ZIPLINE APPLICATION: IRB Protocol, No Contact with Subjects

INSTRUCTIONS

- **Use this form ONLY if your research consists solely of obtaining and using data or specimens from some source other than the subjects** (for example, you are doing a medical records review project).
- **If you are requesting a determination** about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example **1.1** must be answered.
- **Answer all questions**. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

INDEX

1 OVERVIEW

Title: Pathology Department-wide IRB protocol to enable screening of electronic medical records for research purposes

1.1 **Home institution**. Identify the home institution of the lead researcher as listed on the IRB application. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the ***POLICY: Use of the UW IRB****.*

University of Washington Medical Center

1.2 Consultation history. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

[ ] **No**
[x] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

In-person inquiry: July 13, 2017 at the NWABR conference
Emailed a question: July 14, 2017

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[x] **No**
[ ] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

[x] **No**

[ ] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

The purpose of this IRB application is to enable Pathology Department members – to include faculty, Fellows, Residents, and rotating students - to screen electronic medical records (primarily the Department database, PowerPath) and, if necessary, view archival histology and cytology slides (which are also part of the medical/pathology records) for the purposes of:
1) conducting records review studies, or
2) determining feasibility (e.g., whether there are enough patients) to design a future study, or
3) establishing a study dataset for a study of both records and specimens.

Studies covered by this IRB application are "unfunded" (i.e., there are no grants associated with this IRB application).

Follow-up studies, and studies funded by a grant or contract, would require separate, new IRB applications. For example, a study that involves obtaining specimen blocks in order to cut new sections for staining would require a new IRB application.

An example of the type of studies that would be covered under this blanket IRB protocol would be correlative studies. For example, Pathologists frequently seek to refine diagnostic criteria by reviewing slides or specimens together with pathology reports and patient outcomes after treatment. An analysis of the trends and patterns between medical information and morphology (i.e., specimen appearance with respect to various markers and structures) may enable discoveries of new diagnostic biomarkers, and/or development of more predictive scoring systems. Because the research is exploratory, will not be done to guide patient care, and may require the review of even hundreds of records and samples, patients will not be consented.

Note that if a researcher needs to manipulate specimens (e.g., test a new stain), they would need to apply to the IRB for their own IRB application. However, this IRB protocol would enable them to establish a study dataset relatively rapidly for a future study.

To enable the studies to be conducted under this blanket IRB application, we need to request waiver of consent and HIPAA authorization. We will consult with HSD about, or submit separate applications for, any studies which do not clearly meet the regulatory requirements for waivers of consent and HIPAA authorization.

It is the intent of this single IRB application to enable department members to rapidly review medical records and archival slides without needing their own individual IRB applications. Medical records that they will screen will include, and not be limited to, the departmental database, PowerPath (or equivalent departmental database, for example, if PowerPath were replaced). Pathology studies generally always begin with PowerPath screens since this is where the Pathology Reports reside. Patient treatment regimens and outcomes would be found in the other hospital electronic medical records and would be viewed after the PowerPath screen has identified eligible cases. All Department members will be required to receive HIPAA training and in-house training in the use of medical records for research purposes.

Additionally, all Department members will be required to be signatories on the Confidentiality Agreement associated with this IRB protocol. The Confidentiality Agreement will be updated every July, when new residents arrive, so that it stays up-to-date.

This application is for "unfunded" research – that is, research conducted with departmental funds and not external funds. Pathology Department researchers who have grants or other funding sources for which IRB review and approval is needed will have their own IRB applications.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study; genetic analyses of residual clinical specimens.

This Pathology Department-wide IRB application will enable Pathology Department members to conduct retrospective and prospective reviews of electronic patient records and slides for research purposes.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
☐	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	2. Part of an institution, organization, or program's own internal operational monitoring.
☐	3. Improve the quality of service provided by a specific institution, organization, or program.
☒	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☐	6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice

for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.

☐ 7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.

