Community Healthcare System

Central Institutional Review Board

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Informed Consent: Additional Model Language

Addendum III

TOPIC	INSTRUCTIONS	MODEL LANGUAGE
Banking of Data and/or Specimens for Future Use	Include the following language for studies that include banking of biospecimens and/or data as a secondary aim of the study. If the study's primary purpose is to create a data or biospecimen repository, the details of the banking procedures should be laid out in the main body of the consent form. (See Recruitment Registry, Data Repository, and Tissue Repository Guidance for more information about data and specimen repositories.) When describing banking for future research: • Clearly describe the biospecimens and/or data to be banked for future use (including data associated with specimens). • Clearly describe how the biospecimens and/or data will be obtained (e.g. specimens left over from routine tests or procedures vs. specimens collected specifically for banking, data from medical records vs. data from questionnaires conducted specifically for research). Make clear if collecting the specimens/data involves additional procedures that subjects will undergo only if they agree to banking. • Make clear whether the banking of their data/specimens is required, or whether it is an optional part of the study. If banking is an optional study component, describe it in an "Optional Studies" section at the end of the consent document. **Note**: Mandatory banking is typically acceptable only for non-treatment studies. • If there are research activities that will be performed only with banked data/biospecimens (e.g., genetic testing, creation of cell lines), describe these activities in this section. • If you may share the data/samples outside your research team, state this. If the recipient investigators could be outside the University of Wisconsin-Madison, then state this.	**What will happen to my** [**data / samples / data and samples**] after my participation ends? We [will OR would like to, if optional] keep your [data / samples /data and samples] for [X period of time OR an indefinite period of time, meaning we have no plans of ever destroying your data / samples]. Keeping data or samples for future research is called 'banking." The banked [data / samples] will be kept in a secure location for use by researchers. This is what will happen with your banked [data / samples / data and samples]: • We will use the [data / samples / data and samples] in other research projects [if there are limits to potential future uses, add: about [describe any restrictions on the use of data/samples, such as limiting future use to a specific disease category.] • If you may share the data/samples outside your research team, add: the [data / samples / data and samples] may be shared with other researchers at Community Health Care [if sharing outside CHS, add: and outside the CHS. Text to include if banked data/samples are coded: DELETE if not applicable: • The banked [data / samples / data and sample] will be labeled with a code instead of your name. • When we give your [data / samples / data and samples] to other investigators for research projects, they will not be able to use the code to figure out which [data / samples / data and samples] are yours. • The research team will maintain a link your [data / sample / data and samples] and your identifiable Information kept by the study team.

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Banking of Data and/or Specimens for Future Use	• Describe risks related to banking of biospecimens and/or data. Loss of confidentiality should always be identified as a risk of banking. However, if the information being stored is sensitive (e.g. a breach could damage the participant's reputation, or pose legal risks), or if future research with banked specimens may generate sensitive data (e.g. identify predisposition to well-being, relationships, insurability, employability, etc.), then describe these possible consequences of a breach of confidentiality. • If you are banking samples, Commercial Products language may apply; include the commercial products language in this section. • For optional banking, provide yes/no checkboxes that clearly describe each option. For example, if subjects can opt to allow banking of data OR banking of biospecimens, provide separate checkboxes for the subject to complete. If subjects can choose not to have extra specimens collected specifically for banking, but allow banking of left over samples, provide separate check boxes for these choices.	• You can request to have your [data / samples / data and samples] removed from the bank by contacting the research team at any time. Text to include if data/samples will be anonymized for purposes of banking: DELETE if not applicable. • The banked [data / samples / data and samples] will be labeled in a way so that no one can identify which [data / samples / data and samples] came from you. • This means that if you decide at a later time that you do not want your [data / samples / data and samples] used for other research, we will not be able to remove your [data / samples / data and samples] from the bank. This will NOT happen with your banked [data / samples / data and sample]: • Banked [data / samples / data and samples] will not be shared with your health care providers or used in your treatment outside this study. Text to include if banking is optional. Include additional yes/no options if data and samples are banked separately: Please initial one of the lines below to indicate whether or not you agree to optional [data / samples / data and samples] banking. ____ Yes, I agree to have my [data / samples / data and samples] banked for future research purposes. ____ No, I DO NOT agree to have my [data / samples / data and sample] banked for future research purposes.
Certificate of Confidentiality	Include the following language whenever a Certificate of Confidentiality (coC) is or will be obtained for the study. This language was taken from the National Institutes of Health (NIH) website, which is subject to change without notice. Please review the NIH website to check for updated language.	To help us protect your privacy, we have [select either: applied for OR obtained] a Certificate of Confidentiality from the [identify agency granting the CoC, such as National Institutes of Health]. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, expect as explained

