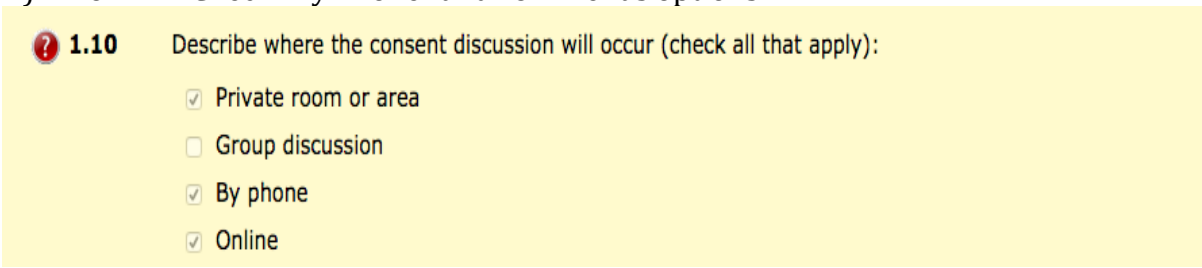
For IRB Modification Form: Adding Phone Consent/E-Consent

A) 1.10 ADD: Check "By Phone" and "Online" as options



B) 1.12 Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points below:

ADD:

The consent process may take place by phone for participants who have barriers to in-person participation. For potential participants who have computer access and capability, the formal study consent process will be conducted using a REDCap-based electronic consent form. The consent form has been developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing the principal investigator to grant and control varying levels of access to study staff. Potential participants would receive an email with a unique link to review the informed consent form online. After the research team explains the study and answers any question, the potential participants can electronically fill in an "Agree" button, followed by their electronic signature. Upon completion of the consent, participants are presented with the option to download a copy of the executed form. The research team will also e-mail a copy of the executed form to the participant. E-consent versioning will be managed using the e-consent Framework in Redcap. Within the e-consent survey options, we have designated the e-consent version number in this application as e-consent version 1. The PDF's of completed responses will have the timestamp, participant name, and e-consent version number inserted in the footer. Future versions of the e-consent will be created by making a copy of the Redcap form and revising it. The old version would be de-activated upon receiving IRB approval for the new version.

If a participant does not have access to a computer at the time of consent potential participants will be provided with a copy of the informed consent form (via mail or email). Once the potential participant has had time to look over the consent form, a study team member will talk with the participant by phone to review the study information and answer any questions. If they choose to continue their participation, they will be asked to sign the consent and return to us either by mail or scanned and emailed or faxed. We will instruct participants to keep a copy for themselves.

In the event participants who consented using the REDCap e-consent would need to be re-consented, we will send the participant a link to the new version to discuss, sign electronically, download, and receive via e-mail as described above.

C) Create the e-consent form in Redcap. A sample can be found at: https://is.gd/MACRO_econsent. This will have to be modified to reflect the current consent form for your study.

D) Download a pdf document of the e-consent to include under Attachments with your modification.

E) The study protocol will likely need to be modified to reflect these changes. Examples of wording to add would be:

1. **ADD** line after describing assessments:

   In the event that in-person assessments or interventions become infeasible (e.g. COVID 19 outbreak), the researchers will carry out these study components remotely (i.e. by phone or REDCap survey).

2. **ADD** to consent process:

   > If a participant uses the RedCap-based electronic consent form, a copy of the executed form will be downloaded and retained by research staff.