



# Navigating the Office and Management and Budget (OMB) Fast Track Clearance “aka” Fast Track 101

NIH Evaluation Special Interest Group  
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October 10, 2012

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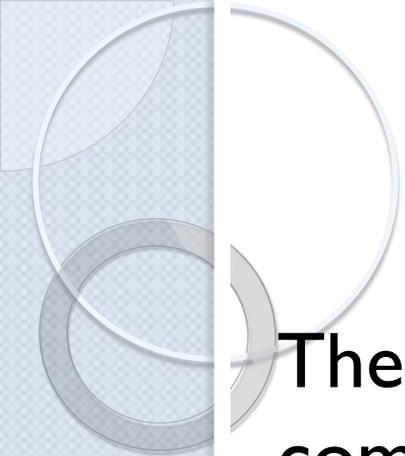
# Agenda

- Overview of the Paperwork Reduction Act
- Overview of Generic Clearances
  - Regular Clearance
  - Fast Track Generic Clearance
- Overview of Fast Track Generic Clearance
- Applying for a Fast Track Clearance
  - Full Clearance Request
  - Sub-Study/Generic IC Clearance Request
- Lessons Learned NCI
- Questions and Answers



# NIH Fast Track Process

## Overview of the Paperwork Reduction Act Process



# Background of Paperwork Reduction Act (PRA)

The PRA began as a response to increased complaints from small business about duplicate and lengthy surveys

- 1940 – Federal Reports Act granted Office of Management and Budget (OMB) authority to approve Information Collections (ICs)
- 1980 – Congress passed the Paperwork Reduction Act (PRA) 5 CFR 1320; The PRA also created the Office of the Chief Information Officer (CIO) and the Office of Regulatory and Information Affairs (OIRA)
- 1995 – Paperwork Reduction Act reissued

# What is PRA Clearance?

PRA Clearance *aka* OMB clearance is the term used to describe the process of seeking the **required** approval from the Office of Management and Budget (OMB) to conduct federally sponsored data collection. The Paperwork Reduction Act of 1995 (PRA) grants OMB the authority to review and approve standardized federally sponsored data collections involving 10 or more respondents. The implementing regulations for the PRA can be found in 5 CFR 1320.

- Agencies **are not** to conduct or sponsor the collection of information unless it has been approved by OMB.
- The Office of Information and Regulatory Affairs (OIRA) is the OMB office responsible for the review and approval of “information collections.”



# Purpose of the PRA Clearance

- Reduce/minimize the paperwork burden the government places on the public.
- Maximize and improve the quality and use of Federal information.
- Use information technology to improve performance of agency missions, including the reduction of information collection burdens on the public.
- Increase program efficiency and effectiveness.
- Minimize the cost to the government to create, collect, use, disseminate, and dispose of information.
- Improve the integrity, quality, and utility of information to all users within and outside the Federal government.
- Ensure proper Privacy and Confidentiality safeguards for data collections that collect personal identifiable information (PII)

# Type of Data Collections that can Require PRA Clearance

## PRA- Types of Data:

- HHS collects data that are voluntary, mandatory, and/or required to receive benefits.

## PRA Data Collection Instruments:

- NIH collects information from the public via the following instruments/mechanisms including but not limited to:

Questionnaires, surveys, applications, surveillance, research, contracts, cooperative agreements, grants\*, policy statements, plans, rules, regulations, posting, notifications, labeling or similar disclosure requirements, focus groups, websites, circulars, directive, instructions, and bulletins, planning requirements, interviews (in-person, web, phone), standard questionnaires used to monitor compliance with agency requirements, any other technique or technological methods used to monitor compliance, third party reporting and recordkeeping requirements, focus group of telephone scripts and/or guides.

