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ClinicalTrials.gov
Protocol and SAP Upload Instructions

For clinical trials with a Primary Completion Date on or after 1/18/17, the regulations require the Responsible Party to, at the time of results entry, upload a protocol document and, if not included in the protocol, a statistical analysis plan (SAP).

REDACTION

- **From Acrobat Pro, navigate to View>Tools>Protection>"Mark for Redaction"**
- **Select "OK"**
- **Highlight with cursor any text that should be redacted.**
- **Select "Apply Redactions"**
- **Select "Yes"**
- **When finished redacting, select "Remove"**
- **Save file as reduced PDF.**

REMOVING METADATA

- **From Acrobat Pro, navigate to File>Properties**
- **Click "Additional Metadata"**
- **In the "Description" section, clear metadata that should be removed.**
- **Do not alter the "Advanced" section.**
- **Click "OK" and "Save"**

PROTOCOL DOCUMENT REQUIREMENTS

- ✓ IRB-approved document
- ✓ PDF/A Format
- ✓ Inclusion of cover page with IRB-approved Title, NCT #, and IRB approval date
- ✓ Version list of amendments:
  - o That have been approved by the IRB; **AND**
  - o Apply to **all** clinical trial Facility Locations
- ✓ Objective(s), design, and methods.
- ✓ Relevant scientific background and statistical considerations.
- ✓ Redaction of:
  - o Names
  - o Addresses
  - o Other personally identifiable information
  - o Trade secrets
  - o Confidential commercial information
- ✓ Removal of:
  - o Metadata

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Guidance on Protocol and SAP Redaction Practices[1]: Information to Disclose

DISCLOSABLE UNDER THE FREEDOM OF INFORMATION ACT (FOIA)

Information listed to the right is generally considered to be disclosable under the Freedom of Information Act (FOIA) and should, therefore, not be redacted from your protocol document or statistical analysis plan. The list is neither exhaustive nor absolute, but is provided here for general guidance.

- **Summaries of clinical safety and effectiveness data;**
- **Summaries of non-clinical safety and effectiveness data;**
- **Summaries of adverse drug reaction data;**
- **Written discussion or analysis of safety or effectiveness data.**
- **A general description (such as what would typically be included in product labeling) of product functions, mechanics, and/or engineering;**
- **A general description of physical characteristics and performance parameters;**
- **Clinical or preclinical protocols or summaries of protocols;**
- **Statistical protocols and analyses;**
- **Information that is proposed to be included in product labeling, such as indications and usage, dosage and administration, and safety information such as warnings and precautions;**
- **Literature references;**
- **Any other information that has been previously publicly disclosed by the sponsor;**
- **Copies of the sponsor's slides to be presented at an FDA advisory committee meeting;**
- **Guidance documents.**

[1] Disclosure and redaction guidance based on the FDA's 2008 guidance document, "Guidance for Industry Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members."

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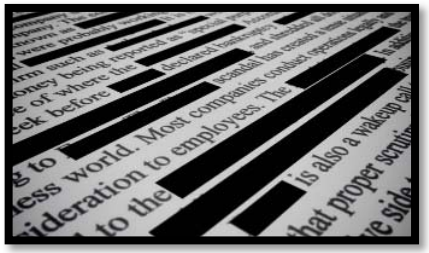

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Guidance on Protocol and SAP Redaction Practices: Information to Redact

EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT (FOIA)

Information listed to the right is generally considered to be exempt from disclosure under the Freedom of Information Act (FOIA). This information should be redacted from the protocol document and, if separate, the statistical analysis plan. The list is neither exhaustive nor absolute, but is provided here for general guidance.

- **Information about product:**
  - **Functions**
  - **Mechanics**
  - **Engineering**
  - **Schematic drawings not in the proposed labeling and not within the scope of the agenda for the FDA Advisory Committee Meeting.**
- **Proprietary physical characteristics and performance parameters not in the proposed labeling and not within the scope of the agenda for the FDA Advisory Committee Meeting.**
- **Manufacturing process information;**
- **Manufacturing quality control information;**
- **Clinical or non-clinical raw data (i.e., FDA considers "raw data" to be a complete data set of case report forms, case report tabulations, or line listings. Data that summarize individual or multiple subject outcomes or results are considered summaries. Summaries may include examples of specific findings.)**
- **Supplier names, customer lists, production costs, inventory information, failure rates of products, production quality control information;**
- **Information for which the release would constitute an unwarranted invasion of personal privacy;**
- **Product formulation information not in the labeling.**