FROM: OFFICE OF RESEARCH/DEPARTMENT OF PATHOLOGY
TO: TISSUE BIOSPECIMEN-BASED RESEARCHERS
RE: RESEARCH TISSUE ACQUISITION POLICY
DATE: DECEMBER 10, 2021

Release Version 01-25-2022

UCSF has a foundational commitment to supporting research biospecimen collection, including tissue acquisition from surgical resections/biopsies done for clinical purposes. We also are required to ensure that research tissue acquisition does not compromise clinical care. This has prompted a review of our research tissue acquisition policies and procedures and discussions with our peer institutions.

Clinical regulations (CDPH CCR22, 70223(g); AFL-16-07; TJC QSA.13.01.01) require tissue gross evaluation of all tissue deemed non-exempt (see **Appendix A** for exempt list and details), that this evaluation be overseen by the Department of Pathology, and that this tissue not be released for research purposes until it is deemed "excess" by the faculty pathologist or faculty pathologist's team. Additionally, human subjects' protection policies require that research participants are informed of potential risks to the collection of research tissues from surgical resections/biopsies done for clinical purposes. The following policy meets these requirements. This policy is consistent with our sister institutions (e.g., UCLA and UCSD).

The Biospecimen Services Program (BSP), formerly called BIOS, will continue operating and collecting existing protocols in good faith with a hard deadline for compliance of March 25, 2022.

- **The Biospecimen Services Program and the Department of Pathology will provide all research biospecimen collection from non-exempt clinical tissue requiring gross evaluation**. Research teams may either utilize the Biospecimen Services Program's board-certified research biospecimen Pathologists' Assistants (overseen by the Department of Pathology) or work directly with a Department of Pathology faculty collaborator to ensure proper grossing and handling procedures are followed. In the latter scenario, the research team remains responsible for all steps other than grossing (e.g., verification of appropriate consent, IRB approval, etc). The Biospecimen Services Program must be notified of all research biospecimen protocols that plan to use a Department of Pathology faculty collaborator for oversight purposes. All existing and future pathologist collaborations must be communicated to the Biospecimen Services Program through the Pathologist Collaborator Form. The deadline for existing collaborations is March 25, 2022. The Office of Research will enforce this policy.
- **Research specimens will be released to researchers only after being determined "excess" based upon Biospecimen Services Program PA or Pathology faculty determination at the time of gross examination.** If the determination at time of grossing is that the tissue could potentially contain diagnostic information, then it will not be classified as "excess" and the sample will be frozen and stored at –80 degrees C (i.e., "embargoed") in a CLIA certified laboratory until a diagnosis is entered in the medical record (see **Appendix B** for the decision tree on how tissue is routed for research requests). Any remaining tissue at that time will be deemed "excess" and may be released for research.
- **All consent forms for protocols involving the research collection of non-exempt clinical tissue requiring gross evaluation must contain approved language from the UCSF IRB.** This language describes the above policy and informs participants that there remains a small risk that tissue

deemed “excess” and released for research purposes could compromise pathologic diagnosis (see **Appendix C** for the UCSF IRB approved language and instructions).

