AGA Digestive Health Outcomes Registry® Research and Publication Guidelines

A PROGRAM OF THE AGA INSTITUTE
AGA Digestive Health Outcomes Registry®
Author Guidelines

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OVERVIEW

As part of its mission, the AGA Digestive Health Outcomes Registry® (AGA Registry™) encourages the submission of Research Proposal Applications [RPAs] from individual researchers and organizations interested in analyzing registry data and publishing the results in peer-reviewed journals in order to improve the quality of healthcare of digestive diseases and to advance the science of gastroenterology and hepatology.

These guidelines were developed to provide authors with an overview of the AGA Registry research and publications process from submission of a research proposal to generation of a manuscript. We require that authors adhere to these guidelines when preparing proposals, abstracts and manuscripts.

Thank you for your interest in AGA Registry-based research. We look forward to helping you develop your proposal into a publishable manuscript and encourage authors to submit them to Gastroenterology or Clinical Gastroenterology and Hepatology.
AGA Registry Research and Publications Team Contact Information

For questions regarding the research and publications process, please contact the AGA Registry Research and Publications (RaPC) team at:

- Email: AGARegistryResearch@gastro.org
- Phone: 301-222-4012
- Fax: 301-222-4010
GENERAL SUBMISSION INFORMATION

To review a list of previously accepted proposals, you may visit the AGA Registry website www.agaregistry.org. Once you have developed your research question(s) focusing on the data available from the AGA Registry, obtain a Research Proposal Application (RPA) form from the AGA Registry website (www.agaregistry.org) and submit it to AGARegistryResearch@gastro.org. Once submitted, a staff member will contact you with an assigned tracking number to use in all correspondence.

The AGA Registry Research and Publications Committee (RaPC) will then review your RPA to determine whether it is within the scope of the AGA Registry and if it is feasible. If approved, your application will move forward to analysis. Staff will contact you with details concerning that process. Authors of proposals that undergo committee review will receive a letter describing the outcome of the review. Authors of proposals that score high enough to move to analysis will also receive a Letter of Understanding (LOU) that describes the responsibilities of the primary author.

GUIDELINES/Criteria for the Evaluation of AGA Registry Research Proposals

The AGA Registry Research and Publications Committee use the criteria established by the National Institutes of Health (NIH) to evaluate research proposals. Each of the following guidelines/criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application.

Note: An application does not need to be strong in all categories to be judged likely to have major scientific impact and thus receive a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

One score will be provided for each applicant, ranging from 1-9; 1 represents exceptional, 9 represents poor.

1. Significance. Does this research proposal address an important problem? If the aims of the proposal are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field of investigation?

2. Approach. Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the proposal? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation. Is the proposal original and innovative? For example: Does the proposal challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the proposal develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigators. Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the proposal (if applicable)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

6. Relevance to AGA’s Mission. Is this proposal relevant to AGA’s mission? Does the proposed research advance the science and practice of gastroenterology and hepatology?
**EVALUATION PROCESS**

After it is determined that the AGA Registry contains the required data needed to carry out the proposal, the AGA Registry Research and Publications Committee will review the proposal to determine if it meets the evaluation criteria listed above. If necessary, the committee will make suggestions to improve the science, feasibility and clarity of the research proposal. The end goal is to have a published manuscript; this will help accomplish the goals of the AGA Registry: to improve the quality of healthcare of gastroenterology and to advance the science of gastroenterology.

**MULTIPLE PROPOSAL SUBMISSIONS**

The principal investigator is the individual who submits the research proposal. A principal investigator may not have more than two active proposals ongoing at one time in the AGA Registry RaPC pipeline. A principal investigator may submit additional proposals for research after submission of the manuscript resulting from the previous application. An active proposal is one that has been submitted to the AGA Registry for RaPC review, but has not resulted in acceptance for publication of a manuscript to a peer-reviewed journal or has been returned by the editorial board of the target journal for revision prior to publication. At such point where a manuscript is accepted for publication or further modification to the proposal is deemed unwarranted, the process will be determined to be completed.

**STATISTICAL ANALYSIS AND DATA INTERPRETATION**

An expectation of the AGA Registry Research and Publications Committee for projects in which data is retrieved and analysis is performed is that a manuscript will be submitted to a peer-reviewed journal within four months of completion of the data analysis or six months after presentation of an abstract at a national meeting, whichever comes first. During preparation of drafts, the statistician assigned to work on the proposal will review tables and statistics, and be available to provide assistance as necessary.

