

November 2022 – Summary of Changes to CHREB Consent Form Templates

1) CHREB Standard Consent Form Template

Old Language	New Language (November 2022)
<p>SECTION: WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?</p> <p>PAGE 9: <i>[If applicable]:</i> By signing this consent form you are authorizing [specify data custodian] to allow the research team access to your individually identifying health information for research purposes. Your signed consent form will also be included in your electronic medical record(s), and your healthcare team will be alerted that you are in a study. This is to ensure your healthcare team has information about the study so that they can treat you safely.</p>	<p>SECTION: WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?</p> <p>PAGE 9: <i>[If applicable]:</i> By signing this consent form, you understand that the research team will have access to your individually identifying health information for research purposes. In cases where the study involves an intervention such as a research-related medication, device, or other therapy, or the project includes research-specific lab tests and/or imaging, your signed consent will also be included in your electronic medical record(s), and healthcare staff will know that you are in a research study.</p>

2) CHREB Clinical Trial or Interventional Study Consent Template

Old Language	New Language (November 2022)
<p>SECTION: WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?</p> <p>PAGE 12: <i>[If applicable]:</i> By signing this consent form you are authorizing [specify data custodian] to allow the research team access to your individually identifying health information for research purposes. Your signed consent form will also be included in your electronic medical record(s), and your healthcare team will be alerted that you are in a study. This is to ensure your healthcare team has information about the study so that they can treat you safely.</p>	<p>SECTION: WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?</p> <p>PAGE 12: <i>[If applicable]:</i> By signing this consent form, you understand that the research team will have access to your individually identifying health information for research purposes. In cases where the study involves an intervention such as a research-related medication, device, or other therapy, or the project includes research-specific lab tests and/or imaging, your signed consent will also be included in your electronic medical record(s), and healthcare staff will know that you are in a research study.</p>

3) CHREB Surrogate Consent and Regained Capacity Consent Template

Old Language	New Language (November 2022)
<p>SECTION: WILL INFORMATION ABOUT MY FAMILY MEMBER'S PARTICIPATION BE KEPT CONFIDENTIAL?</p> <p>PAGE 9: <i>[If applicable]:</i> By signing this consent form you are authorizing [specify data custodian] to allow the research team access to the participant's individually identifying health information for research purposes. Your signed consent form will also be included in the participant's electronic medical record(s), and the participant's healthcare team will be alerted that the participant is in a study. This is to ensure the participant's healthcare team has information about the study so that they can treat the participant safely according to the study protocol.</p>	<p>SECTION: WILL INFORMATION ABOUT MY FAMILY MEMBER'S PARTICIPATION BE KEPT CONFIDENTIAL?</p> <p>PAGE 9: <i>[If applicable]:</i> By signing this consent form, you understand that the research team will have access to the participant's individually identifying health information for research purposes. In cases where the study involves an intervention such as a research-related medication, device, or other therapy, or the project includes research-specific lab tests and/or imaging, your signed consent will also be included in the participant's electronic medical record(s), and healthcare staff will know that the participant is in a research study.</p>

4) CHREB Pediatric (Parental) Consent Template

Old Language	New Language (November 2022)
<p>SECTION: WILL INFORMATION ABOUT MY CHILD'S PARTICIPATION BE KEPT CONFIDENTIAL?</p> <p>PAGE 9: <i>[If applicable]:</i> By signing this consent form you are authorizing [specify data custodian] to allow the research team access to your child's individually identifying health information for research purposes. Your signed consent form will also be included in your child's electronic medical record(s), and your child's healthcare team will be alerted that your child is in a study. This is to ensure your child's healthcare team has information about the study so that they can treat your child safely according to the study protocol.</p>	<p>SECTION: WILL INFORMATION ABOUT MY CHILD'S PARTICIPATION BE KEPT CONFIDENTIAL?</p> <p>PAGE 9: <i>[If applicable]:</i> By signing this consent form, you understand that the research team will have access to your child's individually identifying health information for research purposes. In cases where the study involves an intervention such as a research-related medication, device, or other therapy, or the project includes research-specific lab tests and/or imaging, your signed consent will also be included in your child's electronic medical record(s), and healthcare staff will know that you child is in a research study.</p>