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| Yale Human Research Protection Program |
| Consent Glossary |
| Glossary of preferred and required terms for consent forms |

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| Version: 6.0  10-24-2023 |

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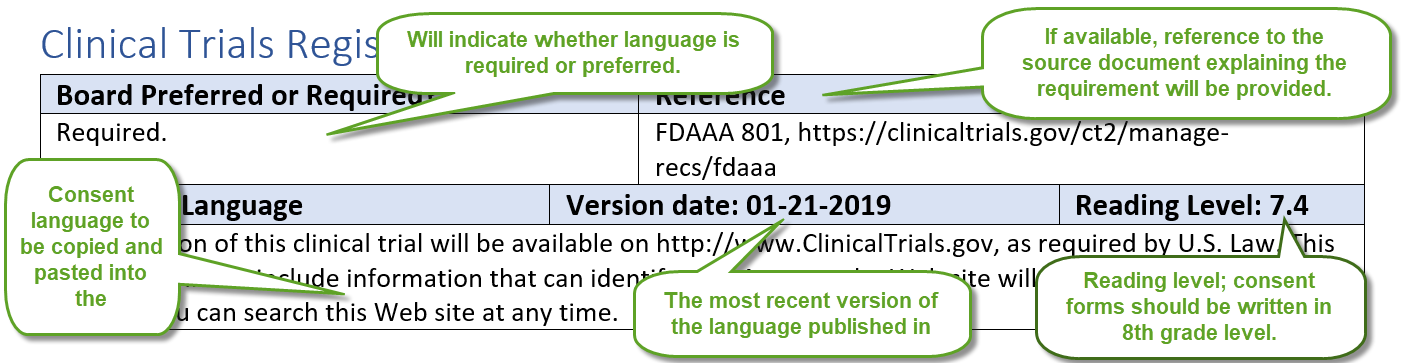
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# Instructions

## Purpose of the Glossary

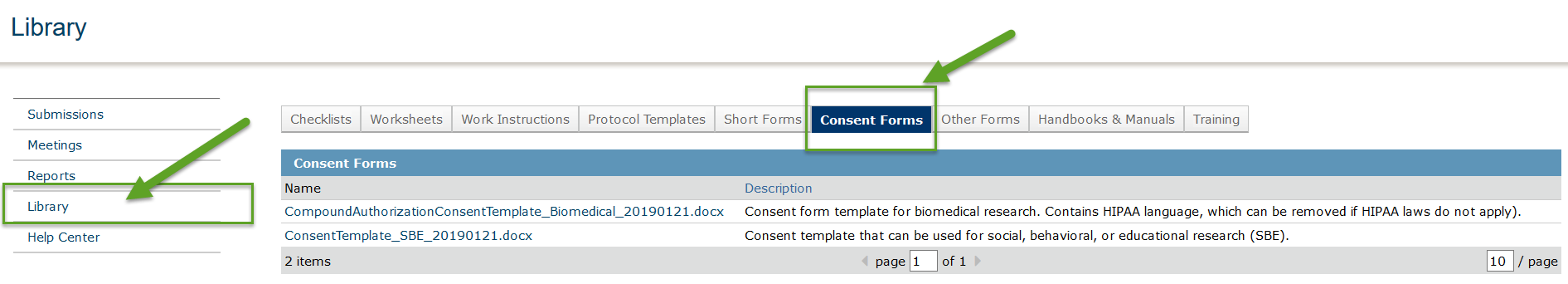
This Glossary contains a compilation of commonly used terms and descriptions of research procedures organized in an alphabetical order. Some of the language may be required either by regulations or by the Yale ancillary committees and some may be preferred (but not required) by the Yale IRBs. Use the boxes in the description of the term to determine whether you can make edits to the language.

The Glossary document will be reviewed and updated every quarter. Check the [Version History](#_Version_History) page for sections that were added, removed, or revised. Each individual section also includes a version date.



## Start with a template

Consent templates are available in the Library section of IRES IRB. Select the one that meets your needs. Read through the guidance provided in the green boxes, draft the consent language, and delete the instructions. Review the terms in this Glossary to select the paragraphs that you may need to use. Review [Resources](#_Resources) page for links to other sites that may provide you with descriptions written in laymen language.



If a sponsor provided you with the consent template, use that template. There is no need to entirely revise the sponsor consent to follow Yale’s templates. Work with your sponsor to revise the language if you believe the consent is written at a grade level too difficult for participants to understand. Review the Glossary document to select paragraphs that you may need to add to the consent template.

## Review for required and additional consent elements

Regulations require certain elements of the consent form to be included in the consent form. Before submitting your consent forms to the IRB, review the [consent elements](#_Consent_Elements,_Common), [consent elements for FDA regulated research](#_Consent_Elements:_FDA) (if your research is FDA regulated), and [HIPAA elements](#_HIPAA_Elements) (if your consent must also include HIPAA authorization). Ensure that your draft consent form includes all of the required elements.

## Proof-read and submit

Check the [Resources page](#_Resources_1) for links to editing and proofing checklists. Ensure that your draft consent forms **include version numbers or dates.** Review the [Researcher Guide: Consent Version Control and Tracking](https://ires-irb.yale.edu/IRB-PROD/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b6DBEE4B18D969241B87026CADF57A14D%5d%5d) in the Help Center section of IRES IRB to choose a method of version control that you like most. Upload WORD versions of your draft consent forms in the Consent Documents page in IRES IRB.

## Statements for consent forms for studies reviewed by external (non-Yale) IRBs

Consent forms for studies reviewed by an external IRB should be based on the IRB approved consent template provided by the coordinating center, sponsor, or the reviewing IRB. The template should only be revised to reflect the applicable institutional and state requirements. It is important NOT to revise other sections of the document unnecessarily or edit the consent form to follow Yale template. When requesting use of external IRB, always provide the template consent form (ensure you have the most recent version of the template as approved by the IRB) and the proposed Yale version of the document showing tracked changes.

