

Database Screening Questions:

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1. Human Subjects - Did the study/scholarly activity involve intervention or interactions with human subjects, human information/data, or human biospecimens?
 - Yes
 - No
2. Was IRB approval obtained?
 - Not applicable – responded “no” to previous question regarding human subjects.
 - Yes - [\(IRB Approval Letter may be requested\)](#)
 - No - I received a determination that the study/activity qualified for exempt status or that it did not require IRB approval from an IRB or another authorized oversight body [\(IRB Exemption Letter may be requested\)](#)
 - No – I did not receive IRB approval or a determination that the study/activity was exempt or that it did not require IRB approval. **Complete and upload an Human Subject Research application** for review by the ASRS Human Research Committee. The ASRS HRC will review the information provided to determine whether the study qualifies as exempt or otherwise not requiring IRB approval. The ASRS HRC is not constituted as an IRB and thus cannot provide IRB approval for activities that require such.

Application that above screener links to:

Please note that the ASRS Human Research Committee is not constituted as an IRB or Privacy Board and thus can only provide determinations for activities that do not require IRB oversight or a HIPAA action (such as a waiver of the research authorization requirement). Likewise, the ASRS Human Research Committee cannot provide determinations for activities that are under the jurisdiction of an IRB or other oversight body (e.g., by virtue of faculty appointment or clinical affiliation). Applicants are responsible for compliance with any rules, regulations, or policies that apply to their scholarly activities.

Name:

Abstract Title:

Date:

1. Please categorize the scholarly activity you are submitting. If more than one category applies, please check all that apply.
 - Single Case Report
 - Case Series of ≤ 10 cases
 - Literature Review
 - Meta-analysis
 - Analysis of data from Vestrum, IRIS, or other large-scale professional database
 - Retrospective Chart Review (other than single case report or ≤ 10 case series)
 - Other

2. Single Case Report

Per ICMJE: *“Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication...Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained.”*

- a. To the best of your knowledge, does this case report include identifying information, photographs, or other information that may lead to the identification of the individual described in the case report?

- Yes, briefly explain:
 No

- b. Was consent obtained from the described individual for dissemination of the case report?

- Yes
 No

3. Case Series of ≤ 10 cases

- a. Per ICMJE: *“Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication...Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained.”*

- i. To the best of your knowledge, does this case series include identifying information, photographs, or other information that may lead to the identification of the individuals described in the case report?

- Yes, briefly explain:
 No

- ii. Was consent obtained from the described individuals for dissemination of the case report?

- Yes
 No

- b. Are the individuals included in the case series your own patients and/or those of other named authors, or are some (or all) patients of other providers?

- Case series includes only my own patients and/or those of other named authors
 Patients of other providers are included, briefly explain:

- c. Does the case series include statistical analysis other than basic mathematic descriptors (e.g., totals, percentages)?

Yes, briefly explain:

No

4. Literature Review

- a. Did this literature review include access to/review of any individual level human data?

Yes, briefly explain:

No

5. Meta-analysis

- a. Did this meta-analysis include access to/analysis of any individual level human data?

Yes

No

- b. If Yes to the above, answer the following:

- i. Did the data include any identifying information?

Yes, briefly explain:

No

- ii. Was the data coded?

Yes, did you/do you have access to the key which would enable re-identification? Yes No

No

- iii. Is there an agreement or terms of use that prohibits re-identification? Yes No

6. Professional Database

- a. Which database(s) did you obtain data from for this study?

Vestrum

IRIS

Other (provide name and hyperlink):

- b. How many records were included?

- c. Did the data include any identifying information?

Yes, briefly explain:

No

- d. Was the data coded?

Yes, did you/do you have access to the key which would enable re-identification? Yes No

No

- e. Do you know, or can you readily ascertain, the identities of any of the individuals included in the dataset?
- Yes, briefly explain:
 No
- f. Is there an agreement or terms of use that prohibits re-identification? Yes No

7. Retrospective Chart Review

- a. Please identify the data sources for the study, check all that apply:
- Records of patients under your care
 Records of patients not under your care but within your practice
 Records of patients outside of your practice
 Other records, briefly describe:
- b. Did the data accessed or used for this study include [Protected Health Information](#) (PHI)?
- Yes, the data included PHI
 Yes, but the data was provided to me as a [Limited Data Set](#) (*Note: this link leads to a decision tool that includes the definition of a LDS, there is no need to complete the decision tool*) under a [Data Use Agreement](#)
 No, the data originally included PHI but was provided to me fully de-identified in accordance with [HIPAA's de-identification standards](#)
 No, the data did not include PHI. Briefly describe the data, the data sources, and address whether the data includes identifying information or if the identities of the subjects are known by the author(s):
- c. If Yes to the above, please indicate whether the PHI accessed or used for the chart review remained protected by HIPAA throughout this study (i.e., it never left the “umbrella” of a covered entity):
- Yes, the PHI was protected under HIPAA at all times during this study, it was never transferred, transmitted, or otherwise disclosed outside of a covered entity
 No, the PHI was not protected under HIPAA at all times during this study. Briefly explain:

8. Other

- a. Please summarize the purpose, methods, and data sources used in this scholarly activity:
- b. Did this activity include **intervention(s)** with subjects? *Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.*
- Yes, briefly explain:
 No
- c. Did this activity include obtaining information through **interaction** with subjects? *Interaction includes communication or interpersonal contact between investigator(s) and subjects (this includes indirect interaction such as via a web-based survey).*
- Yes, briefly explain:
 No

- d. Did this activity include the use or generation of **identifiable private information**? *Private information means (i) information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; and (ii) information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). **Identifiable private information** is private information for which the identity of the subject(s) is or may readily be ascertained by the investigator or associated with the information (e.g., via coding).*

Yes, briefly explain:

No

- e. Did the study include the collection or use of **identifiable biospecimens**? *Identifiable biospecimen means a biospecimen for which the identity or the subject is or may readily be ascertained by the investigator or associated with the biospecimen (e.g., via coding).*

Yes, briefly explain:

No

9. Additional Information

- a. Please provide any additional information that may be helpful to the committee as they evaluate whether the activity is exempt or otherwise doesn't require IRB approval per U.S. federal regulations: