Summary of IRB Consent Form Template Changes, May 2022

Contents

Note About Implementation:

The IRB will require new consent and assent forms submitted on/after **June 1, 2022**, to follow the new templates, with the following exception:

- If applicable to the study, the "Inadequate specimens for diagnosis" statement (page 2) and/or the "Reportable conditions" statement (page 5) must be included in new studies submitted on/after **May 5, 2022**.

Non-Gendered Language

Description of change:	Binary pronouns are replaced by inclusive pronouns and reproductive language is revised to remove gender.	
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Biological Specimens – GWAS • Simple Blood Draw	• Assent forms #1, 2, and 3 • Addendum- General • Expanded Access • Humanitarian Use Device

Introduction

Description of change:	1. "Research Project Director" changed to "Principal Investigator" 2. Introductory paragraphs revised to remove redundancies in naming the PI.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Simple Blood Draw • One-Time Survey • Expanded Access
New Wording:	~~Research Project Director~~Principal Investigator: Holly Smith, M.D., Associate Professor of Psychiatry. UCSF, Room 809, 505 Parnassus Ave, San Francisco, CA. Phone: 415.246.xxxx; e-mail: hollyx@ucsf.edu Study Coordinator: Joan Buttenfield, Phone: 415.246.xxxx buttenx@ucsf.edu This is a research study about *[insert brief mention of general subject matter of study]*. The Principal Investigator, who is the person in charge of this study, or one of the other members of the study team ~~The study researchers, …,[M.D.,] and …, [Ph.D.,]~~ from the *[UCSF Department of . . .]*, will explain this study to you. ***[Important! Remove all grey highlighting from actual consent form]*** **STUDY SUMMARY** *****THIS SUMMARY IS ONLY REQUIRED IF YOUR COMPLETED CONSENT FORM IS LONGER THAN 6 PAGES***** **Introduction:** We are asking you to consider taking part in a research study being done ~~by name the study doctor/researcher~~ at UCSF.

New Section: Usual Care

Description of change:	A section entitled "What is the usual care for my condition?" has been added to the beginning of the consent form. This is in line with FDA recommendations. The goal is to first remind participants of the care a patient would likely receive if not part of the research, and then be provided with information about the research.
Templates affected:	• Biomedical and Cancer • Social or Behavioral
New Wording:	*[Include this section for treatment studies only, otherwise delete]* **What is the usual care for my condition?** The usual care for your condition is… *[in 1-3 sentences, describe the standard clinical care the patient would receive if not enrolled in this study.]*

Can I stop being in the study?

Description of change:	New statement added to comply with FDA regulations regarding the need for consent to continue follow-up after a participant withdraws from the study. This should be used by all studies, not just FDA-regulated ones.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Expanded Access • Specimen Collection- GWAS
New Wording:	If you withdraw from the study, any data or specimens we have already collected from you will remain part of the study records. [Add this if appropriate to the study:] After you withdraw, the researchers may still get information from your medical records if it is relevant to the study (e.g., laboratory results, treatment courses, health outcomes). You must tell the study team you do not want this information to be collected when you withdraw, otherwise it will be collected. [Note to researchers: If the subject does withdraw, remind them that follow-up data will still be collected unless they ask otherwise.]

Inadequate specimens for diagnosis (Research Tissue Acquisition Policy)

Description of change:	New risk statement & instructions to be used in studies involving the research collection of non-exempt tissue derived from clinical specimens (non-exempt means it is not exempt from pathology review), per UCSF's Research Tissue Acquisition Policy. Note to study teams: If you have a study that is subject to this policy, any NEW consent forms submitted for that study must include this language. IRB will hold approval
Templates affected:	• Biomedical and Cancer • Biological Specimens- GWAS
New Wording:	*[Use the following statement if your protocol involves the research collection of non-exempt tissue derived from clinical specimens (in this context, "non-exempt" means the tissue is not exempt from pathology review). See UCSF's Research Tissue Acquisition Policy for more information, and contact research@ucsf.edu if you have questions. Note: This statement is not required for studies collecting designated research biopsies.]* **Risk of inadequate specimens for diagnostic purposes:** Providing parts of your surgically-removed tissue for research could, in rare cases, result in too little tissue being available for your doctors to make a clinical diagnosis (or complete other clinically important tests). To minimize this risk, a Pathologist (or a pathology designee) carefully evaluates every tissue specimen at the time of surgery to decide if it can safely be provided for research. With this process in place, we believe the risk of negatively impacting your clinical care through providing tissue for research is extremely small (below 1%).

