Guidance for Alternate Routes of Consent in Response to COVID-19

In the current COVID-19 environment, many study teams are finding the need to modify their consent process to be in compliance with governmental and Jefferson social distancing requirements. This means using some form of remote consent. To address all options, *remote consent* for the purpose of this document means consent that is obtained through mechanisms and/or interaction that are not person-to-person.

The following are options to consider:

- **Mail or Email** – consent form or consent statement (for some minimal risk research, like survey studies) can be emailed or mailed to individual. In general, use of a written consent form, as opposed to a consent statement, should be accompanied by live interaction with individual, via phone or video conference.
    - **On-line surveys** – In general, consent for on-line survey does not require live interaction with the research participant. Individual reads the consent statement included either in the email or the on-line survey. By their proceeding to complete the survey, they make their consent explicit.
    - **Real-time surveys** – For surveys to be conducted between individuals, verbal consent or written consent is required. The consent interview can be conducted via phone or video conference. (For verbal consent script, use OHR-8H.)

- **Phone consent** - Phone script (OHR-8H) can be used to inform individual of study and to obtain consent via verbal affirmative from individual. Consent is notated by study team. Oftentimes, researcher will create informational letter that is emailed or mailed to individual in advance informing of impending contact from study team, with opt-out option and phone number to call.

- **Video conferencing** – This would include use of Zoom, Skype, Jefferson Teleheath, FaceTime, and other video conferencing options to conduct the consent interview. If a written consent form previously was being used for the study, the researcher can continue to use the consent form in the video environment. If individual agrees to participate, they should digitally sign if using e-consent or physically sign consent form and transmit to researcher via mail, email, fax, or other means. Investigator should then sign and transmit fully executed copy of consent form to participant.

- **E-Consent** – This entails that the consent document itself is presented in an electronic format, with or without concurrent use of video conferencing. Currently, the REDCap e-consent process is being finalized and shortly should be ready for use for COVID-19 studies. As resources to support use of REDCap e-consent are limited at the moment, its use will be limited to COVID-19 studies in

the short term. Investigators considering other e-consent options should contact OHR to discuss in advance of implementing or including in a new IRB application.

All modifications to the consent process should be submitted to the IRB as an amendment. If a new route of consent needs to be implemented urgently to eliminate risk to an individual, you may proceed without prospective IRB approval. Then, you should follow up as soon as possible by submitting a formal amendment to the IRB.

Please contact OHR with questions.