As part of the research process, a senior methodologist from the RaPC will evaluate the methodological approach of the research.

If an outside statistician/methodologist or other outside expertise is required to complete the research, one will be sought on an ad-hoc basis. The AGA Registry Executive Management Board will determine appropriate benefits for the outside experts.
MANUSCRIPT & ABSTRACT REVIEW

The process of manuscript publication often includes the initial submission of an abstract to a research conference. Therefore, after analysis, we encourage the principal investigator (author) to submit his/her abstract to an appropriate venue. Authors should bear in mind; however, that once the abstract is submitted, the timeline for manuscript submission is six months. Additionally, authors should understand that if an abstract is not submitted, manuscript submission is expected within four months after completion of the data analysis. Production of manuscript and abstract drafts should thus begin immediately after the primary investigator (author) receives results of the data analysis from the AGA Registry.

When the draft is finalized, including review by the assigned statistician and the author feels it is ready for submission to a journal [manuscript] or scientific conference [abstract], the author e-mails the draft to AGARegistryResearch@gastro.org for review by the AGA Registry Research and Publications Committee. The AGA Registry Research and Publications Committee will send relevant comments to the author. The author incorporates this feedback into a revised abstract or manuscript before submitting the draft to the desired journal or scientific session.

As part of their AGA Registry Research and Publications Committee review, authors submit the following materials and related information:

- Initial draft for review;
- A copy of the submitted draft, along with notification that the draft has been submitted, the name of the journal/scientific session to which the draft was submitted, and the date upon which the submission was made;
- Notification of acceptance, the date of acceptance, and, in the case of abstracts, the type of presentation [i.e., poster or oral presentation];
- When a manuscript is published, a PDF of the published paper. When an abstract is presented, a copy of the poster or slide presentation.
- Citation of the published manuscript/abstract.

MANUSCRIPT & ABSTRACT PREPARATION: ADDITIONAL COMMENTS

- When the analysis is complete, the author will be responsible for informing the AGA Registry on a monthly basis of the status of the manuscript progress. The status report should be forwarded to AGARegistryResearch@gastro.org with the following information included:
  - Brief status report on progress in writing the manuscript
  - Expected date of completion
  - Name of journal targeted for publication
  - Date of submission (includes all dates for resubmissions to journals), acceptance and projected date of publication [if available]
  - Final outcome

- If the author wishes, an AGA Registry Research and Publications Committee reviewer can suggest an initial target journal, but the final decision regarding the target journal will be left to the author. We strongly encourage authors to submit to AGA journals, including Gastroenterology and Clinical Gastroenterology and Hepatology.

- The statistician will review tables and statistics and be available to assist authors in drafting statistical methods sections. Drafts cannot be submitted for AGA Registry RaPC review until after the AGA Registry verifies accuracy. The author will incorporate comments from the statistician when preparing the draft that is submitted for AGA Registry RaPC review.

- The AGA Registry Research and Publications Committee staff liaison will provide authors with poster and slide templates for use in their presentations. Authors must submit abstract slides and posters in AGA Registry format and adhere to all guidelines related to AGA Registry and registry brand names provided in this document.
In some cases, data analysis won’t lead to the development of a manuscript [e.g., results of analysis are inconclusive]. The author, after conferring with the statistician, should notify the AGA Registry Research and Publications Committee of his/her intention not to proceed and include the justification for this decision.

**Sponsor Statements:** At the end of the manuscript draft [and before the References], authors should add **Sponsorship:** followed by the appropriate registry-specific sponsor statement. See list below.

- AGA Digestive Health Outcomes Registry® is a program of the American Gastroenterological Association Institute.
MEDIA PROMOTION OF SELECTED MANUSCRIPTS AND ABSTRACTS

When a manuscript or abstract has been accepted for publication, the author may be asked to provide supplementary materials in advance of the journal publication date. If promotion of the article is planned, these materials will be used in the creation of promotional content, as well as in the development of a press release and comments to the media (handled by AGA Institute’s communication department). After the embargo has lifted, the AGA Institute marketing department will promote the article to AGA membership, AGA Registry participants and AGA Registry researchers and interested media outlets.

