Guidelines and Requirements for Quality Assurance and Quality Initiative Projects with Renal Pathology

Quality Assurance (QA):

Definition: Systematic process of monitoring and evaluating patient care to ensure it is safe, effective, and meets established standards.

Examples:

- Prevalence, or changes in prevalence, of disease
- Incidence of disease or disease outcomes

Guidelines and Requirements:

- Does not require data/report interpretation
- Does not include additional stains or use of tissue
- Does not alter pathology report or go into the patient medical record
- No new treatment and/or patient management decisions are made
- Data variables are requested and received de-identified
    - Data provided is cumulative without breakdown of histologic features for individual patients
    - Examples: Annual prevalence of PLA2R+ MN for the last 5 years
      Incidence of TCMR in the first year post-transplant for 2024 allografts

- For purposes of internal group discussion, rounds, M&M, etc. only
- Data received MUST be attributed to the renal lab when used in all discussions, rounds, M&M, etc.

Quality Improvement (QI):

Definition: Systematic, ongoing effort to enhance patient care, safety, and outcomes by improving processes, systems, and the patient experience, focusing on making care more safe, effective, equitable, and patient-centered.

To determine QI versus research, please see the resources provided by Providence Research:
https://www.providenceresearch.ca/en/research-ethics-process#quality-improvement--12801
https://arecci.albertainnovates.ca/
Or contact Paula Piper, Operations Coordinator at Providence Research, Paula.Piper@phc.ca

QI requires collaboration with renal pathologists and the renal pathology laboratory.

Renal Pathology Group and Renal Lab Collaboration: Prospective proposal for systems improvement that includes (but not limited to) biopsy ordering, tissue collection, laboratory reporting, communication with the laboratory, etc.

Guidelines and Requirements:

- Requires data review and/or report interpretation by renal pathologists
- Requires re-scoring or re-classification of archival biopsies
- Affects standard operating procedures of the renal pathology laboratory
- Does not include additional stains or use of tissue
- Does not alter pathology report or go into the patient medical record
- No new treatment and/or patient management decisions are made within the scope of the project

- All data variables (lab values, clinical parameters/outcomes, treatments) are shared among all Departments and Divisions involved (i.e. there is full and free exchange of all data in the project)
- Data requested are project-specific and are not to be used outside of the approved project scope without the approval of the renal pathology group. Additional use of data requires additional project submission for renal pathology group approval

- All renal pathologists and operational staff involved must receive appropriate authorship, credit, and acknowledgement for their work and contributions when project is presented or represented in any capacity (group meetings, all rounds, etc.)
- Authorship is required for all renal pathologists involved if study is published or presented at any conference

- Any project including tests, processes, procedures, etc. that are outside standard of care or Health Canada approvals automatically becomes a research project and requires REB submission and approval, AP laboratory approval, and Providence Research approval (when appropriate, see SOP)
- Publication of all QI studies requires REB approval or an official REB waiver and Providence Research approval (when appropriate, see SOP)

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Requesting Physician Date

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Primary Renal Pathologist Date