Different statements may need to be added to the consent form, depending on the nature of the study. The table below includes the most commonly revised sections of the consent document. The HRPP will review the study and may suggest additional revisions.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Section of Consent Template** | **Link to the Glossary Section** | **Description of Revision** |
| 1. | Subject Injury Provisions | Suggested Language:   * [Injury Provisions for industry supported research](#_Industry_(For-profit)_Supported) * [Injury Provisions for registries, research without industry support, and studies funded by federal grants](#_Non-Industry_Supported_Studies,) | The HRPP will verify whether the language is consistent with the contract for industry supported studies.  This section may not require revisions if the proposed language in the template is consistent with the Yale position e.g., in case of unfunded or federally funded studies where participants or their insurance are expected to pay for cost of treatment of research related injuries. |
| 2. | Costs and Payments for Participation | Suggested Language:  [Economic Considerations: Oncology Research and Non-Oncology Research](#_Economic_Considerations:_Oncology) | The information in this section must be consistent with the budget and the contract.  This section may not require revisions when there are no expected costs or payments to participants and the template language adequately addresses the economic considerations. |
| 3. | Payments for Participation - when e-payments are issued | Suggested Language:  [ePayments](#_ePayments) | If e-payments (e.g., a pre-loaded debit card) is used to provide payments for participants.  This section may not require revisions if consent template adequately addresses the payment method. |
| 4. | Payments for Participation – to inform participants that the research stipend is subject to taxation | N/A | When study includes payments for participation (stipends only, not applicable to reimbursements), participants must be informed that the payment is taxable. Suggested language (equivalent may be accepted):  You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments. |
| 5. | Research Costs– to inform participants about available resource to discuss research billing | Suggested Language:  [Billable Services](#_Billable_Services) | If billable services are used, the contact information to Clinical Research Billing Unit must be provided to the participants.  This section may not require revisions if the contact information is provided to the participant in other forms e.g., Contact section of the consent form, or a flyer provided during the consent process. |
| 6. | Confidentiality – when research includes testing for reportable diseases e.g., Hep C | Suggested Language: [Mandatory Reporting](#_Mandatory_Reporting) | If the study includes testing for reportable diseases, the consent form must include information about required reporting.  This section may not require revisions if the consent adequately addresses mandatory reporting to health authorities. |
| 7. | Confidentiality – when research results will be added to EPIC | Suggested Language:  [Electronic Medical Record](#_Electronic_Medical_Record) | If the study includes entering research information into Medical Records, participants must be informed that their information will be available to others.  This section may not require revisions if the consent template adequately addresses availability of the research results in electronic medical record. |
| 8. | Confidentiality – when Oncore is used | Suggested Language:  [Electronic Medical Record – No Research Results](#_Electronic_Medical_Record_1) | If the protocol includes use of Oncore to track status of the participants, information about their active participation in research will be available in EPIC.  This section may not require revisions if the consent template adequately addresses availability of the research information in electronic medical record. |
| 9. | Research Procedures OR Confidentiality – to describe pregnancy testing in minors | Suggested Language:  [Pregnancy Testing in Minors](#_Pregnancy_Testing_in) | When research involves minors and pregnancy testing will be performed, the parental permission form may need to include information about the testing and the return of results. The assent form, if required by the IRB, may need to include similar information.  This section may not require revisions if the consent template adequately addresses the pregnancy testing in minors. |
| 10. | Contact information for Yale HRPP | Suggested Language:  [Contact information for research participants](#_Contact_information_for) | In addition to the consent information to the reviewing IRB, participants should receive contact information for Yale HRPP.  This section may not require revisions if the consent form include the Yale HRPP email address or phone number in other sections. |
| 11. | HIPAA Authorization Section – if the revising IRB serves as the Privacy Board for Yale and research includes collection of PHI | N/A | * Suggested Language (equivalent language may be accepted) for the list of entities that may have access to PHI:   Representatives from Yale University and the Yale Human Research Protection Program, who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.   * Contact Information for HIPAA Privacy Officer:   If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919. |
| 12. | Risks – MRIs conducted at FAS Brain Imaging Center OR MRRC | Required language, equivalent may be accepted IF approved by the applicable ancillary committee:  [MRI](#_MRI) | When research involves MRI scans at FAS Brain Imaging Center or MRRC, language specific to risks of the procedures and issues related to return of the results must be included in the consent forms.  This section may not require revisions if the consent template adequately addresses these issues and the applicable ancillary committee approves the proposed deviation from their template language. |

# Glossary

# Allergic Reaction

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 1-21-2019** | | **Reading Level: 7** |
| There is a risk of an allergic reaction. It can range from rashes to difficulty breathing, shock, and sudden death. | | | |

# ePayments

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested if a pre-paid debit card is used. | | Yale Procedure: [3417 PR.01 Human Research Study Participant Remuneration](https://your.yale.edu/policies-procedures/procedures/3417-pr01-human-research-study-participant-remuneration) | |
| **Consent Language** | **Version date: 12-1-2022** | | **Reading Level: 7.3** |
| We will use a pre-paid debit card to provide payment for taking part in the study. We will have to share your name, address, and telephone number with the banking institution issuing the debit card for ePayments. You may receive a card in the mail with the first payment following completion of the first visit. You will need to activate the card over the phone. Payments for additional visits will be automatically added to your card after completion of each following visit. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments. | | | |

# Billable Services

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language if billable services are used. The contact information to Clinical Research Billing Unit must be included in the consent form. | | Yale Policy: [Research Studies with Billable Clinical Services](https://medicine.yale.edu/ycci/researchservices/compliance/rbc/YSM%20Clinical%20Research%20Billing%20Policy%20Draft%202019.04.01%20_347406_153_47226_v2.pdf) | |
| **Consent Language** | **Version date: 5-2-2022** | | **Reading Level: 13.1** |
| Your study doctor, a member of the study team, or a member of the research billing team will be glad to answer your questions about whether services or tests performed during the course of a research study will be billed to your insurance provider or to you, or about any bills that you may receive during your participation in a research study. Please call the research billing team at 1-877-TRIALS0 (1-877-874-2560) with any questions. You may also contact your insurance provider directly. | | | |

# Certificate of Confidentiality

|  |  |  |  |
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| **Board Preferred or Required?** | | **Reference** | |
| Suggested, can be revised if approved by IRB. | | NIH: <https://humansubjects.nih.gov/coc/suggested-consent-language> | |
| **Consent Language** | **Version date: 1-21-2019** | | **Reading Level: 22.8** |
| This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.  **[Use the following language as applicable]** The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [THE AGENCY] which is funding this project 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 Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.  **[language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.]** The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others**]**.  **[language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.]** The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed, such as including research data in the medical record]. | | | |

# Conflict of Interest

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| --- | --- | --- | --- |
| **Board Preferred or Required?** | | **Reference** | |
| Required | |  | |
| **Required Language** | **Version date: 05-02-2022** | | **Reading Level: 7.4** |
| **Intellectual Property/Patent Interests –**  Dr. XXX [and Dr. YYY, etc.], principal investigator [or investigators] for this study, is [are] named as an inventor [or co-inventors] on a patent application covering [identify the use or method], which is being tested in this protocol. He/she [They] may have a potential financial interest in this research if it leads to the development of products that will be commercialized. If this happens, there is no plan to share any financial gain with you. You may speak with Dr. XXX [and Dr. YYY, etc.] at any time should you have questions regarding these investigator interests.  **Institutional and Investigator Interests in Intellectual Property –**  Dr. XXXXX, the principal investigator for this study, is named as a co-inventor on Yale University’s patent application for the [therapeutic process described in this study, HIC #XXXXX], in which XXXXX is being studied as a potentially effective treatment for YYYYY. S/He and Yale University have a potential financial interest in this process. You may speak with Dr. XXXXX at any time should you have questions regarding institutional or investigator interests.  Or  Yale University and some of the investigators on this study have an application for patent protection with respect to means of data analysis employed in this research. This could lead to financial benefit for the University as well as the investigators and their Department.  **Institutional COI disclosure in consent form (Yale start-up company)**  The Committee considered the potential institutional conflict of interest with conducting this study at Yale, and found that this project may go forward. However, a section must be added to the consent form, entitled, "Investigator/University Interests." It should state, "Yale University has interest in the sponsor of this study, \_\_\_\_\_\_\_\_\_, and may, in the future, receive financial benefit from this relationship." | | | |

# Contact information for research participants

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| **Board Preferred or Required?** | | **Reference** | |
| Required section, equivalent language may be accepted. | | N/A | |
| **Required Language** | **Version date: 06-26-2023** | |  |
| If you have questions about your rights as a research participant, or you have complaints about this research, you can call the Yale Human Research Protection Program at (203) 785-4688 or email [hrpp@yale.edu](mailto:hrpp@yale.edu). | | | |

# Clinical Trials Registration

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| **Board Preferred or Required?** | | **Reference** | |
| Required. | | FDAAA 801, <https://clinicaltrials.gov/ct2/manage-recs/fdaaa> | |
| **Required Language** | **Version date: 01-21-2019** | | **Reading Level: 7.4** |
| A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. | | | |

# e-cigarettes: Flavor Risk

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| **Board Preferred or Required?** | | **Reference** | |
| Recommended. | | N/A | |
| **Consent Language** | **Version Date:7-13-2020** | | **Reading Level: 9.5** |
| The risks linked to the use of e-liquid flavors may be related to a regular and longer-term use. They include the potential for burns to and scarring of the respiratory system. There are also risks related to the chemicals used in the flavors and the effect of heat on the flavors. Another possible risk of the flavored e-cigarettes is a higher potential for nicotine addiction and continued use of the e-cigarettes. In this study, the use is limited to [*three puffs*] of a flavored cigarette. | | | |

