
Clinical Pharmacology and Biopharmaceutics

**Flexible Workplace Arrangements Program for OCPB
(FWAP)**

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PURPOSE This MAPP describes the policies and procedures governing the Flexible Workplace Arrangements Program (FWAP) for all components of the Office of Clinical Pharmacology and Biopharmaceutics.

BACKGROUND

- The Flexiplace and Work-at-Home programs have been combined to create the Flexible Workplace Arrangements Program (FWAP). FWAP permits an employee to perform work away from his/her official duty station on a long- or short- term basis. CDER's FWAP policy and procedures are described under MAPP 4657.2. This MAPP describes the policies and procedures for implementing FWAP in all components of the Office of Clinical Pharmacology and Biopharmaceutics (OCPB), as required under MAPP 4657.2.
- Implementing FWAP within OCPB acknowledges the partnership and team work that occur among reviewers in the Offices of Review Management (ORM), New Drug Chemistry (ONDC), and Clinical Pharmacology and Biopharmaceutics. As such, this plan is patterned after and follows most of the provisions set forth in the ORM plan.
- Implementing FWAP within OCPB requires balancing the need to work as a team with the individual needs of employees. The review work of OCPB is highly demanding, requiring multiple applications to be reviewed concurrently under tight deadlines. To

meet these deadlines, the individual reviewers must work well with the ORM team, with opportunities for frequent and direct (often face-to-face) communication. For this reason, CDER has located all members of the review team together in contiguous space. The implementation of FWAP should not undermine the effectiveness and efficiency of this team effort. At the same time, extended periods of uninterrupted time are valuable for allowing reviewers to devote concerted efforts to reviews. Also, working away from one's official duty station can provide other benefits, such as eliminating long commutes, allowing employees to work more productively, or simply improving their quality of life. Employees may also need to work at home for limited periods of time due to temporary physical limitations. Although there are different reasons for participation in FWAP, employees, supervisors, and managers should ensure that implementing this program is not detrimental to the work of the Center. OCPB's FWAP plan represents an effort to achieve a balance.

REFERENCES

FDA's Master Plan - Flexible Workplace Arrangements Program (1994)
MAPP 4657.2, CDER Flexible Workplace Arrangements Program (FWAP)
MAPP 4657.7, CDER Leave & Absence for Hazardous Weather & Other Emergency &
Administrative Situations
MAPP 5000.1, OPS Alternate Work Schedules (AWS)
MAPP 5000.2, OPS Flexible Workplace Arrangements Program (FWAP)
MAPP 5100.1, OCPB Alternative Work Schedules (AWS)

DEFINITIONS

- **Long-term basis:** Employees work specified days away from their official duty station for more than two consecutive workweeks.
- **Short-term basis:** Employees work a specified number of days away from their official duty station for two consecutive workweeks or less; applies to employees who, due to compelling reasons, need to work away from the official work site. Short-term flexible work arrangements may be based on the need to complete special assignments/projects, medical conditions (e.g., illness, injury), or other reasons.
- **Telecommuting (Satellite) Work Centers:** Alternative work sites for employees who travel long distances between their homes and their official duty stations. See FDA's Master Plan for the specific locations of the centers and the facilities available at these locations.

