# UCSF-JHU Opioid Industry Documents Archive
# Collection Development Policy

## Introduction

The purpose of the UCSF-JHU Opioid Industry Documents Archive (OIDA) Collection Development Policy is to: 1) define the scope of the materials to be collected and preserved in OIDA; 2) outline the process of acquiring these materials; and 3) provide detailed criteria for collecting decisions.

## Mission

The Opioid Industry Documents Archive collects, organizes, preserves, and makes freely accessible publicly-disclosed documents from the opioid industry to enable multiple audiences to explore and investigate information which shines a light on the opioid crisis.

OIDA is a collaborative undertaking between the University of California, San Francisco (UCSF) and Johns Hopkins University (JHU). UCSF's Industry Documents Library (IDL) hosts OIDA within its technical infrastructure and makes the OIDA collections freely cross-searchable with other major industry documents collections hosted by the IDL, including the Truth Tobacco Industry Documents Library. OIDA's Collection Development Policy is informed by the overall IDL Collection Development Policy.[1]

## Research Community

The collections in OIDA are an important resource for:

- Families affected by opioid addiction, overdose, and related harms, and organizations that advocate on their behalf;
- Policymakers and legislators;
- Attorneys;
- Journalists;
- Academic researchers in fields including public health, history, sociology, and anthropology;

[1] The Industry Documents Library is a digital archive of documents created by industries which influence public health, hosted by the University of California, San Francisco Library. Originally established in 2002 to house the millions of documents publicly disclosed in litigation against the tobacco industry in the 1990s, the Library has expanded to include documents from the opioid, drug, chemical, food, and fossil fuel industries to preserve open access to this information and to support research on the commercial determinants of public health.

- Educators;
- Students;
- Healthcare and public health specialists;
- Other interested members of the public.

**Collecting Scope**

OIDA was created in March 2021 to preserve and provide access to documents made public, or released, as a result of opioid litigation and related matters. For the purposes of this policy the scope of these documents is defined as items that have been produced in legal discovery or created for the purpose, or as a result, of a formal legal action or proceeding, including formal investigations and hearings initiated by the U.S. Government, state governments, or local governmental entities.

OIDA also collects documents which relate to the wider opioid industry and its partners, which highlight practices and topics affecting public health. In addition to documents publicly disclosed through litigation, this includes other public records and communications relating to internal company procedures, relationships with outside partners and vendors, government relations, and marketing and advertising.

**Collection Evaluation Methods**

Collecting Criteria:

- Appropriateness: documents that are congruous and in keeping with the mission of OIDA and its stated collecting scope.
- Research value: documents which contain information about people, companies, products and issues that OIDA's Research Community will find useful and informative.
- Evidential value: documents that provide insight about the culture, policies, and decision-making processes of the corporation, organization, or individuals, that created them.
- Uniqueness: whether these documents are readily available elsewhere, particularly online or in another archival repository.
- Value: long-term value to public health research and public health policy as it relates to the opioid epidemic.
- Legal risk: copyright, privacy and confidentiality, litigation status.
- Cost: the required funds to process and preserve compared to the expected research value.

OIDA follows a practice of archival appraisal (see checklist at the end of this policy) to evaluate each potential new collection according to our Collecting Criteria, above. If appropriate, the collection is brought to the OIDA Collections Workgroup for discussion and determination regarding accessioning and priority of processing. OIDA does not conduct a financial appraisal or assign any monetary value to collections.

**Collection Sources**

- Litigation: OIDA collects documents which were produced in legal discovery, during legal proceedings, or presented as evidence during trial, and are either public records or are subject to public disclosure according to legal settlement terms and/or a court order. OIDA solicits and receives these publicly disclosed documents via court order, attorneys (plaintiff's attorneys, class action lawyers, state attorneys general), expert witnesses, and PACER (Public Access to Court Electronic Records) downloads.
- Government documents: OIDA may collect records of and reports from formal investigations and hearings related to the opioid industry initiated by the U.S. Government, state governments, or local governmental entities, especially if these records are not easily accessible or preserved elsewhere.
- Records requests: Freedom of Information Act (FOIA) and state public records requests initiated by other individuals or entities.[2]
- Research files: public opioid industry documents collected or contributed by academics, authors, investigative journalists, and others.
- Research and collecting activities carried out by OIDA staff to preserve opioid industry documents from other possible sources, such as those made publicly available on government, news, or industry websites.

