Notes:

A formal NKU IRB logo, approval and expirations dates will automatically be added to this form upon approval by Mentor IRB.

Consent forms should be written to a 6th - 8th grade reading level and relatively brief.

Green text under each header are sample texts and can be edited and replaced.

Delete these instructions, any unused sample text, and the left column prior to upload into Mentor IRB.

Informed Consent

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| Required: Title exactly as it appears on the protocol. You can have a short title if needed, but it must be listed on the protocol in Mentor IRB.  Optional: Only include “funding organization” if research is being performed for another entity (e.g. government/industry sponsor)  Required: Name and telephone number of PI. | **Study Title:** Click here to enter text.  **Funding Organization:** Click here to enter text.  **Name of Researcher (Principal Investigator):** Click here to enter text.  **Telephone Number:** Click here to enter text. |
| Required (this is a sample statement, can be revised) | **Introduction**  We are asking you to be in a research study so that we can learn new information that may help others. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. |
| Required | **Why are we doing this research?**  In this research study we want to learn more about Click here to enter text..  We are asking you and other people with Click here to enter text. to be in the research, because Click here to enter text.. |
| Required – Include the name of the PI.  Include the name of the entity (if applicable) that is funding the researcher (i.e. NIH, company, etc.) | **Who is in Charge of the Research?**  Click here to enter text. Is the researcher at Northern Kentucky University (NKU) that is in charge of this study.  NKU is being paid by Click here to enter text. to do this study. |
| Optional – Only use criteria that would allow a person to self-exclude (do not list all inclusion/exclusion criteria) | **Who Should Not Be in The Study?**  You cannot be in this study if you have any of the following: |
| Required –  Clearly inform the participant of the study’s procedures. Include approximately how much time the study will take. | **What Will Happen in the Study?**  If you will be asking for consent to video or audio record the session, indicate that here as well. Additional “opt in/opt out” checkboxes can be included in the signature box of the consent to allow participants to consent to some procedures but not all. |
| Required  This section should explain both the direct/immediate benefit from the research to the participant  AND  How the research might benefit others in the future. | **What Are the Good Things that Can Happen from this Research?**  Being in this study may not help you right now. When we finish the study, we hope that we will know more about      . This may help other people with       later on. |
| Required  A statement about the reasonably anticipated risks/inconveniences/discomforts of all intervention and procedures being performed as part of the research. Be sure to include both emotional/mental and physical risks.  Consider using a visual table, if your study involves a potential for serious physical risks.  The document should always include a statement of “unknown risks”. | **What Are the Bad Things that Can Happen from this Research?**  You may be asked questions that make you uncomfortable or cause you to remember situations that were upsetting to you. You do not need to answer any questions that you do not wish to answer and you can stop the testing at any time. If you become very upset during the testing at any time, we will end the testing. We will also offer to have you speak to someone about what you are feeling.  OR  Example - You may become frustrated if you are asked questions during testing that you do not know how to answer. All people are going to be asked questions that they cannot answer. You do not need to answer any question that you do not wish to answer and you can stop the testing at any time.  There may be other risks that we do not know about yet. |
| Required  There should be an explanation of the reasonable alternatives to participating in the research. At a minimum this should include the option of not being in the research. | **What Other Choices are There?**  Instead of being in this study, you can choose not to be in it. |
| Required  The specific steps being taken to protect privacy and confidentiality. This might include, using a private room to conduct study visits, coding of data, limiting access to study data, etc. | **How Will Information About You Be Kept Private?**  Making sure that information about you remains private is important to us. To protect your privacy in this research study we will: |
| Required only if:   1. the research involves more than a single visit/encounter   OR   1. There is a reasonable possibility that the research may identify previously unreported abuse or potential harm to self or others, mandatory reporting of these should be listed here. | **What if We Learn Information During the Research?**  The researcher will tell you if they find out about new information from this or other studies that may affect your health, safety or willingness to stay in this study. |
| Optional  Include this section only if payment is being provided. This section should differentiate “reimbursement” for out-of-pocket expenses FROM per encounter payment for time and effort. All payments should be described on a per encounter basis and not presented as a “grand” total. | **Will You Be Paid to be In this Research Study?**  You will be reimbursed for your time, effort and travel while you are in this research study.  You will be paid $      for each study visit as reimbursement for your time and effort.  **AND/OR**  You will be reimbursed $      for your travel expenses to your study visits. |
| Optional  This section is required for all research protocols that involve more than minimal “physical” or “psychological” risks that may be CAUSED by participation in the study. . | **What Happens if you are Injured from Being in this Study?** |
| Required | **Who Do you Call if you Have Questions or Problems?**  For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.  If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the Chair of the Institutional Review Board, Andrea Lambert-South, Ph.D., at 859-572-6615 or [irbchair@nku.edu](mailto:irbchair@nku.edu). |
| Optional | **What Else Should You Know About the Research?** |
| Optional (only if HIPAA applies) | **Authorization for Use/Disclosure of Health Information for Research**  To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your “protected health information” (called PHI for short).  **What protected health information will be used and shared during this study?**  **Who will share, receive and/or use your protected health information in this study?**  **How will you know that your PHI is not misused?**  **Can you change your mind?**  **Will this permission expire?**  **Will your other medical care be impacted?** |
| Required unless requesting a waiver of documentation of informed consent | **Signatures**  The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.  You will receive a copy of this signed document for your records.  **\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of Research Participant  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_  Signature of Research Participant Indicating Consent, Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_  Signature of Legally Authorized Representative (LAR), Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  If signed by a legally authorized representative, a description of the LAR’s authority must be provided.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_  Signature of Individual Obtaining Consent, Date |