Rodger C. Haggitt GI Pathology Society (GIPS) practice guidelines standard operating procedure (SOP) [Galen Cortina and Marie Robert, authors. March 30, 2015]. This SOP was developed by the executive committees from 2013 to 2015, record of its genesis are in the executive committee minutes, forum minutes and email communications (specifically April 30th, 2014).

Clinical commentary: Guidelines serve as a general rule or principle to advise a course of action.

Technical commentary: The current gold standard for guideline development in medicine is the ‘grading of recommendations, assessment, development and evaluation ‘GRADE’ method. Other guideline systems are comparatively valid, GRADE has the advantage in 1) it is broadly utilized by design and thereby builds familiarity over time and 2) it is hypothesis driven such that accurate structured guideline statements (even with weak evidence or little agreement) can be generated. It is currently not favored as an exclusive format for GIPS due to a lack of infrastructure to adequately employ it in force. Regardless, the guideline process will employ transparency, management of conflicts of interest, involvement of stakeholders, topic selection, research and writing team(s), external review, public comment, governing review, timetable, and publication.

Process:

1. GIPS guidelines are currently in the early stages, if practical considerations force a modification to the process, the process is still considered valid.

2. Topics are identified by polling GIPS members and reviewed by the GIPS executive committee for feasibility. The optimal topic is selected after debate among the executives. A database of topics can be maintained for future guidelines.

3. A senior coordinating author with a recognized track record of research and project leadership will be invited by the executive committee to engineer the guideline. The responsibilities include (but are not limited to) timetable management, accountability to principles of guideline development, selection of a team (with executive committee oversight).

4. The guideline team for a specific topic:

a. A lead author; a recognized leader in GI pathology, able to work with a team, must have a convincing publication track record.

b. Team members; a group devoted to a focused technical review of the pertinent literature, preference given senior recognized leaders or more junior investigators with a publication track record.

c. Oversight for the eventual manuscript comes from an external review panel (selected by senior author with the approval of the executive committee), the executive committee, and public comment targeted to GIPS members.

5. Set a time table. A rule of thumb, guideline development may take 3y from inception to completion. A division of labor for research, data management, rating evidence, management of conflicts of interest, and writing is encouraged.

6. Focused technical review of topics. The review may first begin with a list of hypotheses posed as questions to be answered. Questions are not derived from a Delphic process due to limited infrastructure and often ‘lowest common denominator’ product of the process. The goal is to produce evidence based guidelines rather than opinion base ones.

7. Formulation recommendations as evidence based statements, preferably with a strength of recommendation and quality of evidence modifier attached.

8. A draft of the manuscript is presented to the executive committee for comment and revision.

9. An external review panel critiques the revised manuscript. This panel should be made up of senior GI pathologists with recognition in the field. Revisions are made as necessary and evidence based.

10. Presentation of guidelines to membership. Presentation may take place at the forum or as a website document. Members are notified of the proposed guidelines and are encouraged to review. A period of public comment is to follow.

11. A fully synthesized formal manuscript targeted toward the American Journal of Surgical Pathology, or like publication is prepared and submitted for journal review. This final document must have the approval of the executive committee to bear the GIPS endorsement.