

Data Dissemination Policies and Procedures (D2P2) Overview

SRC fully supports the use of BOLD data to help advance the bariatric and metabolic surgical specialty. SRC developed the Data Dissemination Policies and Procedures (D2P2) to govern the use and sharing of BOLD data with COE participants, outside investigators and other third parties.

The following describes the process by which COE participants and others can submit a formal BOLD data request or publication/presentation request. More specifically, it discusses the types of requests, acceptance criteria, request processes and fees related to data access and dissemination. SRC's Data Access Committee (DAC) and Data Dissemination Committee (DDC) are responsible for implementing and monitoring compliance with the D2P2, which includes review and approval of data-related requests:

- The DAC reviews and approves requests to use BOLD data for research, information, commercial and select internal purposes.
- The DDC reviews and approves manuscripts, presentations and other works containing data from BOLD.

Those interested in accessing the full text of the D2P2 can request a copy by contacting research@surgicalreview.org.

1) Data that Does Not Require Any Kind of BOLD Request

Individual COE Participant Data

COE participants may use their own program data as reported in BOLD for the following purposes without submitting a request for approval by the DAC or DDC:

- Monitoring internal quality assurance and quality improvement processes to satisfy institutional requirements
- Reporting their own statistics and outcomes to inform individual referring physicians, help counsel patients and families, as well as strengthen collaborative decision-making with surgical and nonsurgical colleagues
- Aiding managed care, hospital-surgeon and other contract negotiations
- Promoting and marketing their bariatric program

National Summary Data

COE participants may use the aggregate benchmark data contained in BOLD national summary reports for the following purpose without submitting a request for approval by the DAC or DDC:

- Monitoring internal quality assurance and quality improvement processes to satisfy institutional requirements
- Reporting how their own statistics and outcomes compare to aggregate benchmarks to inform individual referring physicians, help counsel patients and families as well as strengthen collaborative decision-making with surgical and nonsurgical colleagues

2) Data that Requires a BOLD Data Access Request

Individual COE Participant Data

COE participants seeking additional data on their own programs that *is not* contained in the standard BOLD program reports must submit a BOLD Data Access Request.

Research Data

COE participants and third parties seeking data for use in original research or analysis must submit a BOLD Data Access Request. Third parties include:

- Research institutions, individual researchers, clinicians and investigators affiliated or not affiliated with a COE program
- Businesses, payors, government agencies and other industry stakeholders

General Data

Industry stakeholders seeking general data for informational or commercial purposes must submit a BOLD Data Access Request. General data is not intended for use in original research or data analysis projects. Industry stakeholders include:

- Government agencies
- Pharmaceutical, medical device, and other medical or surgical industry-related companies, whether private or public
- Health insurance payors, both public and private
- Employer groups

3) Data Use that Does Not Require a BOLD Data Dissemination Request

COE participants may publish their own data as long as the publication or presentation contains no aggregate benchmark data contained in BOLD national summary reports.

4) Data Use that Requires a BOLD Data Dissemination Request

National Summary Data

COE participants must first submit a BOLD Data Dissemination Request to use the aggregate benchmark data contained in BOLD national summary reports.

Research Data

COE participants and third parties that intend to publish or present BOLD data in original research or analysis must submit a BOLD Data Dissemination Request.

General Data

Industry stakeholders that intend to publish or present general BOLD data must submit a BOLD Data Dissemination Request.

Dissemination Uses

BOLD national summary data as well as research and general data generated through requests require DDC approval if it is to be used for:

- Presentations for professional, educational and society meetings, etc.
- Educational materials
- Grant proposals
- Abstracts and extended abstracts
- Research and manuscripts
- Oral and poster presentations
- Letters to the editor and reviews
- Methodology papers
- News releases, interviews and responses to media inquiries

5) BOLD Data Access Request Process

Request Submission

Parties seeking access to BOLD data must first submit a [BOLD Data Access Request](#) to SRC.

SRC Review

SRC reviews the request form for completeness and contacts the requesting party to obtain any missing information or needed clarification.

DAC Review and Assessment

The DAC reviews the request at its regular meeting and makes one of the following determinations:

- **Approved:** The DAC determines the proposed research project or study has merit and meets the criteria outlined below in section 6.
- **Conditional approval:** The DAC decides to limit the data to be released or impose conditions on the data released.
- **Deferral or referral to staff:** The DAC decides to defer action on the request pending receipt of additional information.
- **Denial:** The DAC determines the proposed research project or study does not have merit or meet the criteria outlined below in section 6.

DAC Notification to SRC and Cost Estimate Preparation

The DAC reports its determination to SRC. If the data request has been approved or conditionally approved, SRC prepares a cost estimate (if applicable).

SRC Notification to Requesting Party

SRC informs the requesting party of the DAC's determination, usually by email.

- **Approved or conditional approval:** SRC sends a Data Release Agreement (DRA) to the requesting party, which must be signed and returned to SRC before the data can be released. The DRA includes the following:
 - Description of the data to be provided
 - Estimated date of release of the data
 - Any fees charged for obtaining the data
 - Authorized and restricted uses of the data
 - Format of the data to be provided
- **Deferral or referral to staff:** SRC specifies the additional information needed.
- **Denial:** SRC provides an explanation of why the request was not approved.

Data Report Delivery

Upon receipt of the executed DRA and payment of any applicable fees, SRC compiles the requested data and forwards the report to the requesting party as specified in the DRA.

6) Considerations for BOLD Data Access Approval

The DAC considers the following factors when evaluating a data request:

Individual COE Participant Data Requests

No COE participant-specific data will be provided to any third party without the written consent of the participant.

Stakeholder requests for COE participant-specific data are considered by the DAC on a case-by-case basis. The terms and conditions of any approved requests are documented in a formal written agreement between SRC and the requesting party, with appropriate authorization obtained from the COE participant(s) involved.

Research Data Requests

- Scientific merit of the proposed research or study
- Ability of the proposed research or study to reasonably advance the current state of knowledge
- Anticipated SRC resources (e.g., staff time and effort) to retrieve the data

- Likely ability of the requesting party to complete the research or study given the requestor's experience, resources and other factors
- Relevance of the requested data to the proposed research or study
- Appropriateness of the requested data for release
- Potential impact of the proposed research or study on stakeholders
- Whether similar research projects or studies are underway or have been approved

General Data Requests

- Stated purpose for the request and intended use
- Anticipated SRC resources (e.g., staff time and effort) to retrieve the data
- Appropriateness of the requested data for release
- Potential impact of the proposed research or study on stakeholders

7) BOLD Data Dissemination Request Process

Request Submission

Parties seeking approval to use BOLD data in a publication or presentation must first submit a [BOLD Data Dissemination Request](#) to SRC.

SRC Review

SRC reviews the request form for completeness and contacts the requesting party to obtain any missing information or needed clarification.

DDC Review and Assessment

The DDC reviews the request at its regular meeting and makes one of the following determinations:

- **Approved:** The DDC determines the proposed publication or presentation meets the criteria for approval outlined below in section 8.
- **Approved with revisions:** The DDC determines the proposed publication or presentation meets the standards for approval but editorial or substantive changes or revisions are required.
- **Not approved:** The DDC determines the proposed publication or presentation shows lack of scientific merit and does not meet criteria for approval outlined below in section 8.

DDC Notification to SRC

The DDC reports its decision to SRC.

SRC Notification to Requesting Party

SRC notifies the requesting party of the DDC's determination, usually by email.

- **Approved:** SRC notifies the requesting party that the request has been approved. The requesting party is then free to present or publish the data in the work approved by the DDC.
- **Approved with revisions:** In the event a request is approved with revisions, SRC works with the requesting party on a timeline for submitting a revised draft. Upon receipt, the revised draft is forwarded to the DDC for review. The committee may approve the draft as revised or determine that the original conditions imposed have not been satisfied. SRC notifies the submitting party of the determination.
- **Not approved:** SRC provides an explanation of why the request was not approved.

8) Considerations for BOLD Data Dissemination Approval

The DDC considers the following factors when evaluating a request:

- Scientific merit of the proposed publication or presentation
- Whether the proposed publication or presentation will reasonably advance the current state of knowledge
- Whether the proposed publication or presentation accurately and fairly reflects the data upon which the publication or presentation is based
- Whether other publications or presentations on the same or similar topics have already been approved or published

9) BOLD Data Dissemination: Post-Approval

Abstracts

If an abstract for presentation at a professional or society meeting is approved, the final presentation including handouts must be submitted to the DDC at least 2 weeks prior to the presentation date. SRC coordinates the submission with the submitting party. The DDC reviews final presentations of approved abstracts on an expedited basis as needed prior to scheduled presentation dates.

News Releases

News releases discussing the findings of DAC-approved research projects or publications must be approved by the DDC and may not be released prior to formal publication. Authors are expected to abide by any applicable embargo limitations imposed by journals or other publishers.

Authorship

Authors will be acknowledged in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, available at www.icmje.org. Among other things, the ICMJE guidelines provide that authorship credit should be based on:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content, and
- Final approval of the version to be published.

Authors should meet all three conditions. The DDC has the right to make authorship recommendations and resolve disputes as to authorship acknowledgement. The DDC may adopt additional authorship guidelines as it deems appropriate.