☒ 8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)

☐ 9. Other. Explain:

1.8 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Energy
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
☐	**Multi-site study** (You are asking the UW IRB to review one or more sites in a multi-site study.)	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
☒	None of the above	

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Subjects will be patients of any age who have been seen at UW and associated medical centers and who have Pathology Reports within the PowerPath database, which is part of the electronic medical records in the UW system. Subjects may be living or deceased.

2.2 Inclusion and exclusion criteria. Describe the specific criteria you will use to decide who will be included in your study. Define any technical terms in lay language.

Subjects will be patients of any age who have been seen at UW and associated medical centers and who have Pathology Reports within the PowerPath database, which is part of the electronic medical records in the UW system. Because this is a Pathology Department IRB application, an inclusion criterion is that patients have undergone a procedure that has resulted in a Pathology report.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will you obtain data about individuals that you know to be prisoners?

See the WORKSHEET: Prisoners for the definition of "prisoner". For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No".

[x] **No**
[ ] **Yes** → If yes, describe the type of prisoners, and which prisons/jails.

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed or submitted.

Population	Worksheet
[x] Children	WORKSHEET: Children
[ ] Children who are wards	WORKSHEET: Children
[ ] Fetuses in utero	WORKSHEET: Pregnant Women
[x] Neonates of uncertain viability	WORKSHEET: Neonates
[ ] Non-viable neonates	WORKSHEET: Neonates

[x] Pregnant women — WORKSHEET: Pregnant Women

"Children" are defined as individuals who have not attained the legal age for consent to treatments or procedures involved in the research and its specific setting. This will vary according to the location of the research (that is, for different states and countries).

a. If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

This application is for records review only. There are no patient interactions, and the results cannot and will not be used to guide care. The risks to the groups indicated above are no greater than the risks to a healthy, non-pregnant, adult population.

2.5 Native Americans or non U.S. indigenous populations. Will you include data or specimens about or from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[x] **No**
[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about *other individuals* from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

[x] **No**
[ ] **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need for to complete your study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number will be considered non-compliance.

[x] **No** → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.

As a Pathology Department-wide IRB application, we cannot predict how many records will be reviewed.

[ ] **Yes** → If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research ***For clinical trials: provide numbers for your site and for the study-wide total number***

3 RESEARCH SETTING

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

3.2 Local context. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research or how it is conducted.

Examples: It would be culturally inappropriate in some international settings to obtain residual clinical specimens for research without consent.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

3.3 Site-specific laws. Describe any local laws that may affect your research. The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before releasing student records.

4 RECRUITING and SELECTING

4.1 Describe how you will identify and select subjects. Include information about: how, when, where, and in what setting. List all sources of information.

Researchers will perform a keyword search of the pathology database, PowerPath. This may be followed by a search in other EMRs at UWMC.

5 PROCEDURES

5.1 **Study procedures**. Using lay language provide a complete description of the study procedures, including the sequence, time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

Each Pathology Department researcher will search the departmental patient database, currently called PowerPath, to identify patients (living or dead) whose pathology reports indicate they have had the disease(s) the researcher is interested in studying. This medical records review will include, but may not be limited to, a PowerPath search. Additionally, archival histology and cytology slides (also part of the pathology records) may be reviewed to verify pathology findings and confirm eligibility.

The types of studies that will be conducted under this IRB application will include:
1) conducting records review studies, or
2) determining feasibility (e.g., whether there are enough patients) to design a future study, or
3) establishing a study dataset for a study of both records and specimens.

Note: Only those studies that meet the criteria for waiver of consent and waiver of HIPAA authorization will be conducted under this IRB Protocol. We will consult with HSD about, or submit separate applications for, any studies which do not clearly meet the regulatory requirements for waivers of consent and HIPAA authorization.

5.2 **Data variables.** Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variable to the **Supporting Documents** SmartForm instead of describing the variables below.

Data variables will depend on the goal of the specific records search. Besides personally identifying information such as name and date of birth, the most sensitive data that may be collected will include drug use, sexual activity, HIV-positivity, etc. All of these types of information often have bearing on the Pathology diagnosis. . Researchers will also record diagnosis and date(s) of service.

