



April 2, 2020

Principal Investigator: Anita Kohli, MD
Sponsor: Arizona Liver Health
Protocol Number: COVID-19 HIV Registry Protocol
Study Title: "COVID-19 HIV Registry Protocol"

Dear Dr. Kohli:

The above-referenced study has been determined by Matthew Pfeiffer, Ph.D. to be exempt according to 45 CFR 46.104:

Exempt Category #2

Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR:

- (1) Submit for review by IntegReview all modifications to the protocol or consent form(s), when applicable, if planned changes to an exempt study might make that study non-exempt from human subject's research, prior to the implementation of the change;
- (2) Protect the confidentiality of all personally identifiable information collected and train your staff and collaborators on policies and procedures for ensuring confidentiality of this information;

If you have any questions please feel free to contact our office at 512-326-3001.

Sincerely,
Angelica Martinez, CCRP
IRB Operations Specialist

Electronically signed by Angelica Martinez, CCRP on 4/2/2020 2:31:01 PM

Note: Electronic signature above is a Part 11 compliant signature produced via IRBManager.

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IRB Registration Numbers: IRB00008463, IRB00003657, IRB00004920, IRB00001035, IRB0000

