Describe the process and guidelines in place with regard to the retention and destruction of PII.

Identify training and awareness provided to personnel (system owners, managers, operators, contractors, etc.) may access PII.

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

Identify the secondary uses for which the PII will be used.

How many individuals’ PII is in the system?

Indicate the categories of individuals about whom PII is collected, maintained or shared.

For what primary purpose is the PII used?

Does the system collect, maintain, use or share PII?

Identify legal authorities governing information use and disclosure specific to the system and the program.

Does the system have Security Authorization (SA)?

Describe the system and describe the information it will collect, maintain (store), or share, based on the purpose(s) identified in the previous question.

Describe the purpose of the system.

Provide an overview of the system and describe the information it will collect, maintain (store), or share, based on the purpose(s) identified in the previous question.

Does the system include a Website or online application available to and for the use of the public?

Identify the method for individuals to opt-out of the collection or use of their PII. If there is no mechanism to opt-out, explain why.

Date Signed:

In what capacity was the system signed?

The FDA uses the PII in CTS to process and respond to submissions.

Information about devices that are under review, or which were not approved, is not shared. The FDA is made public through the CDRH and FDA Freedom of Information Act (FOIA) Offices.

Requests for Designations, Condition of approvals, Device Nomenclature data, Postmarket Surveillance Studies, Compliance Operation Program Support, and eConsults.

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