# Economic Considerations: Oncology Research and Non-Oncology Research

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| **Board Preferred or Required?** | | **Reference** | |
| Recommended. | | N/A | |
| **Consent Language** | **Version Date:5-02-2022** | | **Reading Level: 9.6** |
| If you take part in this study, you will not have to pay for any services, supplies, study procedures, or care that are provided for this research only (they are NOT part of your routine medical care). However, there may be additional costs to you. These can include costs of transportation and your time to come to the study visits. You or your health insurance must pay for services, supplies, procedures, and care that are part of your routine medical care. You will be responsible for any co-payments required by your insurance.  If you need assistance in answering financial questions related to your insurance, contact your study team who can connect you with a representative in the YCCI Clinical Research Billing and QA office at 1-877-TRIALS0 (1-877-874-2560.  For more information on clinical trials, you can visit the National Cancer Institute’s (NCI) website at: http://www.cancer.gov/aboutnci/organization/clinical-center-fact-sheet.  To learn more information about paying for clinical trials and insurance, you can visit the NCI web site at:  • http://www.cancer.gov/clinicaltrials/learningabout/payingfor  • http://www.cancer.gov/clinicaltrials/learningabout/payingfor/insurance-coverage  Another way to get information is to call the NCI at 1-800-4-CANCER (1-800-422-6237) and talk to an Information Specialist, Monday-Friday 8am-8pm EST. You can request free information to be sent to you, such as the Cancer Clinical Trials Factsheet.  **Non-Oncology Research**  If you take part in this study, the costs of supplies, study procedures, or care that are specifically provided for the plan for this Study (which are NOT part of your routine medical care) will be paid for by the Sponsor. However, there may be additional costs to you, which can include your time to come to the study visits. You or your health insurance must pay for services, supplies, procedures, and care that are part of your routine medical care. You will be responsible for any co-payments required by your insurance. | | | |

# Economic Considerations when collecting Social Security number for payment purposes

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested. | | N/A | |
| **Consent Language** | **Version Date: 6-26-2023** | | **Reading Level: 8** |
| Your name, address, and U.S. taxpayer identification number (Social Security Number or ITIN) are  required to process payments and/or to report taxable income to the Internal Revenue Service (IRS).  You must complete a form W-9 to receive payment for participation. This information will not be linked  to any of the study data and will only be used for payment purposes.  If payments across all research studies at Yale equal or exceed $600 per calendar year, Yale will report  the amount to the IRS on Form 1099.  If you do not provide your SSN or ITIN, we cannot issue you a payment for participation. However, you  may still choose to participate in this study. | | | |

# Deception

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested. | | N/A | |
| **Consent Language** | **Version Date: 7-13-2020** | | **Reading Level: 8** |
| Research designs sometimes require that the full intent of the study not be explained prior to participation. We have described the general nature of the tasks that you will be asked to do. However, we will not explain the entire purpose of the study until the end of your participation. At that time, we will debrief you and explain the full purpose of the study. You will have a chance to ask any questions about the study and any of the procedures. You may decide to withdraw from the study or have your data removed. | | | |

# Electronic Medical Record

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| **Board Preferred or Required?** | | **Reference** | |
| Required for research conducted at Hospital, HRU, CHRU. | | N/A | |
| **Consent Language** | **Version Date:** | | **Reading Level: 7.7** |
| We will put information from this study into your Electronic Medical Record (EMR). This will include research test results. Your health care providers will be able to see these test results. Other people or groups such as a health insurance company who have access to your EMR may see this information. | | | |

# Electronic Medical Record – No Research Results

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| **Board Preferred or Required?** | | **Reference** | |
| Required when using Oncore when research participants either have a medical record in EPIC or for whom one will be created. Equivalent language may be accepted. | | N/A | |
| **Consent Language** | **Version Date: 6-26-2023** | | **Reading Level: 7.7** |
| Your record in EPIC, the Electronic Medical Record, will indicate that you are an active research participant during your participation in the study. We will not enter any research test results into your record. The information available in EPIC will include the title of the study and the name of the Principal Investigator. | | | |

# Focus Groups

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| --- | --- | --- |
| **Board Preferred or Required?** | | **Reference** |
| Suggested language. Equivalent language is permitted. | | N/A |
| **Consent Language** | **Version date: 01-21-2019** | **Reading Level: 7.8** |
| We will keep your information confidential. We ask that all focus group members not repeat any information shared during the focus group to others. However, we have no control over what happens outside of the group. Therefore, please, be aware of what you share in the group and do not share anything you hear from others outside of the group. | | |

# Future Research: Storage/Genetic Testing

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| **Board Preferred or Required?** | **Reference** | |
| Suggested language. Equivalent language is permitted. | <https://www.genome.gov/pages/policyethics/informedconsent> | |
| **Consent Language** | **Version date: 01-21-2019** | **Reading Level: 8.0** |
| If you agree, we would like to store some of your samples (called specimens) and related information for future research [for X purpose]. This may help researchers in the future learn more about how to prevent, find and treat [X disease(s)/condition(s)]. We will keep your specimens for as long as we can use them for research [If specific dates of storage are known, describe]. We may use them to make a cell line that will live forever. Future research may look at your genes. A gene is the code in each cell in your body that controls the behavior of that cell. Parents pass the genes down to their children. Genes are responsible for many things about you such as eye color, hair color, blood type and hundreds of other traits. Future research may find out the details of how your DNA is put together. We may use your specimen for whole exome, genome sequencing, or genome wide association studies. That means we will look at all genes, not just those related to a specific disease. The cells may be injected into animals in some of the research.  We may share your specimen and information with other researchers as well. We will do our best to protect your identity. We will code your samples and your information. We will only share coded samples and information with others. They will not be able to link the code to you. We follow strict security safeguards to avoid other people knowing your identity.  Allowing us to use your specimens for research will not help you. We do hope the research results will help people in the future. There is a risk that your information could be used in ways we did not plan [Give examples]. The chance of this happening is very small. We have protections in place to lower this risk [Describe]. There can also be a risk in uncovering genetic information. Researchers may find out new health information about you or your family members. Very rarely, health or genetic information could be misused by employers, health insurance companies, and others. There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers (except those with fewer than 15 employees) to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.  We will use your specimens and information for research only. We will not sell them. It is possible that the research will lead to development of products that will be sold for profit. If this happens, there is no plan to share any financial gain with you. We will not return research results to you or your doctor. If we publish the research results, we will not include your name or any other personal information.  **IF OPTIONAL ADD:**  The choice to take part is up to you. You may choose not to let us share your genetic and other information, and your care will not be affected by this decision. If you decide that we can share your information, you may change your mind at any time. Contact the study staff by phone or mail at [XX phone, XX address] to let them know you do not want your genetic and other information shared any longer. We can either destroy the information or make them anonymous (we will destroy the code linking them to you).  \_\_ I agree to allow my genetic and other information to be stored and used for future research as described above  \_\_ I do not agree to allow my genetic and other information to be stored and used for future research: (initial your choice). | | |