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Certificate of Confidentiality		below. The certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentially does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. Text to include when voluntary or mandatory reporting requirements, such as child abuse or intent to hurt self or others, apply to the study. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of [list what will be reported, such as child abuse and neglect, or harm to self or others.]
ClinicalTrials.gov	Include the following language for studies that must be registered on clincaltrials.gov. When including this language. • Registration may be required due to Food and Drug Administration (FDA) requirements. NIH requirements for studies meeting the definition of clinical trials, or International Committee of Medical Journal Editors' (ICMJE) requirements. Guidance on registration requirements can be found here. • If you have questions about whether your study should be registered contact CT.gov Support, Office of Research Policy at (608) 890-1241 or ClinicalTrials.gov_Support@research.wisc.edu.	A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
Conflict of Interest	Include the following language when a member of the study team has a conflict of interest in an entity that is sponsoring the study or that owns or licenses a technology used in the study	

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Enrolling Employees	Use the following language if your study specifically targets employees as subjects, in place of the template paragraph that says the subject's decision will not affect their treatment relationship with CHS providers.	For studies targeting CHS employees: If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect your employment at CHS, any organizations affiliated with CHS. If you receive health care from CHS, if you decide not to take part in the study, or if you choose to leave the study, your choice will not affect your care through CHS. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose any legal rights.
Genetic Information Nondiscrimination Act (GINA)	• Include the following language in the consent form for studies that involve genetic research relevant to the participant's genome (as opposed to, for example, the genetics of a tumor cell). • Add GINA language to the risk section in the **main body** of the consent form when the genetic research is part of the main study. • Add GINA language to the Optional Studies portion of the consent document when the genetic research is part of optional sub-studies or banking for future research.	The Genetic Information Nondiscrimination Act of 2008 is a Federal law that is supposed to prevent health insurance companies and employers from discriminating against people based on genetic information. There are some limits to this law: • It does not apply to businesses that employ fewer than 15 people. So, if you work somewhere with fewer than 15 employees, your employer could fire you or make other decisions about employment using genetic information. • Regardless of where you work, it does not apply to life insurance, disability insurance, or long-term care insurance. o This means that if you had an abnormal genetic test result, and that result became known, then you could be denied or pay higher rates for life insurance, disability insurance, or long-term care insurance.
Genetic Research: Definition	• Add this language to the **main body** of the consent form when genetic research is part of the main study. • Add this language to the **Optional Studies** portion of the consent document when the genetic research may be done as part of optional sub-studies or in future research using banked specimens. • Include the statement about whole genome testing if the research will (or might) include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).	Some of the tests we will perform on your [blood/tissue/etc.] will be genetic testing, which is done on your DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be. Include the following for who genome testing: We will do whole genome testing for this study. Your "genome" is the complete DNA instruction book. "Whole genome testing" means making al list of the entire order, or sequence, of the DNA in your genome.