As part of its promotional activities, a member of the AGA Institute marketing department will contact the author to request the following items two to three weeks in advance of the publication date:

1. **Talking points outlining the key messages from the research and findings** — Talking points providing the background, study summary and conclusions will be used in the AGA’s statement to the media and in the creation of AGA Registry promotional content.

2. **PowerPoint slides summarizing the research and findings** — When appropriate, slides will be requested from the author, and posted on Gastro.org. The AGA Institute marketing department, along with the AGA Registry Research and Publications Committee Chair, will review the slides; if adjustments are required, a revised version will be provided to the author for final review.

3. **A copy of the article provided to author by the publisher** — To be used in the development of promotional messaging.
AIDS TO MANUSCRIPT AND ABSTRACT PREPARATION

Authors are responsible for following guidelines specific to conferences, meetings and journals selected for submission. We offer the aids listed below as a resource to authors who are preparing manuscripts for submission to the AGA Registry review process.

1) Sample Outline
2) Use of Standardized Language to Describe AGA Registry and its Data
3) Correct Use of AGA Registry Names
4) Data and AGA Registry Limitations
5) Sample Tables and Figures
6) References and Citations
7) Definition of Variables
Sample Outline

I. Background and Study Objectives or Hypothesis

II. Methods
   A. Data Definitions
   B. Statistical Analysis

III. Results

IV. Discussion [Includes AGA Registry data limitations]

V. Conclusion

Use of Standardized Language to Describe AGA Registry and Its Data

The following text is intended to provide an example of language that can be used in the manuscript to describe AGA Registry data.

AGA Digestive Health Outcomes Registry® is a voluntary registry that receives data from more than two hundred participating health care providers. There is a standard data set with written definitions, uniform data entry and transmission requirements, and data quality checks. Details on the data collection process have previously been published. [See section 4 below on references and citations.] For the purpose of this study, we examined registry patients undergoing screening and surveillance colonoscopy for prevention of colorectal cancer from beginning month/day/year, through ending month/day/year. Patients who were undergoing diagnostic colonoscopy for other indications were excluded; all others were included.

Correct Use of AGA Digestive Health Outcomes Registry Names

The AGA Registry requires all authors to adhere to correct use of AGA Registry trademarks and registered trademark symbols, as shown below, in any written communication such as abstract and manuscript drafts, slides, posters, etc. Be sure to superscript the mark TM and ®.

In writing, AGA Digestive Health Outcomes Registry® requires the registered trademark symbol and AGA Registry™ requires the trademark symbol.

Note that trademark symbol and registered trademark symbol must be included in first use of the registry name (including use of the name in the title). Thereafter, the registry name can be used without the ™. If the registry is not mentioned in the title, the trademark or registered trademark symbol must be included upon first use of a registry name in the body of the manuscript or abstract.

Example:

TITLE: Gender Differences in Three Year Outcomes After Screening and Surveillance Colonoscopy: Results from AGA Digestive Health Outcomes Registry®

BODY OF ABSTRACT: Patients entered into the AGA Registry™ up to the first quarter of 2009 formed…

Abbreviations

The only accepted abbreviation for the AGA Digestive Health Outcomes Registry is the AGA Registry or the Registry. No other abbreviation or initials are acceptable.

Data and AGA Registry Limitations

When preparing manuscripts, authors describe the constraints or limitations of AGA Registry data in various ways, several of which are shown below. Authors should remember that AGA Registry was developed to help participating medical professionals identify and close gaps in quality of care; reduce wasteful and inefficient care variations; and implement effective, continuous quality improvement.
processes. While applied research has demonstrated that the use of such data in decision-making can reduce risk and improve care, it must be pointed out that AGA Registry retrospective observational data introduces selection bias. Moreover, the clinical significance of a particular study must take into account the fact that data are abstracted from a heterogeneous mixture of practices. Those practices vary in terms of case mix and the types and number of procedures they provide, thereby impacting data that are accrued. Additional considerations include limited outcomes data and variations in commitment and quality of data collection.

a. **An unequal geographic distribution of participating hospitals leads to selection bias, which limits the proportion of the inflammatory bowel disease population that was evaluated during the period described by this study.**

b. **AGA Registry participating practices vary in terms of the types and number of procedures they provide. This variability can impact on the data that are accrued.**

c. **The extent and what types of data the AGA Registry collects; registries typically need more detailed data, and authors will need to address this limitation.**
## Tables and Figures

All tables should have a title and each descriptive row and column should be labeled appropriately. Number all tables in order of their citation in the text. Include all tables consecutively, one table per page, at the end of the manuscript.

