

## Scientific Evidence Code System Development Protocol

For the COVID-19 Knowledge Accelerator (COKA) Initiative

Protocol as of November 17, 2021 (Revised November 19, 2021 to address attribution of contributorship; Revised December 6, 2021 and December 8, 2021 to address protocol handling of voting (3e) and post-approval changes (7))

This protocol inherits the work from September 17, 2020 through November 12, 2021 completed using the [Code System Development Protocol](#) developed for 4 code systems (Risk Of Bias Code System, Statistic Type Code System, Statistic Model Code System, and Study Design Code System) and published in detail at:

Alper BS, Dehnbostel J, Afzal M, Subbian V, Soares A, Kunnamo I, Shahin K, McClure RC, For the COVID-19 Knowledge Accelerator (COKA) Initiative. Making Science Computable: Developing code systems for statistics, study design, and risk of bias. J Biomed Inform 2021 Mar;115:103685. Published online January 21, 2021. doi: 10.1016/j.jbi.2021.103685.  
<https://doi.org/10.1016/j.jbi.2021.103685>

As of November 16, 2021 we are combining these four code systems into one Scientific Evidence Code System (SEVCO) and adjusting the protocol to maintain the openness, transparency and thoroughness originally intended while transitioning to more efficient methods for development, maintenance and long-term sustainability and stewardship of the code system.

The Scientific Evidence Code System defines terms used for the communication of scientific evidence.

### The Scientific Evidence Code System will include:

**Statistic-related terms** to precisely classify statistic types (such as mean, median, relative risk, mean difference, odds ratio, confidence interval, p value, and measures of heterogeneity), hypothesis test attributes (such as alpha setting and one-tailed test), and statistical model characteristics (such as fixed-effect model and regression model form). Science reports often do not convey complete information about statistical models. Consistent reporting across systems will facilitate interoperability for science communication.

**Study design-related terms** to precisely describe methodology characteristics of scientific observations including exposure introduction (such as interventional or observational), cohort definition (such as parallel, crossover or case-control), and group assignments (such as block randomization or non-randomized assignment). Consistent reporting of research study design across systems will facilitate interoperability for science communication.

**Risk of bias-related terms** to precisely describe concerns with methods or reporting of scientific observations including selection bias (such as gaps in randomization or allocation

concealment), performance bias (such as gaps in blinding), and analysis bias (such as gaps in intention to treat analysis or selective analysis reporting). Consistent reporting of risk of bias across systems will facilitate interoperability for science communication.

### **Protocol Steps:**

1. Maintain one expert working group (combining the expert working groups for risk of bias terms, study design terms, and statistic terms).
  - a. Expert Working Group (EWG) membership will be open to any individual who self-identifies as a relevant expert for the code system. Relevant expertise for a code system may include but is not limited to experience evaluating or expressing the concepts to be included in the code system, either for human interpretation or for machine interpretation.
  - b. We will resend open invitations as email messages to the distribution lists or key representatives for the COKA Initiative, COVID-END, EBH listserv, GRADE Working Group, DECIDE project participants, AHRQ EPC listserv, HL7 CDS and BRR work groups, the Society for Clinical Trials, the Society for Participatory Medicine, International Society for Clinical Biostatistics, and PCORI.
  - c. With the invitation we will share an introduction to what is a code system, why we are doing this, a link to the protocol, and a link to the Project Page where one can join the Expert Working Group. (<https://fevir.net/resources/Project/27845>)
  - d. Set up a code system steering group from the most actively engaged participants, specifically those who join open weekly work group meetings.
2. For each term (to draft content for voting):
  - a. For each relevant ontology, extract the display (or preferred term), synonym list (or alternative terms), and definition(s) that best match the concept, and note closely related variations.
  - b. Review the displays, synonym lists, and definitions available from ontologies.
  - c. Draft a preferred display, synonym list, and definition.
  - d. Enter the draft preferred display, synonym list, and definition into the [Scientific Evidence Code System \(SEVCO\) -- DRAFT ONLY \(Not published for current use\)](#) used for code system development.
3. For each term (for voting for approval):
  - a. When the code system steering group determines the draft term is “ready for vote”, voting will be open to members of the expert working group and the EWG will be emailed a notice that the term is open for voting.
  - b. Voters will either select YES for approval of the term (including display, alternative terms, definition, comment for application, and hierarchical listing regarding parent term) or select NO with the addition of a comment suggesting the change that would make the term acceptable. The voting process will be online and asynchronous.
  - c. The content of individual votes (YES or NO selection, comments, and name of voter) will be visible to code system editors and may be shared during steering group meetings

but will not be generally posted for open viewing outside steering group meetings and active editing of the code system.

