Office of Management and Budget (OMB) Approval Process

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Federal CCF

- http://edocket.access.gpo.gov/2010/pdf/2010-17400.pdf

OMB Notice of Action (NOA) 2010 Federal CCF

- OMB Control #: 0930-0158
- Expiration Date: 08/31/2013
- A sample of the 2010 Federal CCF is available on the
  - SAMHSA website:http://www.workplace.samhsa.gov/
  - OMB website: http://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201007-0930-002&icID=193835

OMB Condition of Approval

- Federal CCF from OMB
- Approved consistent with the following terms of clearance:
  - Previous terms of clearance (Prior to the next approval of this package, the Agency shall provide a progress update on adoption of electronic forms in an effort to reduce burden. SAMHSA is encouraged to explore ways to convert the Federal Drug Testing Custody and Control Form (Federal CCF) into an electronic form.) remain in effect.

OMB Clearance

- The process that an agency follows to ensure compliance with the Paperwork Reduction Act (PRA) of 1995
- P.L. 104-13; 44 USC Part 35
- Implementing Regulations – 5 CFR Part 1320

Objectives of the PRA

- Minimize burden on respondents
- Minimize cost to Federal government
- Maximize quality and utility of information
- Ensure that all applicable laws on privacy and confidentiality are followed
- Allow maximum opportunity for public comment

Information Collection that Require OMB Approval

- Survey that ask the same questions of 10 or more people
- Evaluations that contain, standardized assessments or other similar activities
- Reporting, recordkeeping and disclosure requirements in regulations
- Guidance documents

Government Paperwork Elimination Act (GPEA)

- (OMB) provides procedures and guidance to implement the GPEA of October 21, 1998.
- GPEA requires Federal agencies, by October 21, 2003, to allow individuals or entities that deal with the agencies the option to submit information or transact and maintain records with the agency electronically, when practicable
- The Act specifically states that electronic records and their related electronic signatures are not to be denied legal effect, validity, or enforceability merely because they are in electronic form
- Encourages Federal government use of a range of electronic signature alternatives.

HHS Electronic Document Policy

- FDA:
  - 21 (CFR), Part 11 (62 FR 13430)
    - Criteria under which FDA would consider electronic signature to be equivalent to full handwritten signatures
- Office of the Secretary for HHS:
  - 45 (CFR), Part 160,162,164 (68 FR 8334)
    - Adopt national standards for safeguards to protect the confidentiality, integrity, and availability of electronic-protected health information

Characteristics of Trustworthy Records

- Reliability
- Authenticity
- Integrity
- Usability

SAMHSA's Objective

- SAMHSA will seek public comment specifically on the standards to be established concerning:
  - electronic signature
  - non-repudiation agreement for digital signatures
  - third party software for managing Federal CCF information
  - unique specimen identification number
  - the legally-binding equivalent of traditional hand-written signatures in a forensic arena
  - the security data transmission over telecommunications systems/networks
  - the integrity of document content

The OMB Clearance Process at SAMHSA

Getting Started

- Project Officer makes contact with the SAMHSA Reports Clearance Officer 9 months before OMB approval
- Project Officer and SAMHSA Reports Clearance Officer work together to develop the following:
  - 60-Day *Federal Register* Notice (1st Notice) – Allows the public 60 days to comment on the proposed data collection instruments
  - Data instruments (e.g., forms (Federal CCF) , data elements)
  - Supporting Statement
  - Administrator's memo – Approval to publish the 60 – Day Notice in the *Federal Register*

After the 60 Day Comment Period

- Submit the OMB package for SAMHSA clearance including:
  - Supporting Statements, data instruments, response to public comments, and other attachments
  - 30 – Day *Federal Register* Notice(2nd Notice)
  - Administrator's memo (approval to publish the 30 – day Notice in the *Federal Register* and to submit the clearance package to OMB)

Submitting the OMB Package

- SAMHSA's Reports Clearance Officer publishes 30 – Day *Federal Regist*er Notice
- Once the Notice has published – OMB package is submitted to HHS

HHS Review

- Once HHS reviews and approves the OMB package – they will submit it to OMB
- This could take up to 2 weeks

OMB Review

- OMB has 60 – days to act on a request once it has been logged into their system
- OMB can send questions, comments and /or clarifications

OMB Actions

- Regular Approval – up to 3 years
- Emergency Approval – up to 6 months
- Disapprove
- Withdrawal and resubmit

SAMHSA's Timeline: Months before OMB Approval

(9 months)	(8 months)	(7 months)	(6 months)	(6 months)	(3 months)	(2 months)	(5 months)	
Project Officer meets with SAMHSA Reports Clearance Officer	Draft 60-day Notice: Include data instruments, supporting statement, and Admin. memo- Reviewed and approved by SAMHSA's Reports Clearance Officer	60 -day Notice: Clear through SAMHSA Office Center, (OAS, Exec Sec, OPS)	Publish 60-day Federal Register Notice	Project Officer develops the other attachments to the supporting statements . Reviewed and approved by SAMHSA 's Reports Clearance Officer	SAMHSA Clearance Officer will develop the 30-day Federal Register Notice and Admin. memo	OMB Package Clear through the SAMHSA Office Center (OAS, Exec Sec, OA, OPS)	Publish 30-day Federal Register Notice	SAMHSA Submits OMB package to HHS

HHS and OMB Timeline
Months before OMB Approval

(3.5 months)	(3.5 months)	(3 months)	(3 months)	(1 month)	
OMB package is submitted to HHS Desk Officer – Reviewed and approved	OMB package is submitted to HHS Reports Clearance Officer – Reviewed and approved	HHS Reports Clearance Officer will submit the clearance package to OMB	OMB 60 – day review period – No less than 30 days and no more than 60 days	OMB follows-up with questions and comments if any?	OMB acts on the request and issues a Notice of Action (NOA)