## Future storage for adolescent assents

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| **Board Preferred or Required?** | **Reference** | |
| Suggested language. Equivalent language is permitted. | <https://www.genome.gov/pages/policyethics/informedconsent> | |
| **Asssent Language** | **Version date: 07-13-2020** | **Reading Level: 8.0** |
| If you agree, we would like to store some of your specimens (called samples) and related information for future research [for X purpose]. This may help researchers in the future learn more about how to prevent, find and treat [X disease(s)/condition(s)]. We will keep your samples for as long as we can use them for research [If specific dates of storage are known, describe]. Future research may look at your genes. A gene is the code in each cell in your body that controls the behavior of that cell. Parents pass the genes down to their children. Genes are responsible for many things about you such as eye color, hair color, blood type and hundreds of other traits. Future research may find out the details of how your DNA is put together. We may look at all genes, not just those related to a specific disease.  We may share your sample and information with other researchers as well. We will do our best to protect your identity. We will code your samples and your information. We will only share coded samples and information with others. They will not be able to link the code to you. We follow strict security safeguards to avoid other people knowing your identity.  Allowing us to use your samples for research will not help you. We do hope the research results will help people in the future. We will use your samples and information for research only. | | |

# GINA Language

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| **Board Preferred or Required?** | | **Reference** | |
| Required for genetic research, except NCI CIRB studies. Substantially equivalent language can be approved by the IRB. | | OHRP Guidance: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html> | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 14.7** |
| There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:  • Health insurance companies and group health plans may not request your genetic information that we get from this research.  • Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.  • Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.  However, this federal law does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. | | | |

# Gun Law, Research at Connecticut Mental Health Center

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| **Board Preferred or Required?** | | **Reference** | |
| Required for overnight research at CMHC. Substantially equivalent language can be approved by the IRB. | | <https://www.cga.ct.gov/2013/rpt/2013-R-0216.htm> | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 14.5** |
| It is important for you to know that that there is a law in Connecticut (Public Act 13-3), that may affect you if you participate in this study. The law requires hospitals to report to the Department of Mental Health and Addiction Services (DMHAS) the names of all persons who are voluntarily admitted for psychiatric care. Under the law, DMHAS will report to the Department of Emergency Services and Public Protection (DESPP) the names, addresses, birthdates and social security numbers of all persons who are voluntarily admitted and who are registered gun owners or who apply for a gun registration within six months of admission. The DESPP will revoke the gun permit, confiscate the gun and deny new permits for six months after the admission. You will be affected by this law only if you legally own a gun or are planning to register for one in the next six months. | | | |

# GWAS

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| **Board Preferred or Required?** | | **Reference** | |
| Required for GWAS studies. Equivalent language can be approved by the IRB. | | NIH: Update to NIH Management of Genomic Summary Results Access, Notice Number: NOT-OD-19-023, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-023.html> | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 9.4** |
| We will also give your genetic and other information about you, such as your medical conditions, to the National Institutes of Health (NIH) Genome-Wide Association Studies (GWAS) repository. GWAS studies look at the genetic differences that exist along the human genome, which is the complete set of human genes.  The NIH GWAS repository stores genetic information and individual characteristics about people, like gender, age, medical conditions from people participating in many studies across the country. GWAS shares that information with researchers. We will send this information about you and other people in this study to the NIH GWAS repository. It will be coded and your name and other information that could identify you will be removed. NIH will not identify or make any attempt to identify information as coming from you or any other individual. NIH will share the collected information with researchers who submit applications to NIH to do research with information from the GWAS repository. Special data sharing committees will review those applications and decide whether or not to share the information with the researcher. The researchers who receive your information must promise to keep it confidential and to use it only for the research purpose approved by NIH.  The goal of GWAS studies is to speed up new medical discoveries and treatments by making it easier for researchers to share this information with each other. For example, GWAS data may be used to find out:  • who is more likely to develop a certain illness, such as asthma, cancer, or diabetes, or a condition like high blood pressure or obesity;  • what genes affect the progress of a certain disease or condition; and  • what genes may affect treatments which now may or may not work in certain people.  GWAS research will not directly benefit you but it could lead to a greater understanding of the interaction between genes and health. This knowledge could help others in the future. | | | |

# Images, Risks

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.2** |
| X-rays, CT scans, PET scans, bone scans, and MUGA scans use radiation to make pictures, or images, of parts of the body. Rarely, radiation can cause a new cancer. Sometimes chemicals are put into a blood vessel to make or improve the pictures. These can cause kidney injury, especially in people who already have some kidney damage. | | | |

# Injury Provisions

## Industry (For-profit) Supported Studies

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| **Board Preferred or Required?** | | **Reference** |
| Suggested language. Equivalent language reflecting Yale's position and consistent with the contract (per OSP review) is permitted, as approved by the IRB. | | Yale Position Statement |
| **Consent Language** | **Version date: 027130-2020** | **Reading Level: 12.8** |
| If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.  If you become ill or are physically injured due to the study [drug/device] [provide name of agent] or any investigational procedure specifically required by the plan for this study, the costs of diagnosis and medical care for any such illness or injury caused by the study [drug/device] or properly performed non-standard of care investigational procedure required by the study may be covered by the Sponsor.  If you receive a bill for any costs related to the diagnosis or treatment of your injury, please contact the study doctor.  You will not receive any other kind of payment. There are no plans to pay you for such things as lost wages, disability, or discomfort as part of this study. You do not give up any of your legal rights by signing this consent form.  **Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) language if applicable:**  In the event that you suffer from a research injury for which diagnosis or treatment costs are paid for by the Sponsor, Federal law requires the Sponsor to check to see if you receive Medicare coverage and if you do, to inform the Centers for Medicare & Medicaid Services (CMS, the agency responsible for administration of the Medicare program). To comply with this reporting obligation, the Sponsor or its representative may need to collect and share certain personal information about you, such as your name, date of birth, sex, and Medicare ID number (if you have one), with CMS. This information may be collected directly from you, or from the study doctor, study staff, or other health care providers who treated your illness or injury.  This information may be shared with others, including the Sponsor’s representatives and the Centers for Medicare & Medicaid Services. The Sponsor and its representatives will not use this information for any other purpose. | | |

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## Studies Funded by Merck

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| --- | --- | --- |
| **Board Preferred or Required?** | | **Reference** |
| Recommended. This language has been agreed upon by the company and Yale. | | Yale Position Statement |
| **Consent Language** | **Version date: 07-13-2020** | **Reading Level: 12.8** |
| If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.  If you become ill or are physically injured due to the study [drug/device] [provide name of agent] or any investigational procedure specifically required by the plan for this study, the costs of diagnosis and medical care for any such illness or injury caused by the study [drug/device] or properly performed non-standard of care investigational procedure required by the study may be covered by the Sponsor.  If you receive a bill for any costs related to the diagnosis or treatment of your injury, please contact the study doctor.  You will not receive any other kind of payment. There are no plans to pay you for such things as lost wages, disability, or discomfort as part of this study. You do not give up any of your legal rights by signing this consent form. | | |

## 20.3 Studies Funded by Boehringer Ingelheim Pharmaceuticals, Inc.

|  |  |  |
| --- | --- | --- |
| **Board Preferred or Required?** | | **Reference** |
| Recommended. This language has been agreed upon by the company and Yale. | | Yale Position Statement |
| **Consent Language** | **Version date: 05-02-2022** | **Reading Level: 12.8** |
| What happens if you are injured during this study?  If you are injured while on study, seek treatment and contact the study doctor as soon as you are able. If you become ill or are physically injured due to the study [drug/device] [provide name of agent] or any properly performed investigational procedure specifically required by the plan for this study, the costs of diagnosis and medical care for such illness or injury will be covered by the Sponsor as long as you have followed the directions of the study doctor.  The sponsor does not have a program to provide any other payment or compensation to you, including for lost wages or mental distress. You do not lose any of your legal rights by signing and dating this form.  Any payments made by the sponsor as outlined above require the sponsor to determine if you are covered by Medicare and, if so, to report certain information to Medicare. To do so, the sponsor will need certain personal identifiable information from you, including your name, date of birth, Medicare/Medicaid health insurance claim number, and Social Security number. The sponsor agrees to use this information only for Medicare reporting purposes and those outlined in the Authorization to Use and Share Your Protected Health Information section, which is included at the end of this consent form. | | |