POLICY

1. The Director, OCPB is the approving official for all OCPB FWAP requests.
2. Participation in long-term FWAP agreements is open to employees whose position descriptions include significant work that can reasonably be performed away from the official duty station. Generally, this will apply only to primary reviewers. In addition, it is expected that participants in long-term FWAP agreements will have previously demonstrated their ability to perform work independently and that they have adequate knowledge of applicable regulations and expectations regarding their work to perform that work independently. Supervisors and the approving official will be expected to certify that the above conditions have been met when they approve long-term agreements, and they will be held accountable for ensuring that such conditions remain valid during the term of the long-term FWAP agreement.
3. Employee participation in FWAP is voluntary and may be terminated at any time either at the request of the employee or at the decision of management.
4. All periods of participation in the FWAP, on a long-term and short-term basis, must be approved in advance. Long-term participation requires a FWAP agreement (Attachments B or C of CDER MAPP 4657.2). FWAP agreements may cover a period of no longer than 1 year, and must be renewed at least annually.
5. An employee participating in the FWAP on a long-term basis must work a minimum of four full days each week at the official duty station unless specifically approved to work fewer days at the official duty station by the Director, OCPB on a case-by-case, week-by-week basis. An off-site day that falls on a holiday is counted as an off-site day.
6. An employee participating in the FWAP on a short-term basis is not required to complete a FWAP agreement. However, if the approving official requires it, the immediate supervisor must certify in writing that it is necessary for the work to be performed away from the official duty station. The supervisor may require the employee to submit medical documentation, such as a health care practitioner's statement, if the short-term arrangement is based on a medical condition.
7. Supervisors must ensure that employees working away from the official duty station are readily available by phone, electronic mail, or FAX to management officials, co-workers, and constituents. Employees participating in the FWAP on a long-term basis must ensure that they can report to their official duty station within 3 hours upon request (under normal commuting conditions).
8. Employees participating in the FWAP are expected to attend meetings at the official duty station even when such meetings are scheduled on the employee's day to work at an alternative work site, unless the FWAP is based on medical need. *Failure to do so may*

result in the termination of the employee's participation in the program. In the case of such meetings, the employee may not claim for local travel expenses.

9. The work schedule approved under a FWAP agreement must be observed by the employee. Duty time may not be used for purposes other than official work. Although participation in the FWAP may provide employees more time to accomplish family responsibilities, *the FWAP is not to be used by employees to care for young children or other dependents during the agreed upon scheduled hours of work.*
10. Full-time employees participating in the FWAP may work a maxiflex schedule as follows: Core hours are 9:30 a.m. to 3:30 p.m., Monday through Friday. Flexible time bands for off-site work are between 7:00 a.m. and 9:30 a.m. (start time), and between 3:30 p.m. and 6:00 p.m. (end time). The employee's schedule must be consistent with the nature of the work being performed and the frequency of communication necessary with those at the official work site or with work contacts in other locations. With prior office-level approval, credit time may be earned by eligible employees during the flexible bands. Part-time employees participating in the FWAP must report to work at the time designated in their FWAP agreement.
11. In very exceptional cases, off-site credit time, overtime or compensatory time for special projects or deadlines may be approved in advance by the Office Director. SES, Commissioned Corps, and Title 38 employees are ineligible to earn overtime.
12. Credit time may be earned off site on weekends consistent with the terms set forth in the OCPB AWS MAPP, 5100.1. Under certain circumstances, such as a user fee deadline, eligible employees may substitute a Saturday or Sunday for their off-site workday by earning up to 8 hours. This request must be approved in advance by the employee's Office Director, and employees must account for the time claimed as work.
13. No on-going work schedule that includes a break of more than one hour may be established for an employee participating in the FWAP.
14. On an ad-hoc basis, an employee may switch their scheduled off-site days with prior supervisory approval. If weather conditions are hazardous, approval for switching an approved FWAP day may be granted if requested at the start of the day.
15. Employees participating in the FWAP are not expected to work if the government is closed for the day due to hazardous weather. However, if employees are dismissed early (and the government is not closed) due to hazardous weather, an employee working on FWAP that day is expected to complete his/her tour of duty, unless the lack of contact with dismissed employees makes it impossible to continue working.
16. All pertinent time and attendance, leave, and pay regulations must be observed by employees and managers when an employee participates in the FWAP, including established sign-in/sign-out procedures and documentation.

17. Suitable training/orientation is required and must be conducted for employees approved for participation in the FWAP and their supervisors before an employee begins long-term participation in the FWAP.
18. The Director, Division of Commissioned Personnel, must be notified whenever approval is given to a Commissioned Officer to participate in the FWAP on a long-term basis. The Center's FWAP Coordinator must send a copy of the approved work agreement to the Division of Commissioned Personnel to be recorded as a supplement to the existing billet and to be placed in the officer's official personnel file.

