



RIS Protocol
Number: 35229

Approval Date: 12-Nov-20

PI Name: Dr Shelley Craig

Division Name:

Dear Dr Shelley Craig:

Re: Your research protocol application entitled, "Project AFFIRM: Delivering affirmative coping skills programs to prevent HIV and Hepatitis C"

The HIV REB has conducted a Delegated review of your application and has granted approval to the attached protocol for the period 2020-11-12 to 2021-11-27.

If this research involves face-to-face (F2F) in person research, please note that REB approval alone is not sufficient to commence research. You must wait for an approval letter from the F2F COVID-19 Review Committee. The approval letter will be sent to the Principal Investigator's email address once the Committee has deemed the F2F in-person research ready to start.

Please be reminded of the following points:

- An **Amendment** must be submitted to the REB for any proposed changes to the approved protocol. The amended protocol must be reviewed and approved by the REB prior to implementation of the changes.
- An annual **Renewal** must be submitted for ongoing research. Renewals should be submitted between 15 and 30 days prior to the current expiry date.
- A **Protocol Deviation Report (PDR)** should be submitted when there is any departure from the REB-approved ethics review application form that has occurred without prior approval from the REB (e.g., changes to the study procedures, consent process, data protection measures). The submission of this form does not necessarily indicate wrong-doing; however follow-up procedures may be required.
- An **Adverse Events Report (AER)** must be submitted when adverse or unanticipated events occur to participants in the course of the research process.
- A **Protocol Completion Report (PCR)** is required when research using the protocol has been completed. For ongoing research, a PCR on the protocol will be required after 7 years, (Original and 6 Renewals). A continuation of work beyond 7 years will require the creation of a new protocol.
- If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

Protocol #:24332

Status: Delegated Review App

Version: 0001

Sub Version: 0000

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Expires On: 27-Nov-21

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