## 20.4 Studies Funded by Vertex Pharmaceuticals, Inc.

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| **Board Preferred or Required?** | | **Reference** |
| Recommended. This language has been agreed upon by the company and Yale. | | Yale Position Statement |
| **Consent Language** | **Version date: 05-02-2022** | **Reading Level: 13.6** |
| If you experience an injury or side effects, you should contact your study doctor at <contact information>, or go to the nearest emergency room.  If you become sick or injured as a result of your participation in this study, appropriate medical care for the diagnosis and treatment of the illness or injury will be given to you. If the sickness or injury is a direct result of a properly performed study procedure or because you took or are taking the Study Drug as directed, the sponsor will pay for the reasonable and necessary costs associated with this. No other compensation or payment will be provided to you, including lost wages.  Providing medical care does not mean the sponsor, your study doctor or the study center did anything wrong. | | |

## Non-Industry Supported Studies, Investigator-Initiated Studies, and Registry Studies)

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| **Board Preferred or Required?** | | **Reference** |
| Suggested language. Equivalent language reflecting Yale's position is permitted, as approved by the IRB. | | Yale Position Statement |
| **Consent Language** | **Version date: 01-21-2019** | **Reading Level: 10.4** |
| If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.  Yale School of Medicine and [Specify health care facility, e.g., Yale-New Haven Hospital, the Connecticut Mental Health Center] do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form. | | |

# IV Use

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 6.2** |
| Having an intravenous (IV) line placed is a very safe procedure. There is a slight chance that multiple needle-sticks will be needed to make sure the IV is placed correctly. You might feel a small amount of pain when the IV is placed but it does not last very long. A bruise or a minor infection might develop where the IV is placed. A bruise will go away by itself and it might help if you wrap a warm towel around your arm. Infections can also be treated if necessary. | | | |

# Lumbar or Spinal Puncture

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| --- | --- | --- | --- |
| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. | | N/A | |
| **Consent Language** | **Version date: 02713-2020** | | **Reading Level: 10.4** |
| During and after the procedure, you may have temporary pain and discomfort in your neck and back pain due to the positioning required for the procedure. Lightheadedness or feeling faint may also occur but these feelings usually pass after you sit for a while before standing up. Headache may occur in people who receive an LP. Occasionally, a headache may persist, presumably due to leakage of spinal fluid, and may require additional treatment. Uncommonly a blood patch (injection of some of your blood into the puncture site to patch the spinal fluid leak) may be required. This often relieves the headache immediately.  Although very rare, it is possible that you may have an allergic reaction to the local anesthetic [*name*] used for the LP. This would cause swelling and a rash on your skin where the anesthetic was injected. Please tell us if you have ever had a reaction to local anesthetic before (such as when you were visiting the dentist). Potential but rare risks of lumbar puncture include infection, nausea, dizziness, vomiting, damage to nerves in your back and bleeding into the spinal fluid space as well as rare instances of increased pressure in the skull. The risk of these is very small. To minimize these risks, the LP procedure will be performed by experienced medical professionals who are specifically trained to carry out this procedure.  *Add if applicable:*  Your study doctor may choose to perform the lumbar puncture under fluoroscopy. Fluoroscopy, a standard, FDA-approved imaging procedure, uses x-rays for about 5 seconds to show us the best place to insert the needle. The use of x-rays will expose you to radiation during the procedure. While there is always a slight risk of damage to cells or tissue from being exposed to too much radiation, the exposure risk is considered minimal for this procedure. Your study doctor can provide additional information regarding this use and the radiation exposure. There also may be other side effects that we cannot predict. You should tell the research staff about all the drugs, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks. | | | |

# Mandatory Reporting

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| **Board Preferred or Required?** | | **Reference** | |
| Required. Equivalent language can be approved. | | CT General Statutes, <https://portal.ct.gov/DPH/Epidemiology-and-Emerging-Infections/Reporting-of-Diseases-Emergency-Illnesses-Health-Conditions-and-Laboratory-Findings> | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.5** |
| We will test you for hepatitis and/or HIV. We are required to report positive results to the CT Department of Health. | | | |

# MRI

## 24.1 Research at FAS BIC

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| **Board Preferred or Required?** | | **Reference** | |
| Required if MRIs take place FAS BIC; substantially equivalent language may be permitted if accepted by ancillary committee and IRB. | | <https://brainimaging.yale.edu/about-center> | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.0** |
| Magnetic resonance imaging (MRI) uses magnetic fields and radio waves to take pictures of the body. Millions of people have had MRI scans with no known safety issues. MRI uses a strong magnet, which can pull strongly on some metals. These metals must not be brought into the scan room. They could be pulled towards the magnet and cause serious injuries if they hit you. People entering the scan room must remove all metal from their body, clothing and pockets. This includes jewelry, hearing aids, watches, cell phones, keys, coins, and wallets. Some metal objects could also heat up during the MRI, burning you. Electrical devices such as pacemakers could go wrong or stop working. You must also tell us if you are wearing anything that could contain metal. For example, some medication patches have a metal backing. Some clothing can contain metal fibers that could also heat up during the MRI. We will therefore ask you to fill out an MRI safety form to check if you have anything in your body which might be dangerous in the MRI. It is very important that you fill out this form accurately and ask if you are unsure about anything.  During the MRI scan, you may feel uncomfortable or worried. When the MRI scanner is making pictures, it makes loud tapping, buzzing, and beeping noises. Without protection, this could damage your hearing. We will give you with earplugs and/or headphones to reduce the sound to a safe level. While the scanner is making noises, we will not be able to hear you. We will give you a squeeze bulb for you to contact us.  The MRI scan is intended for research and not to find disease. The researchers are not qualified to medically interpret your scan. If we do see something that may be a concern, we will let you know. You can then decide if you want to discuss this with your doctor. The investigators and Yale University are not responsible for any treatment that you receive based on these findings. The pictures collected in this study are not a healthcare MRI exam and will not be made available for healthcare purposes. | | | |

## 24.2 Research at MRRC

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| **Board Preferred or Required?** | | **Reference** | |
| Required for research taking place at MRRC. Substantially equivalent language may be permitted if accepted by ancillary committee and IRB. | | MRRC Imaging Policy (<https://medicine.yale.edu/mrrc/users/forms.aspx>) | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 9.3** |
| Magnetic resonance (MR) is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure chemicals of different parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines.  You will be watched closely throughout the MR study. Some people may feel uncomfortable or anxious. If this happens to you, you may ask to stop the study at any time and we will take you out of the MR scanner. On rare occasions, some people might feel dizzy, get an upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but please tell the research staff if you have them.  There are some risks with an MR study for certain people. If you have a pacemaker or some metal objects inside your body, you may not be in this study because the strong magnets in the MR scanner might harm you. Another risk is the possibility of metal objects being pulled into the magnet and hitting you. To lower this risk, all people involved with the study must remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the study to walk through a detector designed to detect metal objects. It is important to know that no metal can be brought into the magnet room at any time. Also, once  you are in the magnet, the door to the room will be closed so that no one from outside accidentally goes near the magnet. We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information you think might be important.  This MR study is for research purposes only and is not in any way a complete health care imaging examination. The scans performed in this study are not designed to find abnormalities. The principal investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a health care evaluation of the images. If a worrisome finding is seen on your scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her  recommendation (if any), the principal investigator or consulting physician will contact you, inform you of the finding, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie only with you and your physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that you receive based on these findings. The images collected in this study are not a health care MR exam and for that reason, they will not be routinely made available for health care purposes. | | | |

