosis related diabetes: a cross sectional analysis.
<b>IRB Number:</b>	09-16-01.
<b>Submission Number:</b>	CR00001911
<b>IRB Office:</b>	UH IRB
<b>Approval Date:</b>	6/18/2019
<b>Effective Date:</b>	6/18/2019
<b>Expiration Date:</b>	6/17/2020
<b>Type of Submission:</b>	Continuing Review
<b>Type of Review:</b>	Expedited
<b>Documents Reviewed:</b>	<ul style="list-style-type: none"> <li>• Assent.pdf, Category: Consent Form;</li> <li>• Consent for modification 3.20.19, Category: Consent Form;</li> </ul>

The IRB reviewed this submission.

- Per Federal regulation, changes MAY NOT be made to any element of the current research without prior IRB approval, except to eliminate an immediate and apparent hazard to subjects enrolled in the study.
- Per Federal regulation, the research may not continue beyond the Approval End date. You must submit a continuing review form 6-8 weeks before this Approval End date in order to maintain IRB approval. Failure to maintain IRB approval is human subjects non-compliance. Please note that even if your study falls into a category that does not require an Approval End date, the institution may require a yearly “check-in” to confirm the status of the study.

\*\*\*Approval by the IRB does NOT mean that you have permission to start your study. Prior to starting your study, you may be required to obtain (1) a coverage analysis for studies that involve patient care, regardless of source of funding, and/or (2) a contract with the Sponsor of your study or an agreement with any third-party collaborator that may receive UH or CWRU patient information in any format. Please ensure that all required approvals are obtained before initiation of research activity. \*\*\*

*The UH IRB operates under HHS Federalwide Assurance (FWA) number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600. The CWRU IRB operates under DHHS FWA00004428 and IRB registration number 00000683.*



## **IRB Administration Offices**

---

UH IRB Phone: 216.844.1529

CWRU IRB Phone: 216.368.6925

*The UH IRB operates under HHS Federalwide Assurance (FWA) number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600. The CWRU IRB operates under DHHS FWA00004428 and IRB registration number 00000683.*