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Genomic Data Sharing (GDS)	Include the language below if genetic data may be shared, now or at some time in the future, with public data repositories under the NIH Genomic Data Sharing (GDS) Policy. This includes: • NIH-funded studies • Studies likely to receive NIH funding in the future • Collaborative research with someone who has NIH funding • Studies that will voluntarily share data with public repositories	[At some point in the future], we are [may be] required to share genetic data with federal repositories. [Because this research receives funding from the National Institutes of Health (NIH), we will submit your genomic information to a public repository approved by NIH. NIH is a national research agency and is part of the federal government.] The NIH and other central repositories have developed special data (information) banks that collect the results of genetic studies, especially when the research looks at all or large sections of individual's genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body. These central banks wills store your genetic information and give them to other qualified and approved researchers to do more studies. The data that we share with the federal repositories will be coded in such a way that you would not be able to be identified. We will not share you name, birth date, or any other information that could directly identify you. The link to the code would be kept securely at CHS. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository. We do not think that there will be further risks to your privacy and confidentiality b sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The genetic data could be used to study a wide variety of diseases.
Reproductive Risks	Include this language whenever a study involves drugs, devices, or procedures with potential risks to subjects' reproductive potential, or to embryos, fetuses, or breastfeeding infants. When including this language: • If a study drug/device/procedure is known teratogen, state that is known to cause birth defects. If the risk to embryos or fetuses is unknown, say that the study drug/device/procedure may cause harm. • Specify if the study requires pregnancy testing.	Text to include when risks to embryos/fetuses are unknown, pregnancy testing is not required, and there are no specific requirements for male subjects: The study [drug(s)/device(s)/procedure(s)] may harm a fetus or breastfeeding baby. If you are pregnant or breastfeeding you cannot take part in this study. If you think you may be pregnant, you should not volunteer for this study.

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Reproductive Risks	• If the protocol requires particular methods of contraception, describe the methods in general terms, such as barrier or hormonal methods. If the protocol requires avoiding pregnancy after active study treatment is stopped, inform subjects of this. Provide detailed instructions about contraception in a separate document, not in the consent form. • Avoid wording that assumes all subjects are heterosexual or sexually active. • If your study enrolls minors, see Health Sciences IRBs guidance on Pregnancy testing in Minor Research Subjects and include study-specific information in the parental permission form	Text to include when pregnancy testing is required: The study [drug(s)/device(s)/procedure(s)] may harm a fetus or breastfeeding baby. If you are pregnant or breastfeeding, you cannot take part in this study. If you are able to become pregnant, you must have a pregnancy test before you begin the study [if tests are repeated, add: and while you are in the study]. You should not get pregnant, breastfeed, or father a baby while in this study. All study participants must avoid becoming pregnant or causing a pregnancy while they are [on study treatment/going through study procedures/ for X amount of time after treatment]. Text to include when MRIs are performed for research and the study does not propose to enroll pregnant women (female subjects only): Although there is no evidence that MRI scans cause harm to a fetus, they may be risks to a fetus that are not known at this time. For these reasons, this study is not approved for the enrollment of pregnant women. You should only take part in this study only if you are certain you are not pregnant during this study. _____ Signature of subject and date signed Text to include when contraception is required: Because taking the study drug during pregnancy may cause birth defects, safeguards are required to avoid becoming pregnant or causing a pregnancy. If you or your partner can get pregnant, it is important while on this study for you to either use birth control or not have sex that could result in pregnancy. Check with you study doctor about what kind of birth control methods to use and how long to use them. Some birth control methods might not be approved for use in this study. Women should not breastfeed while on this study drug. Check with your doctor about how long you should wait to breastfeed after you stop study treatment.

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Reproductive Risks		Text to include when study drugs, devices, or procedures may damage subjects' reproductive potential. If you will exclude a gender, delete the unnecessary language: If you can become pregnant, the study [drugs/devices/procedures] may make it difficult or impossible for you to get pregnant in the future. If you can get your partner pregnant, the [drugs/devices/procedures] may make it difficult or impossible for you get your partner pregnant in the future.
Signature Sections	**Instructions for studies including children (<18 years old):** The consent form is used to document parent/guardian permission for the minor child to take part in the study. Only in rare situations are minors allowed to participate in research without parent/guardian permission. • For studies that are no more than minimal risk, or that are more than minimal risk but may offer direct benefit to the child, the IRB may find that the permission of one parent/guardian is sufficient. • Studies that are more than minimal risk but do not offer direct benefit to the child require permission from both parents/guardians unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child. • Older adolescents (typically 15 – 17 years old) may sign the parent/guardian consent form to document their assent to participate, along with the signature of their parent(s)/guardian(s). • If you are using one of the consent form templates that includes HIPAA language, include the text in blue to address HIPPA requirement.	**Agreement to participate in the research study** You are making a decision whether or not to have your child participate in this study. You do not have to sign this form. If you refuse to sign, however, your child cannot take part in this research study. If you sign the line below, it means that you have: • read this consent [and authorization] form describing the research study procedures, risks and benefits • had a chance to ask questions about the research study and your child's participation, and received answers to your questions • decided to allow your child to participate in this study • given authorization for the person's protected health information to be used and shared as described in this form. If ICH-GCP guidelines apply to the study, add: You will receive a signed and dated copy of this form for your records. _____ Printed Name of Parent/Guardian _____ Signature of Parent/Guardian Date