## 24.3 MRI with Contrast

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| **Board Preferred or Required?** | | **Reference** | |
| Required for research taking place at MRRC. Substantially equivalent language may be permitted if accepted by ancillary committee and IRB. | | MRRC Imaging Policy (<https://medicine.yale.edu/mrrc/users/forms.aspx>); FDA Drug Safety Warnings and other applicable FDA Information | |
| **Consent Language** | **Version date: 10-24-2023** | | **Reading Level: 7.7** |
| We will use a contrast agent for the scan. A contrast agent is like a dye, and it is injected into your vein. The dye is called gadolinium. Gadolinium has been used in many patients, and it is approved by the FDA. You might have a warm, flushed feeling during the injection. You can also feel a metallic taste in your mouth for a few minutes.  Some people feel dizzy or queasy or get a headache after the injection. These side effects usually go away by themselves. There is also a small chance of having an allergic reaction. An allergic reaction can cause hives, itching or a hard time breathing.  If your kidney function is below normal, there is a risk of a rare but serious disease called nephrogenic systemic fibrosis. For safety, your kidney function will be tested before you have any dye injected. Small amounts of gadolinium can stay in your body and brain after injection, but this has no known harmful effects.  If you are pregnant, you cannot participate in this study, so we will also test whether you are pregnant before you have any dye injected. It is important to tell the study doctor if you are breast feeding, if you have a history of allergic reactions to MR or CT agents before, if you have a history of kidney disease, seizure, asthma, or allergic respiratory disorders, and if you have anemia or disease that affects red blood cells.  If you have any questions, please, discuss this with the research team as well as your private physician. | | | |

# MTurk

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| --- | --- | --- |
| **Board Preferred or Required?** | | **Reference** |
| Suggested language. Equivalent language is permitted. | | N/A |
| **Consent Language** | **Version date: 01-21-2019** | **Reading Level: 7.3** |
| The survey is anonymous. We will not know your name. We will not be able to connect any identifying information to your survey answers. However, we will know your mTurk number in order to pay you for your time. Your mTurk number could possibly be connected to your public profile, which could, in theory, be searched. We want to stress that we will not be looking at anyone’s public profiles. We will keep the information about your participation in this research confidential. | | |

# Needle Biopsy

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.1** |
| A needle biopsy involves pushing a needle in a part of the body to remove a small piece or several small pieces. Sometimes this is done with some sort of imaging, such as with a CT scan. Needles may cause pain, bruising, and bleeding. A biopsy can also cause other problems. For example, a lung biopsy may cause the lung to collapse, and a liver, bone, or bone marrow biopsy may lead to bleeding. Rarely, a biopsy will spread tumor cells to a nearby area. | | | |

# Needles and Catheters

|  |  |  |  |
| --- | --- | --- | --- |
| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.6** |
| Needles and catheters are involved in many procedures including blood draws, giving medications, and scans. Needles may cause pain, bruising, and bleeding; they can cause light-headedness or fainting. Catheters are put into blood vessels with needles. Catheters may also cause blood clots and infections. | | | |

# Payments for Participation

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| **Board Preferred or Required?** | | **Reference** | |
| Required Language if subjects are paid stipends (see below for additional explanation).  For payments using ecards, add language available [HERE](#_Bank_of_America). | | S.139 - Ensuring Access to Clinical Trials Act of 2015: Taxable income for rare diseases above $2000. | |
| **Additional Guidance:** | | | |
| Consent forms must clearly distinguish between stipends and expense reimbursements. These two terms are NOT interchangeable.  **Stipends** are paid to the study participant at a flat rate without regard to any actual out-of-pocket costs. They are generally included within the per-patient cost of the budget between Yale and the Sponsor and are considered taxable income to the participant. Such payments can be made to subjects using the Bank of America card system (preferred, see section 2 of this Consent Glossary) or by cash/check.  **Expense Reimbursements** are costs reimbursed to the subject based on his/her actual costs incurred (e.g., parking, meals) and not as a flat rate payment. Generally, there are specific sponsor criteria associated with such expense reimbursements such as minimal travel distance, maximum amounts for hotel, meals, etc. and potentially pre-approval requirements before such expenses can be approved. Receipts are normally required to be collected from the participant and submitted to the sponsor, and these costs are invoiced to the Sponsor and not paid automatically. Expense reimbursements are not taxable and if such costs are being included by the Sponsor, expense reimbursement terms should be written into the Consent after the tax language applicable to stipends so there is no confusion as to what is taxable. Expense Reimbursements cannot be made using the debit card system, so mechanism of payment for these (e.g., checks) should be specified. | | | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 8.0** |
| [see separate guidance document for more detailed examples / terms]  You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments. | | | |

# PET Center

## Scanning Procedure with Arterial Catheter Insertion

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| **Board Preferred or Required?** | | **Reference** | |
| Required if PET Center is used. | | PET Investigators Guide 2016-04, (revised version pending), <https://medicine.yale.edu/pet/informationforinvestigators/> | |
| **Consent Language** | **Version date: 05-02-2022** | | **Reading Level: 7.2** |
| An experienced health care provider will insert an arterial catheter in your wrist area. The arterial catheter is about 2 inches long and looks like a regular IV tube, but it is inserted into an artery, not a vein. The blood flow in the arteries can tell us about your blood pressure. If an arterial catheter is in place, we can measure your blood pressure continuously. Thanks to an arterial catheter, we can draw blood quickly, more than once, and without causing you pain. Here is what happens when an arterial line is placed:   * We will clean the skin with betadine solution (contains iodine). It will reduce the risk of an infection. * We will numb your skin with a local anesthetic so that you feel less pain when the catheter is inserted. You will probably just feel pressure but may also feel pain. It would be similar to the pain you feel with an IV. * We will flush the catheter often during your scan with saline (a salt solution) to make sure it does not clog. * After we remove the catheter, we will apply pressure to your skin for a minimum of 15 minutes to prevent bleeding under the skin. * We will apply a pressure dressing (coban) and clear dressing (tegaderm). You will need to keep it clean and dry. Do not exercise too much and do not lift heavy objects weighing more than 5 pounds. Avoid making the same movements for 48 hours. * You may remove the pressure dressing at bedtime and the clear dressing after 48 hours, but do not put your hand and wrist in water for a full 72 hours. Since the catheter is in for a minimal period, there is a low risk of infection. | | | |

## Risks Associated with Use of an Arterial Catheter

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| **Board Preferred or Required?** | | **Reference** | |
| Required if PET Center is used. | | PET Investigators Guide 2016-04, (revised version pending), <https://medicine.yale.edu/pet/informationforinvestigators/> | |
| **Consent Language (Risk section)** | **Version date: 05-20-2022** | | **Reading Level: 6.7** |
| **Important: You cannot take part in the study, if you have ever had a bleeding disorder or are taking medication to thin your blood.**  The insertion of the arterial line may be painful, and you can get bruises. The arterial puncture may cause a spasm, a temporary tightening (constriction) of the muscles in the wall of the artery. You may get a clot and your blood flow will slow down for a little while. You can get a hematoma (swelling of blood within the tissues). The site can bleed or get inflamed (become red, swollen, hot, and painful). These feelings will go away after some time, usually 24 to 72 hours after the procedure. Rarely, you may experience blocking of the artery or nerve damage to the insertion site. The insertion site may not heal as fast, or you may get infection. This is why an experienced health care provider will insert the arterial line and a trained nurse will look after for you.  Check your wrist and arm every day for two days after the study visit with the arterial line. Call right away your study team or the PET Center Physicians, Dr. David Matuskey at 203-370-1403 (voice mail pager) or Dr. Ming-Kai Chen 203-675-0120 (cell), if you notice any of the following:  • You feel a lot of pain  • Your wrist or arm is tender, swollen, or red  • You see some blood or other fluids coming out of the injection site  • The color of your skin changes  • Your arms feel numb  • You feel pins and needles in your arm  • Your arm that had the catheter does not feel as strong  Tell us if you have had a bad reaction to lidocaine, novocain, or other drugs used to numb the skin in the past. You may experience a rare allergic reaction to the medicine used to numb your skin prior to placement of the arterial catheter. Severe allergic reactions can be life threatening. Some things that happen during an allergic reaction are:  • rash  • hives  • having a hard time breathing  • wheezing when you breathe  • sudden drop in blood pressure  • swelling around the face, mouth, lips, tongue, throat, or eyes  • fast pulse  • sweating  If you have any of the above allergy related side effects or symptoms, your study doctor will assess you and treat these symptoms.    Do not take aspirin and other anti-inflammatory drugs (such as Motrin or Aleve) for 7-10 days before arterial line placement and 7-10 days after the study visit. | | | |