- d. If a term has been open for vote for at least six days and has at least five votes and all votes are YES, the term will be considered approved and closed for voting.
  - e. If a term has a NO vote, the steering group will review the comments, determine if any changes to the term are warranted, then:
    - i. If changes are made, when the steering group considers the term “ready for vote” the voting start date will be reset and the term will be open for vote as noted above.
    - ii. If the steering group determines no changes are warranted, the term will remain open for vote, the negative comment will be shared with the expert working group, and EWG voters may change their vote by voting again.
      1. If on repeat steering group review all votes are YES, the term will be considered approved and closed for voting.
      2. If on repeat steering group review there are new NO votes, the steering group will review the comments and determine if changes are warranted.
      3. If on repeat steering group review there are no new NO votes and the original NO vote persists, the person recommending changes will be asked to provide a rationale for deliberation as described below and if not provided within 1 week the term will be considered approved and closed for voting.
  - f. If a term does not achieve universal agreement (cycling through steps a-e above with conflicting suggestions):
    - i. Each person recommending changes will write a rationale.
    - ii. The rationales will be shared with the expert working group prior to a group meeting.
    - iii. The group meeting will discuss and prepare the preferred version. The preferred version and meeting discussion will be shared with the group.
    - iv. Group members will have 48 hours to vote for the presented version.
    - v. The preferred version will become the included version if it achieves at least 80% agreement with at least 5 people voting.
    - vi. If unable to achieve at least 80% agreement with at least 5 people voting, options may include extending the voting period, dropping the item, or preparing for another group discussion.
4. When judged ready by the steering group, we will publish the code system at fevir.net and seek publication of introductory articles to the code system in the biomedical literature. When the code system is published, attribution of contributorship will be shared by:
- a. Listing authors based on anyone who contributed as a “term editor” on any of the terms which occurs through the weekly webmeetings
  - b. Listing endorsers based on anyone who contributed as a “voter” on any of the final-approval votes for any terms
  - c. Listing reviewers based on anyone who contributed as a “commenter” or a “voter” on any of the disagreement votes on any of the terms

- d. All of these listings may be ordered by decreasing number of contribution instances across the code system.
5. After the first published version of the code system is available, for implementation and initial evaluation of the code system, we will:
  - a. identify tools and systems that could use the code system, including consideration of the previously “identified 23 commonly used tools and systems for which the first version of code systems will be developed”
  - b. offer support for implementation and measure the proportion of systems that get engaged.
  - c. evaluate ease of use.
  - d. generate code system change requests as needed.
  - e. track systems that implement the code system and set a regular review interval to inquire about usefulness and change requests.
6. For ongoing maintenance and development of the code system:
  - a. We will maintain an open invitation for anyone to share comments regarding specific code system terms for continued feedback.
  - b. We will maintain an open invitation for code system users to join the expert working group for recognized contribution.
  - c. We will maintain an open invitation for anyone to suggest additional tools or systems with common current use of concepts matching the code system.
  - d. Code system changes may be initiated by change requests from the community.
  - e. The code system steering group will validate that change requests are appropriate for group deliberation (e.g., fits the purpose of the code system, has sufficient rationale, avoids duplication).
  - f. Valid change requests will lead to drafting a preferred display, synonym list, and definition. Voting on changes will then be processed as previously described.
7. If changes are requested after terms are approved while the code system is in development:
  - a. The steering group may change Alternative terms and Comment for application through discussion in open meetings and changes will be reported to the Expert Working Group.
  - b. Changes to the Preferred term or Definition for any term will result in setting the term back to draft and repeating the process for voting for approval. The prior “approval history” will be moved to a different term property but retained for documentation.

Cite as:

Alper BS, Dehnbostel J, Lehmann H, Whaley P, Wilkins KJ, Tufte J, Yurk RA, Ojha N, Afzal M. For the COVID-19 Knowledge Accelerator (COKA) Initiative. Scientific Evidence Code System Development Protocol. Created November 16, 2021. Last revised December 8, 2021. Available at:

<https://docs.google.com/document/d/1pzGLdyVCKcu3s2gfSfPpXDQLIQsFnLZR14ldw0nD1g0>

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**Note to those who would like to participate in any of the Code System Development Steering Groups or the COVID-19 Knowledge Accelerator (COKA) Initiative:**

You can learn more about the COVID-19 Knowledge Accelerator (COKA) project at [https://www.gps.health/covid19\\_knowledge\\_accelerator.html](https://www.gps.health/covid19_knowledge_accelerator.html)

You can find all the progress notes at a Google Drive folder for the project and each Work Group has a Progress Report document where you can find the details.

You can join any of the groups that are now meeting in the following schedule:

| <u>Day</u> | <u>Time<br/>(Eastern)</u> | <u>Team</u>   |
|------------|---------------------------|---|
| Monday     | 8-9 am                    | Project Management                                    |
| Monday     | 9-10 am                   | Systematic Meta-Review Project Group                  |
| Monday     | 10-11 am                  | Computable EBM Tools Development Working Group        |
| Monday     | 1-2 pm                    | Terminology and Ontology WG                           |
| Tuesday    | 10-11 am                  | Recommendation Profile WG                             |
| Tuesday    | 11am-12pm                 | Common Metadata Framework WG                          |
| Tuesday    | 2-3 pm                    | Research Design WG                                    |
| Wednesday  | 8-9 am                    | Knowledge Ecosystem Liaison WG                        |
| Wednesday  | 9-10 am                   | Statistic Standard and Terminology WG                 |
| Thursday   | 9-10 am                   | Computable EBM Tools Development Working Group        |
| Thursday   | 4-5 pm                    | Project Management                                    |
| Friday     | 9-10 am                   | Risk of Bias Terminology and Tooling WG               |
| Friday     | 10-11 am                  | Communications (Awareness, Scholarly Publications) WG |

**To join any of these meetings:**

[Join Microsoft Teams Meeting](#)

+1 929-346-7156 United States, New York City (Toll)

Conference ID: 324 918 025#

[Local numbers](#)

Meeting support by [ComputablePublishing.com](#)

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Email [balper@computablepublishing.com](mailto:balper@computablepublishing.com) if you would like to be added (or removed) to any of the specific meeting invites or to this COKA Distribution List email. You are welcome to join any meeting at any time whether you have signed up or not.