RESPONSIBILITIES

- **Director, OCPB:**

1. Review the OCPB FWAP plan at least annually and decide whether to continue, modify, or terminate it. Any changes will be incorporated in a revised FWAP MAPP.
2. Approve/disapprove individual employee participation in the FWAP.
3. Approve/disapprove exceptions to the OCPB FWAP plan.
4. Be accountable for ensuring that long-term FWAP participants have adequate knowledge of applicable regulations and expectations regarding their work to perform that work independently. Determine, on a continual basis, that the work quality and performance of the employees continue to meet this standard.
5. Determine on a continual basis if the work requirements of certain positions preclude employees in those positions from participating in the FWAP.
6. Approve/disapprove modifications to the terms of employee participation in the FWAP or terminate the participation as necessary when it is in the interest of the Agency/Center.
7. Forward approved agreements to the Center's FWAP Coordinator for maintenance and record-keeping purposes.

- **Division Directors:**

1. Adopt OCPB's plan and distribute to all employees in the Division.
2. Determine on a continual basis if the work requirements of certain positions preclude employees in those positions from participating in the FWAP.

3. Be accountable for ensuring that long-term FWAP participants have adequate knowledge of applicable regulations and expectations regarding their work to perform that work independently. Determine on a continual basis that the work quality and performance of the employees continue to meet this standard. Such determination shall be documented in writing, on an annual basis, to the approving official. If such a determination cannot be made, participation by the employee shall be terminated.
4. Certify in writing (if required by the approving official) that it is necessary for an employee to perform work away from official work site on a short-term basis.
5. Emphasize that the FWAP is *not* to be used to care for young children or other dependents during the agreed upon scheduled hours of work.
6. Determine timekeeping mechanism to be used by participants (e.g., employee logs in and out via e-mail or phone).
7. Inform timekeeper of employees participating in FWAP, and of any official changes made to work agreements.
8. Review and sign the FWAP agreement and forward to the FWAP Coordinator for review.

- **Center FWAP Coordinator in the Division of Management Services:**

1. Advise supervisors and employees concerning the implementation of the FWAP.
2. Disseminate FWAP materials and information.
3. Ensure that employees submit requests to participate in the FWAP (if required).
4. Review agreements for adherence to pertinent laws, regulations, and policies, including hours of work, pay, and leave before forwarding to approving official.
5. Forward agreements to the approving official.
6. Maintain appropriate documentation concerning program participation (e.g., signed agreements, data for annual reports).
7. Handle day-to-day responsibility and accountability for the program. This includes ensuring that the agreements are completed in a timely manner and are in conformance with applicable rules and regulations, appropriate approvals are obtained, employees and their supervisors are trained **prior** to participation in the program.

8. Provide appropriate training for employees participating in the FWAP and their supervisors.
 9. Arrange, through Division of Compensation, Benefits, and Training (DCBT), employee use of satellite work centers.
 10. Submit required data regarding employee participation to DCBT no later than December 30 each year.
 11. Sign each agreement.
- **Employees:**
 1. Discuss participation in the FWAP or modifications to a FWAP agreement with their Division Director.
 2. Complete and submit to their Division Director a FWAP agreement for approval/nonapproval by the Director, OCPB, if requesting long-term participation.
 3. Accurately and personally record starting time and ending times using the approved timekeeping mechanism.
 4. Submit to their Division Director written requests for exceptions to the OCPB FWAP plan for approval/nonapproval by the Director, OCPB.
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PROCEDURES

- Employee will discuss participation in FWAP with his/her Division Director.
- Division Director and employee will attend a training session with the Center FWAP Coordinator to discuss Agency/Center policies, procedures, work agreements, questions/concerns (if not previously trained).
- Employee will complete and submit the appropriate FWAP agreement (civilian or Commissioned Corps) to Division Director.
- Division Director will review agreement for completeness, sign the agreement indicating initial approval, and forward to the CDER FWAP Coordinator for review.
- CDER FWAP Coordinator will review the agreement and forward it to the Office Director, OCPB.

- Director, OCPB will approve/disapprove the agreement and return it to the CDER FWAP Coordinator.
 - The CDER FWAP Coordinator will maintain a record of all participants and provide any requested information to the Agency and/or Center management.
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EFFECTIVE DATE

This guide is effective upon date of publication