# Phase 1 Description

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.7** |
| You are considering a Phase I clinical trial. Your doctors do not think there are any approved cancer therapies that can treat your disease, help control symptoms of your disease, or prolong your life. This is a first in human use of an experimental anticancer agent. You may not get any benefits by taking part in this study. We will do everything we can to prevent or lessen any side effects you may experience. However, we do not know for sure if we will be able to do that. There is a risk of injury that may be severe, life-threatening, or even fatal. | | | |

# Placebo Studies

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 5.4** |
| We will give you a study drug. It will either contain [name of drug] or placebo [pills/infusion] with no medicine. | | | |

# Pregnancy Testing

## Parental Permission

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| **Board Preferred or Required?** | | **Reference** | |
| Required section - equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 06-26-2023** | | **Reading Level: 8.9** |
| Your daughter will be asked to have a pregnancy test before starting this study. If your daughter is age 13 or older, only she will be told the results. If she is pregnant, we will also advise her to get care for her pregnancy and to get the support of an adult. If your daughter is under age 13 and has a positive pregnancy test, we are required to report the pregnancy to the Department of Children and Families. | | | |

## Assent

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| **Board Preferred or Required?** | | **Reference** | |
| Required section - equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 06-26-2023** | | **Reading Level: 9.3** |
| We will ask you to have a pregnancy test before you start this study. Only you will be told the results. If you are pregnant, we will also advise you to get care for your pregnancy and also to get the support of an adult. You will be asked not to be in the study, or you will be removed from the study if your pregnancy test is positive. If you are younger than age 13 and have a positive pregnancy test, we will report your pregnancy to the Department of Children and Families.  You need to know that your parents may ask you why you cannot be in the study or why you were asked to leave the study. So, if there is any chance that you are pregnant or you might become pregnant during the time of this study, we would recommend that you think really carefully about whether you should be in the study. It is okay if you decide that you do not want to be in the study or to stay in this study. You do not need to give a reason for not being in the study. | | | |

# Prisoners as Participants

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted. | | [IRB Policy 320 IRB Review and Approval of the Participation of Prisoners in Research](https://your.yale.edu/policies-procedures/policies/320-irb-review-and-approval-participation-prisoners-research) | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.6** |
| Taking part in this study will not change your sentence, the length of sentence, or your parole. Your living conditions, medical care, food, amenities, or chances for income will not change. You will get the same standards that you would typically receive in prison. | | | |

# Psychology Subject Pool

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| **Board Preferred or Required?** | | **Reference** | |
| Required if Psychology Subject Pool is used. | | Yale Department of Psychology: <https://psychology.yale.edu/resources> | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.8** |
| Your involvement in this study is important for our research. We hope that you will find your experience in this study meaningful. There are other ways to meet your “experimental participation” credits for this course. You will receive information in class regarding your options. You can talk to your instructor about these options. | | | |

# Radiation

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019 – YNHH**  **Version date: 05-02-2022 – PET Center** | | **Reading Level: 12.9** |
| **Study takes place at YNHH**  This research study involves exposure to radiation from *[Describe: e.g., research required extra head CT scan*]. Please note that this radiation exposure is not necessary for your medical care and is for research purposes only. Although each organ will receive a different dose, the amount of radiation exposure will receive from this study is equal to a uniform whole-body exposure of *[XX]* rem. This calculated value is known as the “effective dose” and is used to relate the dose received by each organ to a single value.  This amount of radiation is well below the dose guidelines established by the federal government and adhered to by the Yale-New Haven Hospital Radiation Safety Committee for research subjects. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about YY extra years' worth of this natural radiation.  *(Note: average natural exposure is 300mrem or 0.3rem, so compare XX to 0.3rem)*  **Study takes place at Yale Pet Center**  This research study involves exposure to radiation from PET imaging. If you take part in this research, you will be exposed to a small to moderate dose of radiation from the radiolabeled probes used for the PET scans and associated with the transmission scans. Please note that this radiation exposure is not necessary for your medical care and is for research purposes only. The Yale University Radiation Safety Committee (RSC) and *[ insert correct committee: Radiation Investigational Drug Committee (RIDC); Radioactive Drug Research Committee (RDRC)]* have both reviewed the use of radiation in this research study and have approved this use as involving slightly greater than minimal risk and necessary to obtain the research information desired. The total amount of radiation you will receive in this study is from [*insert #]* transmission scans -used to optimize the PET scan -and [*insert #]* injection[s] of radioactive material (*XX mCi insert radiotracer name*). This radiation is in addition to what you may get as part of your regular medical care and what you receive from natural radiation in our environment. Everyone is exposed to low levels of natural radiation, called ‘background radiation.’ This background radiation comes from outer space and from rocks and minerals in the soil and is greater at higher altitudes. The average yearly background radiation in the United States is about 300 mrem. The amount of additional radiation you will get from participating in this study is about *[insert # of mrem]* mrem. This is equal to about [*insert # of years*] years’ worth of natural radiation. The amount of radiation involved in this research is small but may slightly increase your risk of getting cancer. Scientists are not certain about the actual cancer risk at these low doses, and there may be no risk at all, but to be conservative we assume that any amount of radiation may pose some increased cancer risk. | | | |

# Randomization

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 6** |
| You will be “randomized” into one of x study groups: [describe the groups]. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctors will choose the group. You will have an [equal/one in three/etc.] chance of being placed in any group. [If blinded: Neither you nor your doctors will know what group you are in [if appropriate: but your doctors can find out if medically necessary.] | | | |

# Reproductive Risks Unknown

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted. | | N/A | |
| **Consent Language** | **Version date: 01-21-2019** | | **Reading Level: 7.6** |
| We do not know whether this drug could damage genes or have negative effects on development of the fetus. There are no research studies on animals on this topic. | | | |