In general, OIDA cannot accept document contributions that:

- are outside of its collecting scope as defined in this Policy;
- come with a substantial processing cost without a related funding source;
- are readily available and accessible in other archives;
- are not authorized for public disclosure due to permanent legal restrictions such as a protective order, confidentiality agreement, or other formal settlement terms.

Exceptions to this policy may be made in certain cases. For instance, OIDA may partner with another library or archival organization to collect digital copies of highly-relevant documents held by that institution, in order to make them cross-searchable with OIDA's collections for the benefit of researchers and the public. OIDA may also consider collecting documents which are currently under restriction, if it is likely that the restriction will eventually be lifted and the documents can be made public.

**Funding**

OIDA was created and funded in part through settlements of public interest lawsuits by states. OIDA does not purchase any documents or collections. Funding is dedicated to archival processing and long term-preservation, including file management; creation of metadata;

[2] Due to potential conflicts and resource limitations, OIDA does not independently pursue FOIA requests.

screening and redaction of legally protected information (such as social security numbers); development of subject guides and other resources for users; document storage costs; and data servers and infrastructure to enable free online access to the collections.

As of July 2024, OIDA includes over 3 million publicly available documents and expects to more than double that figure over the next two to three years.

**Document Contributions**

OIDA partners with various organizations, researchers, journalists, attorneys, and others to share and make publicly available digital copies of documents that illuminate the causes, affected parties, and other factors that contributed to the opioid epidemic.

Those providing documents to OIDA agree to grant UCSF, JHU, and OIDA users full permission to download, enhance, describe, excerpt, re-use, and publish online all contributed documents and their contents. OIDA credits the contributing individual or organization in all document description, as appropriate.

OIDA welcomes inquiries regarding contribution of documents via the IDL website: https://www.industrydocumentslibrary.ucsf.edu/about/donate/.

**Deaccessioning and Disposition Policy**

OIDA may remove and deaccession documents or collections determined to be out of the scope of our collecting policy. Examples of documents which may be deaccessioned include documents which are wholly unrelated to activities undertaken by opioid manufacturers, distributors, pharmacies, and associated companies (such as junk mailings or emails solely regarding employee personal matters).

If deaccessioning of documents or collections is necessary, OIDA is guided in this process by archival best practices, including the Society of American Archivists' (SAA) Guidelines for Reappraisal and Deaccessioning; SAA's Core Values Statement and Code of Ethics; and the ACRL Code of Ethics for Special Collections Librarians, established by the Rare Books and Manuscripts Section (RBMS) of the Association of College and Research Libraries (ACRL). OIDA will do its best to adhere to any specifications or wishes provided by the document contributor at the time of accession when considering the disposition of any documents from the collection.

**Take-Down Policy**

*Copyright and Intellectual Property*
The Industry Documents Library and OIDA make every effort to ensure that they have appropriate rights to ingest and provide access to documents and collections. Please contact IDL staff with any questions or concerns regarding the copyright of specific documents, or to make a take-down request. Take-down requests will be acknowledged within ten business days

and reviewed for further action. The IDL may work with UCSF's Office of Legal Affairs to make determinations about copyright and appropriate use.

*Protection of Personal Information*

Most of the documents in OIDA were created as internal records by corporate entities related to the opioid industry. Many of these documents are subject to public disclosure by order of the Court, under the terms of settlement agreements reached in litigation, or have been released through Freedom of Information Act (FOIA) or public records requests. These documents may contain personal information (such as addresses, phone numbers, or social security numbers) related to patients, employees, or other individuals, which may be considered protected data under applicable state and federal law. OIDA takes great care to ensure that any protected information is identified and redacted before documents are made public, while also ensuring that data of crucial relevance to these cases, and to transparency and accountability, remain open.

"Protected information" includes:

- Personally Identifiable Information (PII) such as social security number, driver's license number, or home address;
- Protected Health Information (PHI) such as medical record number, date of birth, or diagnostic image;
- Other sensitive personal information as defined by applicable state and federal privacy laws;
- Information regarding company employees' personal matters unrelated to the company or its products, including but not limited to emails discussing vacation or sick leave, family, or other personal matters.

Information which is NOT redacted:

- Under the document disclosure terms of Mallinckrodt's settlement, "'Confidential personal information' does not include the names of Mallinckrodt's officers, directors, employees, agents, or attorneys."[3]
- Under the document disclosure terms of McKinsey's settlement, "'Confidential personal information' does not include the names of officers, directors, employees, agents, or attorneys of McKinsey, Purdue, Endo, Johnson & Johnson, or Mallinckrodt, or of a government agency."[4]
- Under the document disclosure terms of Teva's settlement, "'Confidential personal information' does not include the names of Teva's officers, directors, employees,

[3] Order Granting Certain Debtors' Motion for Injunctive Relief Pursuant to 11 U.S.C. §105 With Respect to the Voluntary Injunction. In re: Mallinckrodt PLC, et al., v. State of Connecticut, et al. United States Bankruptcy Court for the District of Delaware, Case No. 20-12522, Document 196-1

[4] Assented-To Motion for Entry of Judgment. In re: Commonwealth of Massachusetts v. McKinsey & Company, Inc, United States. Suffolk County Superior Court.

consultants, agents, or attorneys or of prescribers or of officials of a government agency."[5]

- Under the document disclosure terms of Allergan's settlement, "'Confidential personal information' does not include the names of Allergan's officers, directors, employees, consultants, agents, or attorneys or of prescribers or of officials of a government agency."[6]

If protected information which has not been redacted is found in a public document, the following steps are taken:

1. immediately remove the document from public access, pending review;
2. conduct a full review of the document under guidance from UCSF legal and privacy experts;
3. determine if the document does contain protected information and if that information has been inadvertently released;
4. if the document contains protected information, take steps to mediate, including alerting IT Security;
5. determine if:
    a. the document should be redacted and published in redacted form;
    b. the document does not require redaction and can be re-published in its original form;
    c. the document contains wholly personal or protected information and should be removed (deaccessioned) from the archive.
6. Provide a written response and explanation if requested.

Please contact IDL staff with any concerns regarding personal information in the collections. Current contact information can be found at https://www.industrydocumentslibrary.ucsf.edu/help/ask-us/.

**Policy Implementation and Revision Dates**

The OIDA Collection Development Policy was implemented in August 2023 and revised in August 2024. The Policy will be reviewed annually and revised as needed.

**References:**

[5] Final Teva Global Settlement Agreement and Exhibits. August 29, 2023. Retrieved from https://nationalopioidsettlement.com/wp-content/uploads/2023/08/Final-Teva-Global-Settlement-Agreement-and-Exhibits-8.29.23.pdf

[6] Final Allergan Global Settlement Agreement and Exhibits. August 29, 2023. Retrieved from https://nationalopioidsettlement.com/wp-content/uploads/2023/08/Final-Allergan-Settlement-Agreement-8-29-23.pdf

Guidelines for Reappraisal and Deaccessioning, Society of American Archivists, last modified May 2017, https://www2.archivists.org/sites/all/files/GuidelinesForReappraisalDeaccessioning_2017.pdf

Core Values Statement and Code of Ethics, Society of American Archivists, last updated August 2020, https://www2.archivists.org/statements/saa-core-values-statement-and-code-of-ethics

ACRL Code of Ethics for Special Collections Librarians, Rare Books and Manuscripts Section, Association of College and Research Libraries, last updated June 2020, https://rbms.info/standards/code_of_ethics/

**OIDA Archival Appraisal Checklist**

1. What is the provenance of the records? Are the materials from an archival collection, litigation, FOIA request, or something else?
2. Is original order maintained? If archival materials, is original folder order retained? If litigation materials, are Bates numbers present?
3. What is the date range and extent of the collection?
4. What do the records document? What issues, people, companies, or trade associations are most obviously represented?
5. What is the relationship of the records to the current collection?
6. How do the records fit the goals of OIDA's mission?
7. How do the records fit the goals of OIDA's collection policy?
8. Is the information or record duplicated elsewhere in the collection?
9. What is the storage medium? Is the information documented elsewhere in an easier-to-use format?
10. What are the costs of acquiring and preserving the records?
    a. Identify any salient technical issues, such as poor OCR, need for extensive redaction, etc.
    b. Identify document boundary definition needs: do PDF files or pages need to be separated or combined into document-level units?
    c. Determine level of indexing: document-level or page-level? In-house or at vendor? Estimate cost.
11. How do legal guidelines apply to the records? Assess copyright risk: check for reprints/published material, number and identity of potential copyright holders, commercial value, likelihood of receiving significant attention. Can 17 U.S. Code Section 107 (Fair Use) or Section 108 (Reproduction by Libraries and Archives) be applied? Has permission been granted from any holding library or archives?
12. How do records retention schedules apply to the records?
13. What restrictions apply to the records? Assess privacy, confidentiality, and personal safety issues: are there Social Security Numbers, individual postal or personal email addresses, or phone numbers? Is Protected Health Information (PHI) present? Is the source a whistleblower?
14. What archival value (informational, evidential, intrinsic, historical) do the records have?