5.3 **Data sources.** For all types of data that you will access or collect for this research: identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source). List all sources.

Data will be obtained from reviewing the electronic medical record (which may be limited to PowerPath) and possibly archival slides. For some researchers, it is possible that all of the data they need may be found in the Departmental database.

5.4 **Consent.** Will subjects have provided their consent for the proposed use of the data and specimens you plan to obtain?

For example: suppose you are obtaining specimens from a repository created and managed by another investigator (not part of your team). Will the repository have obtained consent from the subjects when the specimens were placed in the repository, for future sharing of the specimens?

- [x] **No**
- [ ] **Yes** → If yes, describe the nature of the consent and uses of data/specimens to which the subjects consented.

5.5 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: Describe which data are:

- Retrospective (i.e., exist when you submit this application to HSD)
- Prospective (i.e., do not yet exist at the time when you submit this application)
- Both retrospective and prospective (for example, past and future school records)

Data will be retrospective and prospective.

5.6 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

__Access__ means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".
__Identifiable__ means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.
__Direct identifiers__ are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.
__Indirect identifiers__ are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.
__Key__ refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.
__Obtain__ means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from __accessing__, which means to view or perceive data.

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

We will have access to pathology reports, which contain names, dates such as date of birth, medical record numbers, and accession numbers.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

[ ] There will be no identifiers.

[ ] Identifiers or the key have been (or will have been) destroyed before you have access.

[ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

[ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you <u>obtain</u> any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

We will obtain names, medical record numbers, and accession numbers in order to obtain linked medical record and specimen data for each case.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data).

☐ You will store the identifiers with the data. Describe the data to which this applies:

☒ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

For medical records review and feasibility studies we will create a key by assigning a study number for each patient. The study number would be linked to the case accession number (the identifier). We will store the key separately from the data.

Studies involving establishment of a study dataset for a future study of records and specimens (for example, that involves preparation of sections for additional staining), will be similarly conducted, with data and identifiers kept separately and with a link maintained.

☐ You will store identifiers separately from the study data, with no link between the

identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

Not applicable

5.7 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.

5.8 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015?

[x] **No**
[ ] **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

[ ] **No**
[ ] **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.9 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper or oral.

[ ] **No** → If no, skip the rest of this question; go to question **5.10**
[x] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

We will access patient names, age, gender, medical record numbers, and accession numbers, as well as health information such as diagnoses and treatments. The purpose of this is to identify appropriate study cases.

b. Is any of the PHI located in Washington State?

[ ] **No**
[x] **Yes**

c. Describe how you will access or obtain the PHI. *Be specific.*

PHI will be obtained by searching the pathology database and/or other electronic medical records.

d. Provide the following assurances by checking the boxes.

[x] The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

[x] You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Privacy Policy #25. THIS IS ONLY FOR UW RECORDS.

[x] There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.10 Genomic data sharing. Will you obtain or generate genomic data (as defined at *https://gds.nih.gov/13faqs_gds.html)?*

[x] **No**
[ ] **Yes** → If yes, answer the question below.

a. Is this research funded by NIH through a grant or contract application submitted to NIH on or after January 25, 2015?

[ ] **No**
[ ] **Yes** → If yes, you must comply with the NIH Genomic Data Sharing policy. Complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

5.11 Data and specimen sharing/banking. Do you plan to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **NO** if your only sharing will be through the NIH Genomic Data Sharing described in question 5.10.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include: informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the NIH dbGaP database, the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

[ ] **No**
[x] **Yes** → If yes, answer all of the questions below.

a. Describe what will be stored, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

PHI will be stored for studies involving establishment of a study dataset for a future study of both records and specimens.

b. Describe what will be shared, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

PHI will NOT be shared; only the researcher who has conducted the search will maintain the PHI.

c. Who will oversee and/or manage the sharing?

N/A

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

PHI will be stored for a future study of both records and specimens. IRB approval will be sought for that second study.

e. Consent. If you will obtain consent for this future sharing or release, describe the consent process.

