



CONTINUING REVIEW APPROVAL

DATE: November 06, 2020

TO: T Jake Liang
NIDDK - DK - Liver Diseases Branch

FROM: National Institutes of Health (NIH)
Institutional Review Board (IRB)

RE: **IRB #:** 91DK0214
Sponsor #: NA
iRIS Reference #: 550677
Evaluation of Patients with Liver Disease

Approval Date: 11/05/2020
Expiration Date: 11/04/2021
Review Level: Full Board (11/05/2020)
Subjects Approved: 8000
Risk Level: *Greater than Minimal Risk - 45 CFR 46

This continuing review was reviewed and Approved under the National Institutes of Health's Federalwide Assurance (FWA00005897) in accordance with Federal regulations (45 CFR 46)

The following regulatory determinations apply:

Pediatric Risk:
(45 CFR 46.404): Not greater than minimal risk

***Assent:**
Assent from some or all under 45 CFR 46.408/ 46.116/ 21 CFR 50.55

Parental Permission:
One parent signature

Pregnant Women/Fetuses/Neonates:
Inclusion of pregnant women approved under 45 CFR 46.204 (Minimal Risk)

***Adults Who Are/ Become Decisionally Impaired:**
Category A- Category A: Research not involving greater than minimal risk



***Surrogate Consent:**

Use of LAR / Next of Kin

Documentation of Informed Consent:

Written consent in accordance with 45 CFR 46.117

Waiver of Informed Consent:

Waiver/alteration approved 46.116(c) or (d)

*** indicates regulatory determination is new or has changed**

Federal regulations and NIH policy require prompt reporting of any unanticipated problems involving risks to subjects or others, or serious harm involving subjects, to the IRB. In addition, changes in research activities may not be initiated without prior review and approval by the IRB, except when necessary to eliminate apparent immediate hazards to subjects.

If you have any questions, contact the IRB Office at 301-402-3713 / email: IRB@od.nih.gov.