Radiation Risks

Description of change:	The Radiation Safety Committee has revised its standard statements to: • Include separate statements for pediatric participants, with "my child…" language • Simplify the language • Add instructions to only include the reproductive risk sentence if the study involves participants who are able to become pregnant, and to only include the breastfeeding warning if the study involves nuclear medicine. • Important: There are no changes to the actual risks associated with different levels of radiation.
Templates affected:	• Biomedical and Cancer • Expanded Access
Revised Wording:	Section too lengthy for summary document. See templates.

Possible Benefits

Description of change:	Instructions added. Wording has been simplified and is now consistent across templates. Removed statements that researchers hope the experimental treatment works, that randomization might present a benefit, and the cancer-specific statement.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Biological Specimens- GWAS • Phone Consent- Main Study • Expanded Access
New Wording:	**Are there benefits to taking part in the study?** *[Use one of the following two statements exactly as written. Do not modify or add to either statement.]* *[If there is a potential for benefit:]* You may or may not benefit from participating in the study. *[If no direct benefit to the subject is anticipated:]* There will be no direct benefit to you from participating in this study.

How will my specimens and information be used?

Description of change:	There are no longer two statements to indicate whether data/specimens will or will not be shared with other researchers. Now there is a single statement that says data/specimens **may** be shared.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Simple Blood Draw • Specimen Collection – GWAS • One-time Survey (Note: no references to "specimens") • Phone Consent- Main Study • Expanded Access

New Wording:	*[Delete "the italicized references to specimens" if not applicable to this study]* Researchers will use your *specimens and* information to conduct this study. Once the study is done using your *specimens and* information, we may use the *remaining specimens and* information collected for future research studies or share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

Commercial Use of Specimens

Description of change:	The statement about commercial use of specimens has been expanded to include "information obtained from your specimens" to be more aligned with the UCOP recommendations regarding the Moore Clause.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Simple Blood Draw • Specimen Collection – GWAS • Expanded Access
Revised Wording:	*[Include the following statement only if applicable to your study:]* **Commercial Use:** Your specimens and/or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.

How will my genetic information be shared?

Description of change:	• Added new instructions, an optional reference to VA, and a sentence about possible re-identifiability. • Replaced "your group" with "a particular race, ethnicity, sex or gender"
Templates affected:	• Biomedical and Cancer • Specimen Collection- GWAS
Revised Wording:	**How will my genetic information be shared?** Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. We may give certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF *[if applicable, add "or SFVAHCS"]*, including to an unrestricted or controlled access government health research database, but we will not give them your name, address, phone number, or any other identifiable information. We cannot guarantee that no one will ever be able to use this information to identify you. Research results from these studies will not be returned to you [describe any rare instances that this may occur]. *[Note about the above paragraph: Please do not delete or edit the reference to "unrestricted or controlled access" databases. This statement will allow for flexibility when submitting genomic data to databases in the future.]*

	Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, sex or gender as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with ~~your group~~ a particular race, ethnicity, sex or gender. In some cases, this could reinforce harmful stereotypes.