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Signature Sections		_____ Printed Name of Parent/Guardian _____ Signature of Parent/Guardian Date _____ Printed Name of Subject (age 15 -17) _____ Signature of Subject (age 15 -17) Date _____ Signature of Person Obtaining Parental/Guardian Date
Permission and Authorization and Child Assent	**Instructions for studies including adults who lack capacity to consent:** • An IRB must specifically approve inclusion of adults who lack consent capacity. • Adults who cannot provide informed consent may be enrolled in research only in certain situations per Indiana law. • Community Healthcare System follows state law, which specifies who may serve as a legally authorized representative (LAR) and provide surrogate consent on behalf of a person who lacks capacity. • The consent form must direct the LAR to base his/her decision about study participation on the subject's wishes, or, if the subject's wishes cannot be determined, on what the LAR believes to be in the subject's best interest.	**Agreement to participate in research study** If you are a Legally Authorized Representative (LAR) for the person being invited to take part in this study, you are deciding where the person can be in this research study. You do not have to sign this form. If you refuse to sign, however, the person cannot take part in this research study. If you sign the line below, it means that: • you believe the person wants, or would want, to be in the study; • OR, if you cannot find out if the person wants to take part, you believe that participating in the study is in the person's best interest. • you give authorization for the person's protected health information to be used and shared as described in this form.
Authorization	**Studies including adults who are unable to read:** • **This applies only to studies that are obligated to adhere to ICH-GCP guidelines.** • If the study is likely to enroll adults who are unable to read (or the subject's LAR is unable to read), ICH-GCP requires that an impartial witness be present for the whole consent process, make sure everything is read	Use the signature area below only when necessary. If the participant [participant's LAR] cannot read, and you are the witness to the consent process, your signature indicates that: • you were present for the whole consent process; • you have made sure that the information in the consent form (any other written information) was accurately explained to the participant

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	correctly, and make sure that all the subjects' questions are answered. • Per ICH-GCP guidelines, an impartial witness is a person who is independent of the trial, who cannot be unfair influenced by people involved in the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject. • In addition to the signature blocks for the subject and the person obtaining informed consent, the consent form must include a signature block for the impartial witness, with an explanation that this block is only to be used when necessary. • Note: An impartial witness should only be used when the subject (or subject's LAR, if applicable) cannot rad. If the subject/LAR can read in their native language, but not in English, ICH-GCP requires the consent form to be provided in a language that the subject can read and understand.	[participant's LAR]; • all the participant's [participant's LAR's] quest ins have been answered • the participant [participant's LAR] freely consented to take part in the study. _____ Printed Name of Impartial Witness _____ Signature of Impartial Witness Date
Electronic Signatures	Consent documents may be presented to potential participants in an electronic format. See HS IRBs Electronic Consent Guidance for detailed information. When signed consent is required, there are several acceptable methods for obtaining an electronic signature; these are detailed in the guidance document. Below is an example of one method of documenting informed consent in an electronic form. • Include blue text if you are using a consent template that includes HIPAA language.	**Agreement to participate in the research study** You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you check the box and fill in your name below, it means that: • You have read this consent and authorization form. • You have had a chance to ask questions about the research study, and the researchers have answered your questions. • You want to be in this study. • You give authorization for your protected health information to be used and shared as described in this form. **Step 1. Check the box below** ☐ By checking his box and typing my name below, I am electronically signing my application.

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		First Name Middle Initial: Last name: Suffix: