

## **2021 Mallinckrodt**

approved within 30 days after regulatory approval or 18 months after study completion, whichever occurs later.

**B. Third-Party Data Archive**

1. Mallinckrodt shall share the above information via a third-party data archive that makes clinical data available to Qualified Researchers with a bona fide scientific research proposal.
2. The data archive shall have a panel of reviewers with independent review authority to determine whether the researchers are qualified, whether a research application seeks data for bona fide scientific research, and whether a research proposal is complete.
3. The panel may exclude research proposals with a commercial interest.

**C. Non Interference**

1. Mallinckrodt shall not interfere with decisions made by the staff or reviewers associated with the third-party data archive.

**D. Data Use Agreement**

1. Any data sharing agreement with a Qualified Researcher who receives shared data via the third-party data archive shall contain contact information for Mallinckrodt's pharmacovigilance staff. Every agreement shall require the lead qualified researcher to inform Mallinckrodt's pharmacovigilance staff within 24 hours of any determination that research findings could detrimentally impact the risk-benefit assessment regarding the product. The lead Qualified Researcher may also inform regulatory authorities of the safety signal impacting the risk-benefit assessment. Mallinckrodt's pharmacovigilance staff shall take all necessary and appropriate steps upon receipt of such safety information, including but not limited to notifying regulatory authorities or the public.

**E. Cost**

1. Mallinckrodt shall bear all costs for making data and/or information available.

**V. PUBLIC ACCESS TO MALLINCKRODT DOCUMENTS**

**A. Documents Subject to Public Disclosure**

1. The following documents shall be produced by Mallinckrodt to each Settling State and are subject to public disclosure in perpetuity as part of an industry-wide document disclosure program, except for the redactions authorized by Section V.B:

- a. All documents, indices, and privilege logs Mallinckrodt produced to any of the Settling States prior to the Petition Date, including in litigation and in response to investigative demands or other formal or informal requests related to opioids.
  - b. All documents, indices, and privilege logs Mallinckrodt produced in the Opioid Multi-District Litigation (*In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804 (N.D. Ohio)) and the New York litigation (*In re Opioid Litigation*, 400000/2017 (Suffolk County)) prior to the Petition Date.
  - c. All documents, indices, and privilege logs Mallinckrodt has produced in other litigation related to opioids, excluding patent litigation.
  - d. All filings, motions, orders, court transcripts, deposition transcripts, and exhibits in the possession, custody, or control of Mallinckrodt from litigation related to opioids, excluding patent litigation.
2. All documents produced under this provision shall be provided in electronic format with all related metadata. Mallinckrodt and the Settling States will work cooperatively to develop technical specifications for the productions.

**B. Information That May Be Redacted**

1. The following categories of information are exempt from public disclosure:
  - a. Information subject to trade secret protection. A “trade secret” is information, including a formula, pattern, compilation, program, device, method, technique or process, that (a) derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure and use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Even if the information falls within the definition, “trade secret” does not include information reflecting sales or promotional strategies, tactics, targeting, or data, or internal communications related to sales or promotion.
  - b. Confidential personal information. “Confidential personal information” means individual Social Security or tax identification numbers, personal financial account numbers, passport numbers, driver license numbers, home addresses, home telephone numbers, personal email addresses, and other personally identifiable information protected by law from disclosure. “Confidential personal information” does not include the names of Mallinckrodt’s officers, directors, employees, agents, or attorneys.

- c. Information that is inappropriate for public disclosure because it is subject to personal privacy interests recognized by law (*e.g.*, HIPAA), or contractual rights of third parties that Mallinckrodt may not abrogate.
- d. Information regarding Mallinckrodt employees' personal matters unrelated to Mallinckrodt, including emails produced by Mallinckrodt custodians discussing vacation or sick leave, family, or other personal matters.

**C. Redaction of Documents Containing Protected Information**

1. Whenever a document contains information subject to a claim of exemption pursuant to Section V.B, Mallinckrodt shall produce the document in redacted form. Such redactions shall indicate that trade secret and/or private information, as appropriate, has been redacted. Redactions shall be limited to the minimum redactions possible to protect the legally recognized individual privacy interests and trade secrets identified above.
2. Mallinckrodt shall produce to each Settling State a log noting each document redacted. The log shall also provide fields stating the basis for redacting the document, with sufficient detail to allow an assessment of the merits of the assertion. The log is subject to public disclosure in perpetuity. The log shall be produced simultaneously with the production of documents required by Section V.F.
3. In addition to the redacted documents, Mallinckrodt shall, upon any Settling State's request, also produce all documents identified in Section V.A above in unredacted form to such Settling State at the same time. The redacted documents produced by Mallinckrodt may be publicly disclosed in accordance with Section V.E below. The unredacted documents produced by Mallinckrodt to a Settling State shall be available only to such State unless Mallinckrodt's claim of exemption under Section V.B is successfully challenged in accordance with Section V.C.4 or the trade secret designation expires in accordance with Section V.D.
4. Anyone, including members of the public and the press, may challenge the appropriateness of redactions by providing notice to Mallinckrodt. If the challenge is not resolved by agreement, it must be resolved in the first instance by a third party jointly appointed by the Settling States and Mallinckrodt to resolve such challenges. The decision of the third party may be appealed to a court with enforcement authority over this Agreement. If not so appealed, the third party's decision is final. In connection with such challenge, a Settling State may provide copies of relevant unredacted documents to the parties or the decisionmaker, subject to appropriate confidentiality and/or in camera review protections, as determined by the decisionmaker.

**D. Review of Trade Secret Redactions**

1. Ten years after Mallinckrodt completes the production of its documents in accordance with Section V, Mallinckrodt shall review all trade secret assertions made in accordance with Section V.B.1 and all non-manufacturing trade secret designations shall expire. The newly unredacted documents may then be publicly disclosed by a Settling State in accordance with Section V.E. Mallinckrodt shall produce to each Settling State an updated redaction log justifying its designations of the remaining trade secret redactions as manufacturing trade secrets.

**E. Public Disclosure through a Document Repository**

1. Each Settling State may publicly disclose all documents covered by Section V through a public repository maintained by a governmental, non-profit, or academic institution. Each Settling State may specify the terms of any such repository's use of those documents, including allowing the repository to index and make searchable all documents subject to public disclosure, including the metadata associated with those documents. When providing the documents covered by Section V to a public repository, no Settling State shall include or attach within the document set any characterization of the content of the documents. For the avoidance of doubt, nothing in this paragraph shall prohibit any Settling State from publicly discussing the documents covered by Section V.

**F. Timeline for Production**

1. Mallinckrodt shall produce all documents required by Section V.A within nine months from the Petition Date.

**G. Costs**

1. Mallinckrodt shall be responsible for its allocable share of all reasonable costs and expenses associated with the public disclosure and storage of Mallinckrodt's documents through any public repository.

**H. Suspension**

1. Mallinckrodt's obligation in Section V shall be suspended on the nine-month anniversary of the Petition Date, unless and until two corporate defendants in opioid-related litigation other than Mallinckrodt have agreed or been ordered to publicly disclose opioid-related documents. For the avoidance of doubt, Insys Therapeutics, Inc. shall constitute one of the two necessary defendants based on the "Liquidating Trustee Disclosure Requirement" provisions of the Second Amended Joint Chapter 11 Plan of Liquidation confirmed by the United States Bankruptcy Court for the District of Delaware on January 16, 2020.