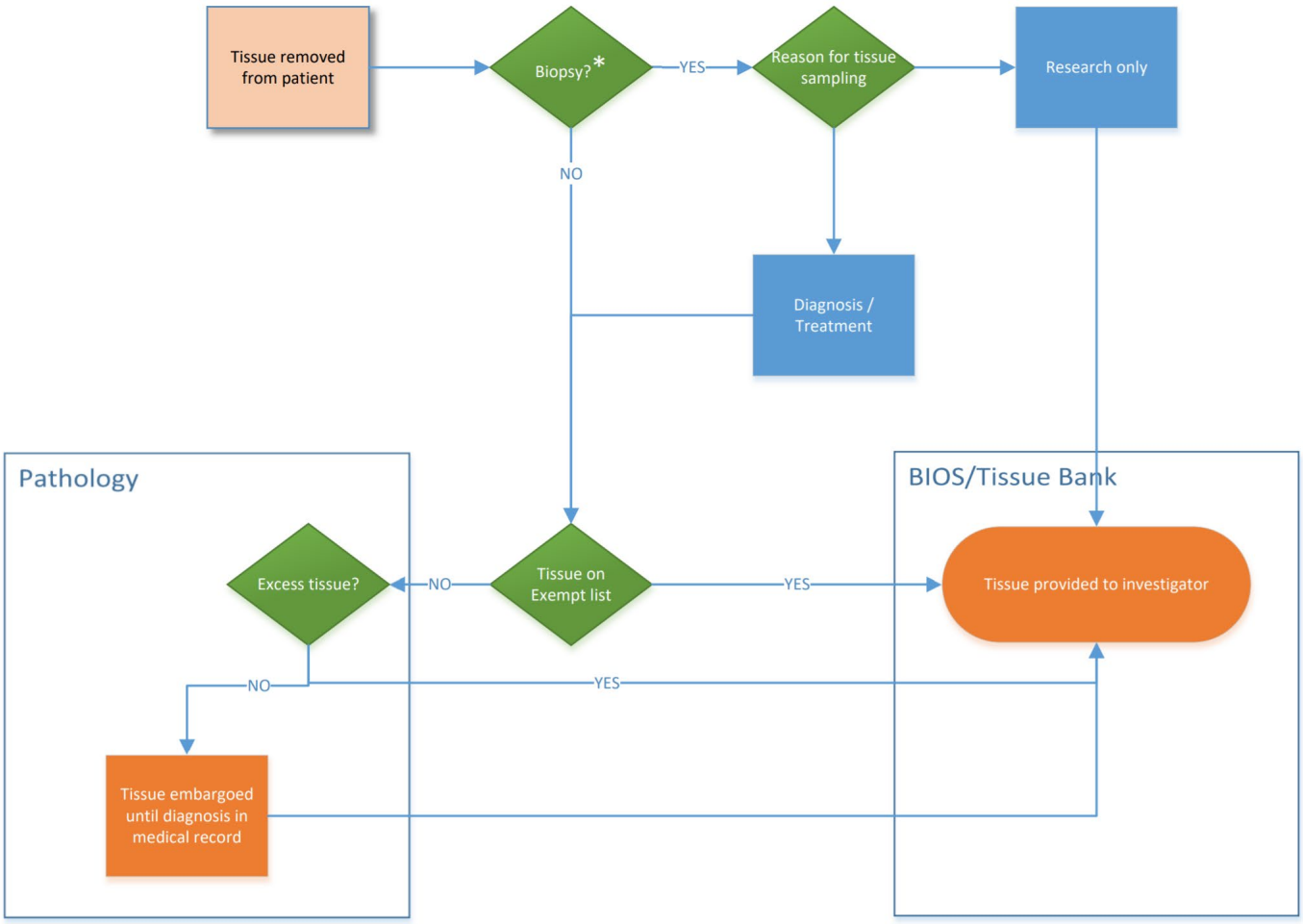
We recognize that this policy represents a change to some research protocols and will require additional work from study teams to comply. We also realize that some research protocols will require immediate receipt of research tissue specimens that this policy disallows. The Office of Research is committed to helping find solutions to issues raised by this change. Please contact us at research@ucsf.edu.

APPENDIX A: EXEMPT TISSUE

Policy #: 1.03.06 Exempt Tissue Policy Perioperative Services

As of a 2021 exempt tissue policy revision, only resection tissue that is otherwise considered exempt can be considered exempt for research purposes. The exempt tissue policy is maintained by the OR committee with input from Pathology. *In vivo* biopsies for research are not required to be submitted to pathology, with appropriate patient consent.

APPENDIX B: DECISION TREE



*Biopsy is defined as a specimen that does not require gross evaluation by a Pathologist or pathology designee, beyond measurements, and is small in size, for example if it were to be submitted for microscopic evaluation it could fit within one pathology tissue cassette. A biopsy that is submitted for research is not suitable for a subsequent clinical care pathology report; if this is necessary, then multiple biopsies should be performed and directed appropriately.

APPENDIX C: UCSF IRB APPROVED CONSENT FORM LANGUAGE

Use the following text if your protocol involves the research collection of non-exempt tissue derived from clinical specimens. The additional UCSF IRB approved consent form language 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%)."

Instructions from IRB for updating consent forms:

Modification Form Question	**Answer**
1.8 Modification level	**Minor**
1.9 New protocol version	**No**
1.10 Changes to clinical activities	**No**
1.11 Changes to study design	**No**
1.12 Types of changes being made	**Any other type of change**
1.13 Personnel changes	**No**
1.14 Are any of these changes being made as a result of an adverse event	**No**
1.17 Do any of these changes affect the Risk/Benefit ratio	**No**
1.18 List any minor and/or administrative changes and provide justifications where appropriate:	**Copy and paste the following:** **The following language be added to the Risks section of the consent form, per the newly issued UCSF Biospecimen Services Program Policy. This is the only change being made.** **"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%).”
1.19 Does this modification require changes to the Study Application	**Yes** **The new risk language must be added to the application section titled “Risks.”** **To edit/attach the revised application, click the “Save” button and then click “Click here to attach the application”**
1.20 (First question) Do you need to attach any revised consent forms	**Yes** **The new risk language must be added to the consent form discussion of possible risks.** **Click “Select or Revise Existing” to edit the consent/upload the revised consent**
1.20 (second question) Do you need to attach any new or revised Study Documents	**No**
1.21 Studies involving CTSI CRS	**Leave blank**
1.23 Are there any changes in financial interests	**No**