

# US Department of Health and Human Services

## Privacy Impact Assessment

**Date Signed:**

09/12/2016

**OPDIV:**

FDA

**Name:**

Administrative Applications: FACTRS and AC Online Nominee Submission

**PIA Unique Identifier:**

P-5753593-831952

**The subject of this PIA is which of the following?**

Minor Application (child)

**Identify the Enterprise Performance Lifecycle Phase of the system.**

Operations and Maintenance

**Is this a FISMA-Reportable system?**

Yes

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

Yes

**Identify the operator.**

Agency

**Is this a new or existing system?**

New

**Does the system have Security Authorization (SA)?**

Yes

**Indicate the following reason(s) for updating this PIA.****Describe the purpose of the system.**

This PIA addresses two systems, the FDA Advisory Committee Tracking and Reporting Systems (FACTRS) and the Advisory Committee Online Nominee Submission system (ACONS). These systems are both related to the operation of FDA Advisory Committees. Advisory Committees are charged with tasks that require meaningful, broad-based participation in forming FDA regulatory policy and disseminating safety and regulatory information to key stakeholders.

ACONS enables individuals to apply to be considered to serve on an Advisory Committee, as that term is defined by the Federal Advisory Committee Act (FACA). Advisory Committees normally include members of the public who serve as special government employees (SGEs). They may be paid or unpaid. They are individuals with expertise or experience that is valuable to a defined goal or task to be completed by a government agency. ACONS facilitates agency consideration of individuals who apply to serve in these roles.

FACTRS is a technical solution enabling tracking and management of the membership and activities of Advisory Committees. FACTRS receives application data from ACONS and serves as a document sharing and work sharing platform for users (who are all FDA employees) involved in assessing applicants for participation in Advisory Committees. Sharing is among FDA employees and no PII is shared from this system outside the FDA. FACTRS can also be used to generate reports on recruitment, appointment, and information gathering activities, when required by FDA executives, Congress, or other oversight body. It is also used to track membership appointments, expirations of appointments, vacancies, meeting dates, meeting-related products such as agendas and meeting minutes, and work products of Advisory Committees.

**Describe the type of information the system will collect, maintain (store), or share.**

ACONS stores the following data fields: name, e-mail address, phone number, education, work and volunteer experience, and any other qualifications relevant to the ability to represent and communicate expertise and/or perspectives. These other qualifications could conceivably include education records or military status.

FACTRS may contain all application materials submitted through ACONS (saved as attached documents) and may additionally contain data concerning committees for which an individual is being considered, general assessments of qualifications, and application status. It may also contain documents created by or in support of Advisory Committees, such as agendas, meeting minutes, notices, and work products.

Neither system requires FDA users to have system-specific logon credentials. FACTRS uses a single-sign on multi-factor authentication scheme, and ACONS pulls data directly into FACTRS and no FDA user/evaluator needs to log on to the system.

**Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.**

ACONS provides users an opportunity to apply for Advisory Committee positions. This information is submitted via a web-enabled application, but the web site does not post any information submitted by applicants.

The centralized FACTRS system supports FDA Advisory Committee business processes related to application assessment, and includes functionality that incorporates records management and automation. FACTRS is a web-based application designed to create and manage meetings and tasks of the Advisory Committees as well as track conflict of interest (COI) and nomination processes.

FDA retrieves information from FACTRS using PII (individuals' names). Individuals may be applicants or accepted FACA members (Special Government Employees, or SGEs). Retrieval is for the purposes of evaluating individuals' applications, assigning accepted individuals to committees or particular tasks, verifying that information held by the FDA is up-to-date and accurate, and reviewing the status of an individual's membership on a FAC.

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

Yes

**Indicate the type of PII that the system will collect or maintain.**

Name

E-Mail Address

Mailing Address

Phone Numbers

Certificates

Education Records

Military Status

Employment Status

Information related to conflicts of interest, including financial or professional interests of the individual

Any other information related to an individual's qualifications to serve on an Advisory Committee

Advisory Committee service information (term of service, previous service, etc.)

Previous volunteer service

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

Employees

Public Citizens

Applicants are public citizens. Accepted applicants are special government employees (SGEs).

Note that in the future, this system may include "patient representatives," but these individuals will not be "patients" of any FDA office or institution.

**How many individuals' PII is in the system?**

500-4,999

**For what primary purpose is the PII used?**

Evaluate candidates for Advisory Committee positions and accept them into those roles; manage membership of committees; track activities and products of Advisory Committees.

**Describe the secondary uses for which the PII will be used.**

None.

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

Federal Food, Drug and Cosmetic Act (21 U.S.C. 371 et seq), as modified by the Food and Drug Administration Amendments Act (FDAAA) of 2007, states at sec. 379d-1(b)(1)(A) that "The Secretary shall (1) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups; seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities, and take into account the advisory committees with the greatest number of vacancies." Recruitment strategies are discussed in section (b)(1)(B), and section (b)(2) notes that the Secretary must evaluate applications by reviewing "the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment." These systems collect the information necessary to conduct these evaluations. Further, the collection and use of much of the information concerning Advisory Committee activities is required by the the Federal Advisory Committee Act (5 U.S.C. Appendix 2), and the Government in the Sunshine Act (5 U.S.C. 552b).