Reportable Conditions

Description of change:	1. Language has changed to indicate that SFDPH wants positive HIV test results even if previously diagnosed (it used to only apply to *new* positive cases), and SFDPH may share these results with the participant's home county health department if it's not SF. 2. Added instructions to review website guidance on HIV+ reporting requirements 3. Added note that investigators shouldn't share identifiable information with laboratories unless it's for COVID-19 testing, per CA state law 4. Created separate statements for different types of reporting (HIV, COVID, and other) so it's easier for study teams to either include or delete the entire statement.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Simple Blood Draw • Expanded Access
New Wording:	*Instructions for the below statements:* • *Use these statements if the study involves testing of reportable conditions such as (but not limited to) HIV, tuberculosis, hepatitis B, hepatitis C, COVID-19, etc., **for research purposes*** • *Delete information about tests that will not be performed in this study* • *If testing for HIV, see the guidance at https://irb.ucsf.edu/hiv-reporting-requirements-research-involving-hiv-testing for how to securely report results to the SF Department of Public Health* • *Only share participant PHI with laboratories if COVID-19 testing is being conducted, as the laboratories are required by California State law to report all results (positive, negative, and inconclusive)* *[Include if study involves HIV testing:]* California regulations require reporting **all** positive HIV test results (not just new cases) to the county public health department. The required report includes CD4+ count (or T-cell count), viral load, and viral genotype. The San Francisco Department of Public health may share the results with the participant's home county health department if they do not live in San Francisco County.

	[Include if study involves testing of other reportable conditions such as—but not limited to—tuberculosis, hepatitis B, and hepatitis C:] California regulations require that **new** cases of *[state the reportable diagnosis/diagnoses here]* be reported to the county public health department. *[Include this sentence if study includes COVID testing for research purposes:]* All COVID-19 test results (positive, negative or inconclusive) must be reported to the county public health department. *[Include if **ANY** of the 3 above statements apply:]* The reports include details like participant name, social security number, and other identifying information. Information about these infections is used to track these diseases statewide and nationwide. Other than this required reporting, test results will be treated confidentially by the study staff and personally identifying information will not be reported to other departments or agencies. For a full list of reportable conditions, go to the following link: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ReportableDiseases.pdf

Organizations that might see PHI

Description of change:	Added OHRP and VA to the list.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Simple Blood Draw • One time survey • Expanded Access • Phone Consent- Main Study
Revised Wording:	Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study: • Representatives of the Sponsor *[List Sponsor(s), as applicable]* • Representatives of the Research Consortium *[name the Consortium OR remove if this is not a Consortium study]* • Representatives of the National Institutes of Health *[remove if this is not an NIH-funded study]* • Representatives of the University of California • Representatives of the Food and Drug Administration (FDA) *[remove if this is not an FDA-regulated study]* • Representatives of the Office of Human Research Protections (OHRP) *[remove this if the study is not conducted or supported by an HHS entity, e.g., NIH, CDC, FDA, AHRQ, CMS, HRSA, etc.]* • Representatives of the Department of Veterans Affairs *[remove if this is not a VA consent form or a VA-funded study]* • [list any other agencies – in or outside the US – that might inspect research records]

Certificate of Confidentiality

Description of change:	1. Instructions to researcher revised to include more information. 2. New language added for inclusion in the consent for studies that have a CoC. This wording is taken from the NIH's suggested language. Previously, this wording was only *linked to* in the consent template, now the wording is inserted directly into the template.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Expanded Access
New Wording:	***[Sensitive research information/Certificate of Confidentiality (CoC):*** *If you might obtain identifiable, sensitive information from subjects (e.g., use of addictive products, illegal conduct, sexual behavior, etc.) you should have a CoC. Review the IRB's guidance at https://irb.ucsf.edu/certificate-confidentiality-nih to understand the protections afforded by the CoC and the exceptions to those protections, and for instructions on how & when to add the following language to your consent forms. Note: Federally funded studies initially approved after December 2017 likely already have a CoC, even if sensitive data is not being collected. Others can apply for one. If Federal funding runs out, you should apply for a new CoC if you are still conducting data collection activities.]* This research is covered by a Certificate of Confidentiality. It prevents State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal information (by subpoena/court order or otherwise) about research participants. The Certificate DOES NOT: • stop legally required reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. • stop a sponsoring United States federal or state government agency from reviewing research records to monitor or evaluate programs. • stop disclosures required by the federal Food and Drug Administration (FDA). • prevent your information from being used for other research if that is allowed by federal regulations. The Certificate does not stop you: • from releasing information about your involvement in this research. • from having access to your medical record information.

