Department of Pathology Blanket IRB

Pathology and Laboratory Medicine Outcomes Research and Biomarker Discovery

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Protocol ID: 2018-1510

~ Items in **RED** cannot be performed, while items in **GREEN** will be completed by the PI and administrative team ~

Project Summary: The primary purpose of this protocol is to provide a research plan for pathology researchers and their collaborators that will allow them to conduct retrospective evaluations (with ongoing accrual prior to and beyond the submission date of this protocol) using diagnostic pathology materials that are collected as part of standard of care clinical procedures at UW Health and the materials subsequently processed in Department of Pathology and Laboratory Medicine and/or or the Wisconsin State Lab of Hygiene. The ability to conduct ongoing retrospective research using archived samples and relevant clinical data that are acquired as part of a patient's clinical care is an important part of quality assurance/quality improvement (QA/QI) and clinical outcomes research. These observational data and prospective research projects may generate data that help guide future changes in pathology technology and implementation, establish hospital policies, improve patient safety, improved cost-effectiveness of pathology services and improve patient outcomes.

Research Design and Methods: This protocol will facilitate research conducted on existing data and biospecimens from patients, including cancer patients, who have undergone diagnostic procedures at UW Health. This proposal is targeting all aspects of the Pathology Laboratory including: Anatomic Pathology and Clinical Pathology. Areas within Anatomic Pathology include Cytopathology, Surgical Pathology, Hematopathology and Autopsy Pathology while Clinical Pathology includes Hematology, Toxicology, Molecular Pathology, Blood Bank/Transfusion Medicine, Coagulation/Immunology, Flow Cytometry, Microbiology, and Clinical Chemistry.

No subjects will be prospectively screened for this research. Clinical management will not be altered in any way by the activities of this protocol. Patients will not undergo any procedures as part of or for purposes of this research. Only remnant (excess to be discarded) and/or archived tissue/blood (used for clinical diagnosis) collected during standard of care procedures will be used for study purposes. Additional testing on residual clinical specimens may be performed to evaluate new biomarkers. Although the proposal only involves retrospective research, ongoing accrual of retrospective data (i.e., prior to and beyond the time of IRB submission) would form an important part of this protocol. With respect to molecular and/or genomic testing, **whole exome and whole genome sequencing will *NOT* be permitted**. Targeted molecular studies to confirm findings identified in the clinical assay data will be permitted.

Procedure for use of protocol: Prior to the collection of specific data, investigators will submit a proposed project summary to the Research Support administrative team. This summary will be used to evaluate the study design for each project and confirm that the data request is appropriate for use with this protocol. Summaries will include the purpose, background, specific aims, and methods (data source, eligibility criteria, analytic plan, etc) for the project. Investigators will also be required to submit quarterly updates on their research as well as a final report upon completion of the project. The Research Request Form created for this protocol will require researchers to provide the following information prior to the start of a project: a list of study team members, specific aims/background, data to be collected, analytic plan, etc. **VA, Meriter and Outreach patient cases will be *excluded* from this protocol.** Vulnerable populations such as minors will only be targeted when there is direct clinical or scientific relevance to do so. A summary of all research conducted under this protocol will be documented.

Archived biospecimens may be used for tissue microarray (TMA) creation, additional histochemical techniques and targeted genetic or molecular testing which will be limited to specific genes and biomarkers and will not include germline testing or whole exome/genome sequencing. In order to generate the database for patient outcomes that were used in the TMA, there are databases that are maintained by other departments about patient quality metrics. These databases may house abundant information and would streamline creation of a TMA such that each patient case would not need to be accessed by the pathologist to extract the data. The data can be shared with pathology from the primary clinical team (i.e., breast, Gyn Onc, rectal, genitourinary, sarcoma, etc.) and **the name of the QA/QI or IRB-approved database that will be used will need to be included as a change of protocol.** The TMA would stay with the individual investigator in the Department of Pathology and may be used for future research. If the PI distributes the TMAs outside the Department (but still within UW),

these TMAs must be coded**. If the PI wishes to share outside UW, then a change of protocol and an MTA with data use agreement will need to be completed**.