### Sample Table:

<table>
<thead>
<tr>
<th>Variables</th>
<th>2005–2006 (n = 14,190)</th>
<th>2007–2008 (n = 13,941)</th>
<th>Total (n = 28,131)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at listing, y, median (IQR)</td>
<td>53 (45–59)</td>
<td>54 (40–59)</td>
<td>54 (40–59)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>9090 (65)</td>
<td>8694 (64)</td>
<td>17,784 (64)</td>
</tr>
<tr>
<td>Race/ethnicity, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>1073 (3)</td>
<td>1113 (3)</td>
<td>2186 (3)</td>
</tr>
<tr>
<td>Asian</td>
<td>426 (3)</td>
<td>472 (3)</td>
<td>907 (3)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1993 (14)</td>
<td>2038 (15)</td>
<td>4031 (14)</td>
</tr>
<tr>
<td>Other</td>
<td>339 (2)</td>
<td>412 (3)</td>
<td>751 (3)</td>
</tr>
<tr>
<td>White</td>
<td>10,260 (73)</td>
<td>9,806 (71)</td>
<td>20,066 (72)</td>
</tr>
<tr>
<td>Diagnosis, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcoholic</td>
<td>2564 (18)</td>
<td>2439 (17)</td>
<td>5003 (15)</td>
</tr>
<tr>
<td>Cholestatic</td>
<td>1260 (9)</td>
<td>1152 (9)</td>
<td>2412 (9)</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>6203 (44)</td>
<td>5959 (43)</td>
<td>12,162 (43)</td>
</tr>
<tr>
<td>Other</td>
<td>4095 (29)</td>
<td>4391 (31)</td>
<td>8486 (30)</td>
</tr>
<tr>
<td>MELD score, median (IQR)</td>
<td>15 (12–21)</td>
<td>15 (12–21)</td>
<td>15 (12–21)</td>
</tr>
<tr>
<td>Bilirubin, mg/dL, median (IQR)</td>
<td>2.5 (1.4–4.8)</td>
<td>2.5 (1.4–5.0)</td>
<td>2.5 (1.4–5.0)</td>
</tr>
<tr>
<td>Creatinine, mg/dL, median (IQR)</td>
<td>1.0 (0.8–1.4)</td>
<td>1.0 (0.8–1.4)</td>
<td>1.0 (0.8–1.4)</td>
</tr>
<tr>
<td>INR, median (IQR)</td>
<td>1.4 (1.2–1.7)</td>
<td>1.4 (1.2–1.7)</td>
<td>1.4 (1.2–1.7)</td>
</tr>
<tr>
<td>Scantum, mg/dL, median (IQR)</td>
<td>137 (133–139)</td>
<td>137 (133–139)</td>
<td>137 (133–139)</td>
</tr>
<tr>
<td>Status at 90 d after registration on waiting list</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alive</td>
<td>8012 (54)</td>
<td>5374 (54)</td>
<td>17,386 (54)</td>
</tr>
<tr>
<td>Died</td>
<td>964 (7)</td>
<td>940 (7)</td>
<td>1904 (7)</td>
</tr>
<tr>
<td>OLT</td>
<td>4194 (30)</td>
<td>3981 (29)</td>
<td>8175 (29)</td>
</tr>
</tbody>
</table>
Sample Figure:

All figures should have a title and each axis should be labeled appropriately. Number all figures in order of their citation in the text. Include all figures consecutively, one figure per page, at the end of the manuscript.
References and Citations

List references using superscripted Arabic numerals by order of appearance in the text. Cite personal communications and unpublished data directly in text without being numbered. All abbreviations should follow the Index Medicus abbreviations.

Follow Gastroenterology requirements for style:

Article (list 3 authors followed by et al):

Book:

Article in Book:

Definitions of Variables

Definitions of variables are available from the AGA Registry website under the Elements/Definitions link for the AGA Registry.