Are there any costs to me for taking part in this study?

Description of change:	Instructions added about when and how the cost language should be used, and what happens if they deviate from the required language Note: The wording is slightly different for the social/behavioral template.

Templates affected:	• Biomedical and Cancer • Social or Behavioral • Expanded Access
New Instructional Wording:	**Are there any costs to me for taking part in this study?** *[For any human research study that includes the use of ANY clinical procedures (including the administration of drugs, devices, and/or tests), the UCSF IRB requires investigators to include one of the standard statements below.]* *[NOTE: Any deviations from the standard statements (including additional language) are discouraged, will result in delays, and must receive approval from OCTA Quality Improvement & Compliance Officer, Jeanna Julo -- Jeanna.Julo@ucsf.edu. You will be required to upload documentation of OCTA approval in the IRB submission. The IRB does not negotiate the language on behalf of the study team.]*

Will I be paid for taking part in this study?

Description of change:	1. The payment section has been split into two sections, 1 for payment and 1 for reimbursement. Previous template wording lumped payment and reimbursement into one section without differentiating between the two, though they refer to different things. Payment is for the participant's time/effort/inconvenience, and reimbursement is to cover a participant's out-of-pocket expenses like travel, meals, lodging, and parking. 2. New sentence stating that payment/reimbursement by check requires a SSN. 3. Optional language has been added for studies using a third-party payment & reimbursement company. Please note that if the company has a separate information sheet or consent form about the payment/reimbursement process, the IRB does NOT need to review it.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • One-time survey • Simple blood draw (Note: info about third-party payers and reimbursement not included in One-Time Survey and Simple Blood Draw templates)
New Wording:	**Will I be paid for taking part in this study?** In return for your time and effort, you will be paid *[$XXX]* for taking part in this study. *[Describe any pro-rating or bonuses and specify method and timing of payment.]* *[Include the following statement if participants will be paid by check*:] If you are paid by check, the researchers are required to collect your Social Security number and home address for check processing purposes. *[Include the following statement if you are using a third-party payment method like Greenphire, Clincierge, Colpitts, etc. Amend the statement if necessary so it is accurate regarding the system being used.]*

	A company called [*company name*] is working on behalf of the study to pay participants. [*Company name*] will need to collect certain personal information about you to set up your payment account. *[If the company has a separate informational document or consent sheet about how the payment system works, include the following sentence in this consent form.]* You will be given a separate document from *[company name]* with detailed information about the payment process. *[Note: Do not submit the company's document/s to the IRB.]* *[Include the following if participants will be paid more than $599.99 in a calendar year]* The Internal Revenue Service (IRS) must be notified when a participant is paid $600 or more in a year, so your payment will be reported to the IRS. You must give the researchers your address and Social Security number for IRS reporting purposes. *See the IRB website for more info on subject payment and sample consent form language.]* *[OR, if there is no payment:]* You will not be paid for taking part in this study. **Will I be reimbursed if I pay expenses related to my participation in this study?** You will be reimbursed for expenses if you take part in this study. *[Describe what expenses, e.g., travel, meals, lodging, parking, and specify method and timing of reimbursement.]* *[Include the following statement if participants will be reimbursed by check:] If you are reimbursed by check, the researchers are required to collect your Social Security number and home address for check processing purposes.* *[Include the following statement if you are using a third-party reimbursement method like Greenphire, Clincierge, Colpitts, etc. Amend the statement if necessary so it is accurate regarding the system being used.]* A company called [*company name*] is working on behalf of the study to reimburse participants. [*Company name*] will need to collect certain personal information about you to set up your reimbursement account. *[If the company has a separate informational document or consent sheet about how the reimbursement system works, include the following sentence in this consent form.]* You will be given a separate document from *[company name]* with detailed information about the reimbursement process. *[Note: Do not submit the company's document/s to the IRB.]* *[See the IRB website for more info on subject reimbursement and sample consent form language.]* *[OR, if there is no reimbursement:]* You will not be reimbursed for expenses if you take part in this study.