The inclusion of projects that are specifically targeting cancer patients will be reviewed by the UW Carbone Cancer Center (UWCCC) Protocol Review and Monitoring Committee (PRMC). When a project targeting cancer patients is proposed, a copy of the pathology research request form (PDF) will be sent by the pathology administrative team to the appropriate Disease Oriented Team (DOT) for sign-off, **then an amendment will be sent to the PRMC for their review and approval as a distinct correlative study housed under the main umbrella protocol within UWCCC's OnCore**.

Confidentiality protections, sharing of data, and disposition of data: This study has a waiver of subject/parent informed consent and assent from minors. In addition, there is a waiver of individual authorization or parental authorization, for research use of PHI for this study. Each patient enrolled will be assigned a study identification code that will be unique to the investigator and their project. Privacy and confidentiality will be protected by the use of subject numbers in lieu of any direct identifiers. Coded data will be kept on departmental or hospital password protected computers/departmental servers or stored in ICTR's REDCap database. Data collected will not be reused or disclosed for other purposes. A separate log including patient ID, name, and medical record number will be kept electronically. Digital images may be acquired and used for research. These images are being obtained from standard of care pathology slides/tubes/reactions or graphs. It may be that videos may be made to demonstrate a procedure, chemical reaction or technique from standard of care samples and no patient identifiers will be included in the video. Coded data may also be shared with other institutions and/or vendors. UW investigators will often work with outside institutions or vendors to test new instrumentation, biomarkers or techniques. For these projects, all data will be coded. **For sharing of data with internal investigators/collaborators, this *MUST* be done using a REDCap database (**for more information, go to https://ictr.wisc.edu/redcap/**).** This database permits access to the investigator's data while ensuring that the data remains secure. No directly identifiable information will be shared with personnel outside the UW. In cases where the data/specimens are not completely de-identified, entities outside the UW will obtain IRB approval from either their own institutions IRB or an independent IRB. **In addition, sharing coded data/specimens and/or limited data sets will require a change of protocol to add these collaborators to the application.** All patient data will be coded and de-identified (when possible) before statistical analysis and before publication, scientific conference, or any presentation outside of the University. The link to directly identifiable subject information will be destroyed upon completion of the individual study.

*****Since this is a retrospective review of samples, potential discrepancies that would impact patient care may be identified (also known as **Adventitious Findings**). Should this occur, the case in question should be brought to the Departmental/UW Health AP/QI committee, UW Health Risk Management and to the IRB for further guidance.******

Case Reports/Series: Case reports have a useful role in medical research and evidence-based medicine. This protocol permits investigators to utilize existing biospecimen for additional testing to better characterize the case(s) of interest for their case report. The additional data generated ***CANNOT*** be reported in the patient's medical record or used for patient care/treatment and would only be used for educational and publication purposes. A waiver of consent may be requested for a case report/series. When consent is not obtained for a case report/series, all measures should be taken to prevent identification of the patient. There should be no date of service or reference to items that may potentially identify the patient. The specimen should not relate to a unique enough condition/disease that the person's identity might be determined in combination with other publicly available information. Identifying information associated with the sample(s) should not be provided to any collaborators or sponsors outside of the institution. Prior to publishing under this waiver of consent, investigators will submit their manuscript/presentation for review by the HIPAA compliance office to confirm the data has been appropriately de-identified. If the investigator would rather not edit the presentation of their findings based on feedback from the HIPAA privacy officer/coordinator, or in cases where they know upfront that an individual may be identified in the publication, consent/authorization will need to be obtained prior to analyzing the specimen(s). Consent templates are available upon request.

Individuals who have completed CITI and HIPAA training can view the full protocol in UW ARROW (https://arrow.wisc.edu/).

Additional questions/concerns/need for clarification….please contact Kristina at matkowskyj@wisc.edu or (608) 265-4235.