When external IRBs are used for Hackensack Meridian Health (HMH) research studies (such as Western IRB (WIRB), Advarra, or any other IRB in which HMH decides to relinquish jurisdiction to via an IRB reliance agreement), the consent form(s) which the external IRB is responsible for reviewing/approving must include require institutional language provided by HMH.

The following language represents the required institutional language to be inserted into consents forms to be reviewed/approved by an external IRB (excluding NCI’s CIRB; see ‘Note’ below) and used at HMH for research purposes. This language has been extracted from the HMH consent form template. It is not a complete consent form template. All shaded areas indicate instructions; please edit and/or delete accordingly when placing the language into the consent form(s).

Note 1: WIRB and Advarra maintain records of this institutional language and will review (in addition to HMH’s review as part of the eResearch submission process) to ensure language is appropriately incorporated.

Note 2: This document is not applicable when using the National Cancer Institute Central IRB (CIRB); CIRB maintains separate consent language requirements per HMH’s Institution Worksheet on file with CIRB.

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| **Institutional Language that needs to be added to Consent Form** |
| **Who is conducting this study?**Principal Investigator: [Insert name here]Sub-Investigators: [Insert names here]Hackensack Meridian Health Sites: [Insert HMH sites here]Sponsor: [List study sponsor(s) here]  |
| **How will information about me be kept private?**What information do researchers want to use?As part of this research study, personal information about you will be collected. This will include information from [include all that apply: medical records, procedures, samples, surveys, interviews and tests, etc.]. Information related to your medical care will go in your medical record. This could include physical exams, imaging studies (x-rays or MRI scans) or tests done in the clinical lab. Research staff will view your records only when required as part of their jobs and are required to keep your information private. Who can see my information? Information may be shared with the following: * Members of the research team and other authorized staff at Hackensack Meridian Health (HMH);
* People at HMH who oversee and evaluate research, including the Institutional Review Board and Compliance programs.
* People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP);

[Include the following only if applicable]* Representatives of [insert sponsor name] who is the study sponsor funding this research;
* [list lab names who receive identifiable specimens], who is testing your blood/urine/tissue sample(s);
* The Data Coordinating Center at [for multi-center research studies – include the data coordinating center];
* Groups monitoring the safety of this study; the study’s Data Safety Monitoring Board;
* The Food and Drug Administration;
* Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability. [Only include this statement when applicable – i.e., tests for sexually transmitted diseases, HIV, AIDS, child abuse, etc.]

Information that could identify you will not be shared with anyone outside of the research team unless you provide your written consent on this form, or it is required or allowed by law. Laboratory test results will appear in your medical record with the exception of [list any exceptions, e.g. genetic tests, non-CLIA approved test results, confidential data which must be protected] which are performed only for this research study. The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. No publication or presentation will include any information that could identify you.How will my information be protected? * Give a brief description of how personal information, research data, and related records will be coded, stored, etc. to prevent access by unauthorized personnel by editing the below language. Only include and edit applicable language below.
* If any other uses are anticipated, explain how specific consent will be obtained.
* If applicable, state when individual identifiable data will be destroyed.
* If a Certificate of Confidentiality is required, the language provided by the agency regarding the certificate should be inserted in this section.

In addition to the data security description, include: We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Data or specimens collected in this study might be used for future research or distributed to another investigator for future research without your consent. If used for future purposes, the data and/or specimens will not include any information that could identify you, such as your name, medical record number or date of birth. If applicable: Your samples and/or data will be shared with outside laboratories, including [insert lab names] for analysis (and storage, if applicable) but they will not know who you are. Instead, your samples and/or data will be labeled with a [insert whatever is appropriate e.g. study number, code, etc.]. Identifying information such as your name, birth date or medical record number will not be shared with them. If applicable, include the following for NIH-funded studies that generate large-scale human genomic data such as GWAS, SNP, genome sequence, gene expression:Your data will be shared through databases that may be publicly available to anyone. The data will not include identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to try to re-identify you.  **If the protocol includes use/access of protected health information (PHI), the following HIPAA language is required:** Any of your health information used in this research study is protected by a law called the Health Information Portability and Accountability Act (HIPAA). Anyone involved in this research as indicated above may have access to that information. Some people or groups outside of HMH might not have to follow the same privacy rules. Once any information is shared outside of HMH and given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.  Your permission to use and share the information and data from this study will not expire. You may cancel this Authorization at any time by notifying the research team in writing. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization. Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct the research.  |
| **What if you are injured because of the research study?**If the sponsor is willing to provide treatment, compensation, etc., this information should be reflected here. The following paragraph is to be included only if the sponsor is not paying and will replace any other language. If you are injured as a direct result of your participation in this study, you may seek medical attention at the medical provider of your choice. However, you and/or your insurance company/third party payer will be billed for all routine medical, diagnostic, laboratory and pharmaceutical costs associated with the treatment of your illness or injury. You will be responsible for any deductibles or co-payments that would normally be associated with your insurance coverage. There will be no financial compensation offered by Hackensack Meridian Health. |
| **Does the institution or researcher have financial interest in this study?**If the study is sponsored: Hackensack Meridian Health is receiving financial support from [insert sponsor name] to conduct this research study. If researcher has financial interest (COI committee may also provide required language): The principal investigator has disclosed a financial interest or other compensation from the study sponsor, [insert name of sponsor]. [Describe the nature of the financial interest]. If HMH has institutional financial interest: Hackensack Meridian Health (HMH) has financial interests relative to this study. HMH has [insert nature of interest here (e.g., intellectual property interests in product under evaluation, business relationship with or equity interests in the company sponsoring the research)]. As a result of these interests, HMH could ultimately potentially benefit, either directly or indirectly, from the outcomes of this research.If you have questions about this financial disclosure please call the Research Integrity Office 201-880-3669. |
| **Who can I call if I have questions or problems?** You are encouraged to ask questions before deciding what you want to do. If you decide to take part, feel free to ask questions at any time during your participation. For questions about this research project, please contact: Insert PI contact information (phone number, pager number, etc.)Insert other Research Team (coordinator, sub-investigators, etc.) contact info. For questions regarding your rights as a research participant or any research-related concerns, you can call the Hackensack Meridian Health Research Integrity Office at 201-880-3669.  |
| **Signature section(s)**(Both date and time of initial consenting should be collected.)  |