# Reproductive Risks: Men; Research at St. Francis and other hospitals within the Trinity Health of New England

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| **Board Preferred or Required?** | | **Reference** | |
| Required for research conducted at Trinity Health of New England, e.g. St. Francis Hospital. Can be used as an addendum to consent form. | | <http://www.trinityhealthofne.org/forms-and-templates> | |
| **Consent Language** | **Version date: July 2017** | | **Reading Level: 11.9** |
| **IMPORTANT INFORMATION ABOUT REPRODUCTIVE RISKS**  **MEN**  <insert here> drugs such as the ones offered as part of this clinical trial can affect an unborn child. If you are a man able to have children, it is important that you do not father a child while you are taking part in this study, and perhaps even for some time after you stop taking the study drugs. Your doctor will discuss this in detail with you.  Trinity Health Of New England sites are dedicated to your health and well-being. While abstinence is the most effective way of preventing a pregnancy, we understand that you may consider other methods of pregnancy prevention. Sites within Trinity Health Of New England will not provide contraception products as part of this study, nor does it endorse, approve, or intend contraception, other than abstinence, by complying with the requirements of this study.  <insert here> drugs such as the ones offered as part of this clinical trial may affect your ability to father a child in the future. Your doctor will discuss this in detail with you.  The “Reproductive Risks” section of this Informed Consent Form discusses what forms of pregnancy prevention are adequate for use in this study and which forms are not. The “Risks Section” may also discuss options to preserve your ability to father a child in the future. You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention.  As a Catholic Healthcare system, Trinity Health Of New England abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Trinity Health Of New England neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.  Patient Initials \_\_\_\_\_\_\_\_\_ | | | |

# Reproductive Risks: Women; Research at St. Francis and other hospitals within the Trinity Health of New England

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| **Board Preferred or Required?** | | **Reference** | |
| Required for research conducted at Trinity Health of New England, e.g. St. Francis Hospital. Can be used as an addendum to consent form. | | <http://www.trinityhealthofne.org/forms-and-templates> | |
| **Consent Language** | **Version date: July 2017** | | **Reading Level: 11.9** |
| **IMPORTANT INFORMATION ABOUT REPRODUCTIVE RISKS**  **WOMEN**  <insert here> drugs such as the ones offered as part of this clinical trial can affect an unborn child. If you are a woman able to have children, it is important that you do not become pregnant while you are taking part in this study, and perhaps even for some time after you stop taking the study drugs. Your doctor will discuss this in detail with you. Women who are breast feeding should stop breast feeding while taking part in this study.  Trinity Health Of New England sites are dedicated to your health and well-being. While abstinence is the most effective way of preventing a pregnancy, we understand that women may also decide to use other methods of pregnancy prevention. Sites within Trinity Health Of New England will not provide contraception products as part of this study, nor does it endorse, approve, or intend contraception, other than abstinence, by complying with the requirements of this study.  The “Reproductive Risks” section of this Informed Consent Form discusses what forms of pregnancy prevention are adequate for use in this study and which forms are not. You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention.  As a Catholic Healthcare system, Trinity Health Of New England abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Trinity Health Of New England neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.  Patient Initials \_\_\_\_\_\_\_\_\_ | | | |

# Secondary Research with Data and Biospecimens

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| **Board Preferred or Required?** | | **Reference** | |
| Suggested language. Equivalent language is permitted.  For more information see <https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf> | | <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-213.html> | |
| **Consent Language** | **Version date: 12-02-2022** | | **Reading Level: 7.6** |
| **Introduction-Description**  This study is collecting data and biospecimens from you. We would like to make your data and biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data and biospecimens for **[*Insert time frame as indicated in the study protocol*].** Your data and biospecimens may be shared with researchers around the world.  However, the decision to share your data and biospecimens is controlled by **[*indicate which entity has control*].** To get your data and biospecimens, future researchers must seek approval from **[*indicate which entity has control*]**. The researchers must agree not to try to identify you.  **Option #1: If the data and biospecimens are coded and can be linked back to the identity of the participant:**  We will protect the confidentiality of your information to the extent possible. Your data and biospecimens will be coded to protect your identity before they are shared with other researchers. **[*indicate which entity has the code key*]** will have a code key that can be used to link to your identifying information. The code key will be securely stored.  **Option #2: If the data and biospecimens cannot be easily linked back to the identity of**  **the participant:**  Your name and identifying information will be removed from any data and biospecimens you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and biospecimens.  **Voluntary Participation and Withdrawal of Consent from Storage and Sharing**  **Option 1: When sharing of data and biospecimens will be optional (e.g., for studies that have potential benefit):**  It is your choice whether or not to let researchers share your data and biospecimens for research in the future. If you say “yes,” you can change your mind later. If you say “no,” you can still fully participate in this study. If you change your mind and no longer wish to have us store or share your data and  biospecimens, you should contact **[*insert contact info*].** We will do our best to honor your request and to retrieve any data and biospecimens that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data and biospecimens we will not be able to retrieve them. In addition, if the data and biospecimens have already been used for new research, the information from that research may still be used. We will **[*fill in what will happen to the biospecimens after they are retrieved*]** any biospecimens we have or are able to retrieve.  Please initial **[or sign depending on institutional practice]** next to your choice:  \_\_\_\_\_\_**YES,** use my data and biospecimens in other research studies  \_\_\_\_\_\_**NO, do NOT use** my data and biospecimens in other research studies  **Option 2: When sharing of data and biospecimens will not be optional (e.g., where sharing is integral to the purpose of the study):**  Participating in this study means you agree to share your data and biospecimens. You can change your mind later, but researchers might still use your data and biospecimens if they have already been shared. If you do not want your data and biospecimens used for other projects, you should not participate in this study.  **Risk and Benefits**  **[Risks]** We will do our best to protect your data and biospecimens during storage and  when they are shared. However, there remains a possibility that someone could identify  you. There is also the possibility that unauthorized people might access your data and  biospecimens. In either case, we cannot reduce the risk to zero.  **[Benefits]** You will not receive any direct benefit from sharing your data and  biospecimens. However, sharing your data and biospecimens may contribute to research  that could help others in the future.  **Commercial Application**  The use of your data and biospecimens may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur. | | | |

# Resources

[PRISM [Program for Readability in Science & Medicine]](https://www.kpwashingtonresearch.org/about-us/capabilities/research-communications/prism): Readability Toolkit and Online Training

[PRISM Editing Checklist](https://your.yale.edu/policies-procedures/other/prism-editing-checklist)

[National Comprehensive Cancer Network database:](https://www.nccn.org/education-research/nccn-oncology-research-program/informed-consent-language-database) database containing more than 2,300 standardized lay language descriptions of risks and events associated with clinical research.

# Consent Elements, Common Rule, 45CFR46.116

## Basic Elements of Informed Consent (2018 Common Rule Standards)

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

## Additional elements of informed consent (2018 Common Rule Standards)

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) 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).

# Consent Elements: FDA Regulated Research, 21CFR50.25

## Basic Elements of Informed Consent, FDA Regulated Research

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

## Additional Elements of Informed Consent, FDA Regulated Research

(1)A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

# HIPAA Elements

Please, see [HIPAA Elements for Research](https://privacyruleandresearch.nih.gov/pdf/authorization.pdf) document for the description of the Core Elements and Authorization Required Statements.

# Version History

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| --- | --- | --- |
| Version # | Date | Description |
| 1.0 | January 21, 2019 | Initial effective date. |
| 2.0 | July 13, 2020 | Revised Lumbar Puncture (expanded on the risk),  Added ‘In case of Injury’ language for specific sponsors,  Added proposed deception language,  Added suggested adolescent language for future storage of samples,  Added suggested ‘Economic Considerations’ language for oncology research |
| 3.0 | May 2, 2022 | Revision to the Radiation section to add PET Center language  Addition of COI disclosure language  Addition of the language for billable services  Addition of guidance regarding payments and reimbursements  Addition of In Case of Injury language as approved by additional sponsors |
| 4.0 | December 1, 2022 | Remove BoA card specific language  Add MMSEA language  Add Economic Considerations: Non-Oncology Research language |
| 5.0 | June 26, 2023 | Added section with description of language for consent forms for studies reviewed by external IRBs;  Added language for pregnancy testing in minors;  Added contact information to HRPP;  Added alternative language for studies utilizing Oncore but when research tests results are not entered into EPIC; Added language for when collecting SSN for payment purposes |
| 6.0 | October 24, 2023 | Revise MRI with contrast language |