N/A

f. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data. Do not attach your template agreement forms; the IRB neither reviews nor approves them

[x] **Confirmed**

5.12 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

[x] **No**

[ ] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State. See the **WORKSHEET: Children** for details.
- The generic age of consent may be different in other states, and in other countries.

☐ **No** → If no, go to Section 7.

☒ **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent n your population(s) If it is not possible to know the age of the subjects (for example, some research involving social media or the Internet) make a statement to that effect. If there is more than one answer, explain.

0-18 years of age

☐ **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 7.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will you obtain parental permission for:

☐ All of your research procedures	→ Go to question **6.2b.**
☒ None of your research procedures	→ Use the table below to provide your justification, and skip question 6.2b.
☐ Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain parental permission. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission	Reason why you will not obtain parental permission	Will you inform them about the research?[2] YES	NO
0-18	Review of Pathology Reports and specimens	The studies are exploratory and results will not and cannot be used to guide care. The studies are minimal risk,	☐	☒

	and will not adversely affect the children or their parents. With the large number of records that will be screened, a requirement to administer informed consent would render the research impossible. Please also note that Pathologists generally do not have direct contact with patients or their family members. Contacting them for the purposes of reviewing Pathology Reports and specimens for research purposes would not be of benefit to them and may be viewed as an invasion of privacy.		
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *Will you inform them about the research beforehand even though you are not obtaining active permission?*

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If you checked both boxes, explain:

6.3 Children who are wards. Will you know whether the data or specimens you obtain are from a child who is a ward of the State or any other agency, institution, or entity?

[x] **No**
[ ] **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 PRIVACY AND CONFIDENTIALITY

7.1 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[x] **No**
[ ] **Yes** → If yes, will you obtain subject consent for this use?

[ ] **Yes**
[ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

7.2 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[x] **No**
[ ] **Yes**

7.3 Retention of identifiers and data. Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your consent form, state something like "the link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (exisitng paper application that are being "converted" into a Zipline application).

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Data and Records" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***http://www.uwmedicine.org/about/Documents/UWMRRS-1.5.pdf***

[x] **Confirm**

7.4 Certificates of Confidentiality. Do you have or are you planning to obtain a federal Certificate of Confidentiality for your research data?

[x] **No**
[ ] **Yes**

7.5 Data and specimen security protections. Identify your data classifications and the security protections you will provide, referring to the ***ZIPLINE* GUIDANCE: Data and Security Protections** guidance document for the minimum requirements for each data classification level. ***You cannot answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

5

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels.

We will follow the protections except as explicitly outlined in other sections of the application.

8 RISK / BENEFIT ASSESSMENT

8.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks. Do not describe data security protections here; these are already described in question 7.5.

- *Consider physical, psychological, social, legal, and economic risks, including risks to financial standing, employability, insurability, educational advancement or reputation.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data*
- *As with all questions on this application, you may refer to uploaded documents.*

There is a risk of harm if the PHI were inadvertently released. This risk will be minimized by use of the data security measures described above and throughout the application.

8.2 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

[x] **No**
[ ] **Yes** → If yes, identify the procedures.

8.3 Individual subjects findings.

a. Is it likely that your research will unintentionally discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition?

[x] **No**
[ ] **Yes** → If yes, explain whether and how you would share the information with the subject.

b. Do you plan to routinely share the individual results of your study procedures with the subjects – such as genetic test results, laboratory tests, etc.?

[x] **No**
[ ] **Yes** → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

8.5 Commercial products or patents. If a commercial product or patent could result from this study, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

Not applicable

9 RESOURCES

9.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

9.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

This IRB application is intended to cover multiple study teams, each under a separate PI. Team communication takes place in person and by email. Generally, Pathologists work closely together, particularly when there is a mentee-mentor relationship. Communications are weekly and sometimes daily.

Because this application is so broad, the department will give presentations annually on the uses and limitations of this IRB Protocol.

10 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

10.1 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

10.2 Financial Conflict of Interest. Does any member of the team have a Financial Conflict of Interest (FCOI) in this research, as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to this research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research.