**Are records on the system retrieved by one or more PII data elements?**

Yes

**Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being use to cover the system or identify if a SORN is being developed.**

**Identify the sources of PII in the system.**

Online

**Identify the OMB information collection approval number and expiration date**

The POC is in the process of coordinating with Records Management Staff to determine if an information collection approval number is necessary.

**Is the PII shared with other organizations?**

No

**Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.**

Individuals submit all information themselves at the time of collection via a web-enabled tool. The relevant web page on FDA.gov provides detailed information on what information applicants must submit and the application and evaluation process generally.

**Is the submission of PII by individuals voluntary or mandatory?**

Voluntary

**Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.**

The program itself is voluntary; however, the information is mandatory to appropriately screen potential applicants for the skills and experience necessary to become an Advisory Committee member.

**Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.**

If the agency changes the collection, use, or sharing of PII data in this system, the affected individuals will be notified by the most efficient and effective means available and appropriate to the specific change(s). This may include a notice on the web site, or e-mail notice to the individuals. However, no such changes that would affect the rights or interests of the individuals are anticipated.

**Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.**

Individuals (Advisory Committee members and applicants for Advisory Committee positions who are the subject of records) may exercise the rights available to them under the Privacy Act. The Privacy Act permits information subjects whose records are retained in systems of records to request (i) notification of the existence of, (ii) access to, and/or (ii) amendment of records about themselves. Advisory Committee members may address any such issues by contacting the FDA coordinator of their Advisory Committee; using the FDA Advisory Committee Information Line; or using general FDA contact information. Any such concerns would be reported to appropriate parties which may include the system administrator, the FDA Privacy Office, the Computer Security Incident Response Team, or a Help Desk. Any changes to an individual's name or address would need to be updated using a Standard Form 50 or 52, just as would be the case with other FDA employees, and the data would be updated in FDA's human resources information system.

**Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.**

PII is used transactional to address a specific business function (identifying and appointing Advisory Committee members). It would not represent a benefit to the public or to FDA to maintain PII and update or correct it after it has been used for the intended purpose. However, there is periodic review of an individual's term of service, in that each term lasts two years (as required by FACA) which may then be extended or the individual may ask to serve on another committee. This information is tracked and notices are given by FACTRS.

PII is used transactional to address a specific business function (identifying and appointing FAC members). PII is not used persistently, and no periodic reviews are made. Applicants are responsible for ensuring the information they provide is accurate and relevant; appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199, to protect the PII's availability and integrity.

**Identify who will have access to the PII in the system and the reason why they require access.**

**Users:**

"Users" are FDA employees receiving application materials. Users require full access to systems in order to conduct activities related to selecting members, managing and overseeing Advisory Committees.

**Administrators:**

There are three users with the Office of Information Management that have full administrative access to conduct management and oversight of the information system.

**Developers:**

Developers will not normally have access to PII, but may in the course of maintaining the systems or providing technical assistance.

**Contractors:**

Some developers may be direct contractors and will have access under the same circumstances as developers.

**Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.**

Users who require access to the information system need to have supervisor approval and sign off before access is granted. The user's supervisor will use an account creation form to specify the minimum information system access that is required in order for the user to complete his/her job. The agency reviews the access list for the system on a quarterly basis to review and adjust users' access permissions, and to remove unnecessary accounts from the system.

**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.**

Management establishes roles for individual personnel, with role-based restrictions permitting access only to information that is required for each individual to perform his/her job.

**Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.**

All personnel/users are required to complete FDA's IT Security and Privacy Awareness training at least annually.

**Describe training system users receive (above and beyond general security and privacy awareness training).**

A user manual is available that walks the user through each step and functionality of FACTRS. This is available from a link on the FDA intranet via the Advisory Committee Oversight and Management page. Access to training is restricted through system access control.

All users are instructed on adhering to the HHS Rules of Behavior in the context of their work involving this system. For additional privacy guidance, personnel may contact the agency's privacy office. Privacy program materials are provided to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA.

**Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?**

Yes

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

FACTRS and ACONS records are currently retained under General Records Schedule 26, Temporary Commissions, Boards, Councils and Committees ,” Item 4, “Committee Management Records .” These records include those kept on requests for approval of committee nominees and appointment of nominees. These records are to be destroyed or deleted when they are six years old.

**Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.**

Administrative Safeguards include training and awareness provided for all users; system manuals that advise on the proper use; implementation of Need to Know and minimum necessary principles when awarding access, and others. Technical Safeguards include that PII entered via ACONS is immediately pulled into FACTRS, removed from the public site, and is not accessible to other users of ACONS or fda.gov. FACTRS resides behind the FDA firewalls. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls. More broadly, appropriate controls have been selected from the National Institute of Standards and Technology’s (NIST’s) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

**Identify the publicly-available URL:**

<https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>

Note: web address is a hyperlink.

**Does the website have a posted privacy notice?**

Yes

**Is the privacy policy available in a machine-readable format?**

No

**Does the website use web measurement and customization technology?**

Yes

**Select the type of website measurement and customization technologies is in use and if it is used to collect PII.**

Session Cookies that do not collect PII.

Sessions don't time out

**Does the website have any information or pages directed at children under the age of thirteen?**

No

**Does the website contain links to non- federal government websites external to HHS?**

No

**Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?**

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