Treatment and Compensation for Injury

Description of change:	1. The Social/Behavioral template now includes the T&C statement (it wasn't in there previously), with instructions that the statement should be used for Expedited categories 2 and 4. 2. Instructions been revised to be more specific and helpful to users and to clarify that the IRB office is not in the position to negotiate the T&C language.
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Simple Blood Draw • Specimen Collection – GWAS • Expanded Access
Revised Wording:	**What happens if I am injured because I took part in this study?** *[Include this section if you are conducting a greater-than-minimal-risk study or a **category 2 or category 4 expedited review** study (e.g., studies that involve blood draws or noninvasive, routine clinical procedures for research purposes)]* It is important that you tell your study doctor, _____ *[investigator's name(s)]*, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call ~~him/her~~ them at _____ *[telephone number]*. **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor *[sponsor name]*, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814. *[NOTE: **This statement must be used without changes** unless any of the following situations apply:* *(1) the Sponsor requests MMSEA 111 Language* *(2) this is a clinical trial of a COVID-19 countermeasure and the PREP Act applies* *(3) this is a VA study or this consent form will be used at a VA site (for UCSF/VA studies)* *(4) the Sponsor chooses to remain silent on this point, in which case all reference to "the study sponsor" should be omitted from the above statement.* *(5) the sponsor is the NIH, in which case all reference to "the study sponsor" should be omitted from the above statement. The NIH does not have a program in place to provide compensation for research-related injury and should not be listed in this section.*

	For (1)-(5), see the IRB website and the notes section at the end of this template for standard wording for each of these situations. ***No other changes may be made to the UCSF statement.*** *The IRB office is not in the position to negotiate indemnification agreements. If the Sponsor refuses to approve the study with the UCSF statement, please refer them to the UCSF Risk Management and Insurance Services office.]*

What are my rights if I take part in this study?

Description of change:	New statement explaining that participants who request access to their research records might be denied while the study is still being conducted. This statement should be used for clinical trials where research data might/will be added to the medical record. In general, the Privacy Rule gives patients the right to inspect their PHI. However, the Privacy Rule has an exception to the right of access for research results and records for ongoing clinical trials.
Templates affected:	• Biomedical and Cancer • Social or Behavioral
New Wording:	*[Include this paragraph only if you are conducting a clinical trial and will upload research data/records/forms into APeX. It refers to the Privacy Rule and participants' right of access to research records and results:]* You may request a copy of the health information collected from you as part of this research after the study is completed. You may not have access to this information while the study is still being conducted.

Who can answer my questions about the study?

Description of change:	1. The contact info statement no longer requires a PI to be named. 2. Revised National Clinical Trial (NCT) statement: ○ Added line for study team to include the NCT number, or to state that it is Pending. ○ Added instruction to the study team if the NCT number is pending: "It is the study team's responsibility to submit a Modification Form to revise the consent form and the IRB application to add the NCT number. You may still enroll if the NCT number is not yet assigned."
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Simple Blood Draw • Specimen Collection – GWAS • Expanded Access • One Time Survey
New Wording:	**Revised contact statement:** You can ~~talk to your study doctor about~~contact the research team with any questions, concerns, or complaints you have about this study~~. Contact your study doctor(s) _____ *[name(s)]*~~ at _____ *[telephone number(s)]*.

	New NCT statement: [*This NCT statement must be included verbatim if the study meets the FDA's definition of a clinical trial.*] 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. The National Clinical Trial (NCT) number for this study is [*enter the NCT number or "not yet assigned."*]. *[If the NCT number is not yet assigned: It is the study team's responsibility to submit a Modification Form to revise the consent form and the IRB application to add the NCT number. You may still enroll if the NCT number is not yet assigned.]*

NOTES TO PERSON PREPARING CONSENT FORM

Description of change:	Additional alternative T&C statements are now included in full: • VA • Studies where sponsor wants to remain silent, or sponsor is NIH
Templates affected:	• Biomedical and Cancer • Social or Behavioral • Simple Blood Draw • Specimen Collection – GWAS • Expanded Access