Consent documents – October 26, 2020
Summary of changes

Contents

Adult Consent Form

Section	Previous	New	Rationale
Header	IRB TEMPLATE Version 2.1 – 1/17/2020- Do not alter this text box	IRB TEMPLATE Version 2.2 – 1/17/2020- Do not alter this text box	IRB template version section updated.
What will happen if you take part in the study?	N/A	The group will be asked to [UPDATE]. No questions will be directed to you individually, but instead will be posed to the group. You may choose to respond or not respond at any point during the discussion. The focus group discussion will be audiotaped so we can capture comments in a transcript for analysis.	Inclusion of Focus Group consent language

If you choose not to be in the study, what other treatment options do you have?	N/A	Even though we will emphasize to all participants that comments made during the focus group session should be kept confidential, it is possible that participants may repeat comments outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can, but remain aware of our limits in protecting confidentiality.	Inclusion of Focus Group consent language
How will information about you be protected?	NA	Every effort will be taken to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. Your name will not appear on any transcripts; instead, you will be given a code number. The list which matches names and code numbers will be kept in a locked file cabinet. After the focus group tape has been transcribed, the tape will be destroyed, and the list of names and numbers will also be destroyed.	Inclusion of Focus Group consent language
		Include one of the statements below if your study will utilize unencrypted messaging (e.g., unencrypted e-mail or text messaging]. [Option 1-Most Common] The study team would like to message you by (insert technology(ies); e.g. text messaging or e-mail), however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team. If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-	

		encrypted (un-protected) messages specific to this study. _____ Yes, I consent to the study team utilizing the following (insert mechanism; e.g. cell phone number, email) to send communication: _(List e-mail, cell-phone #)_____ _____ No, I do not consent to receive un-protected communication from the study team. [Option 2-Only for Studies Designed to Investigate Messaging] As the purpose of this research is to study (insert technology(ies)), by signing this consent on the last page of this form you are giving permission for the study team to contact by the mechanism identified below that you provide. This communication may contain personal information about you and may be sent or received by the study team member's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notification requests to contact the study team. If you do not want to receive un-protected communication that may contain personal information, then you should not consent to participate in this study. If you have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities concluded, or you withdraw from the study, you will no longer receive un-encrypted (un-protected) communication specific to this study. The study team may use the following (insert mechanism; e.g. cell phone number, email) to send communication: _(List e-mail, cell-phone #)_____	

Consent Addendum for Unencrypted Communication

Section	Previous	New	Rationale
Consent Form	N/A	Creation of addendum	To provide a mechanism to document an initial consent for currently-enrolled subjects or the documentation for a change in contact information for future use

Focus Group Consent Form

Removal of separate consent form for Focus Groups. The Adult Consent Form has been updated to include the relevant sections in an effort to streamline the consent process and reduce the number of consent forms.