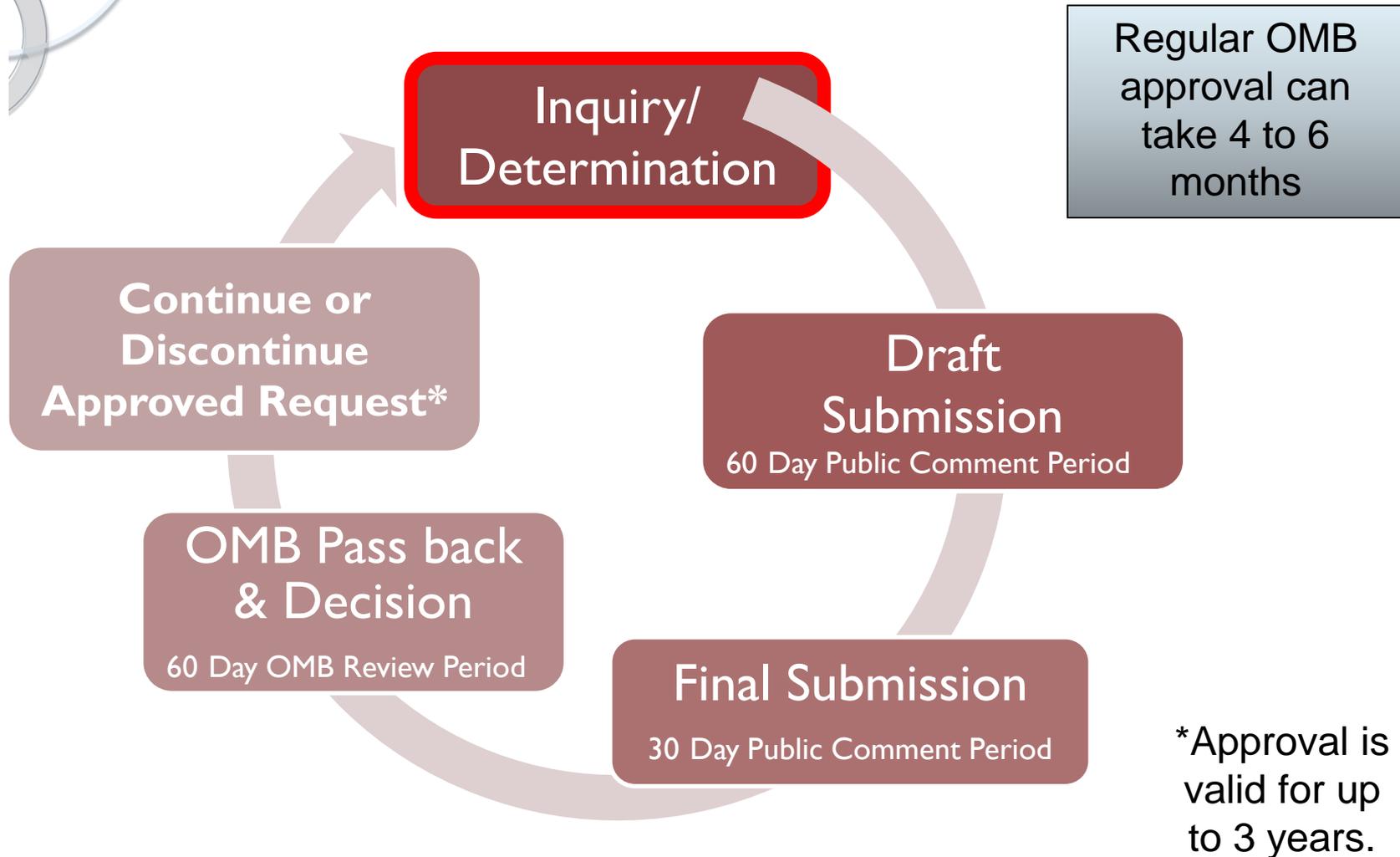
*\* In rare cases, grants can require clearance.*

## PRA Data Usage:

- Federal data is used to in variety for both long term and short term goals. This includes but limited to:

Program planning, program evaluation, policy development, general enforcement, application to qualify applicants for receipt of benefits and/or funds, interagency agreements, industry compliance, Reports to Congress, regulatory/legislative obligations, directives, health care prevention program, program development, child support enforcement, voluntary/mandatory surveillance, tracking, monitoring, customer satisfaction, public/private projects, etc.

# PRA Submission Cycle

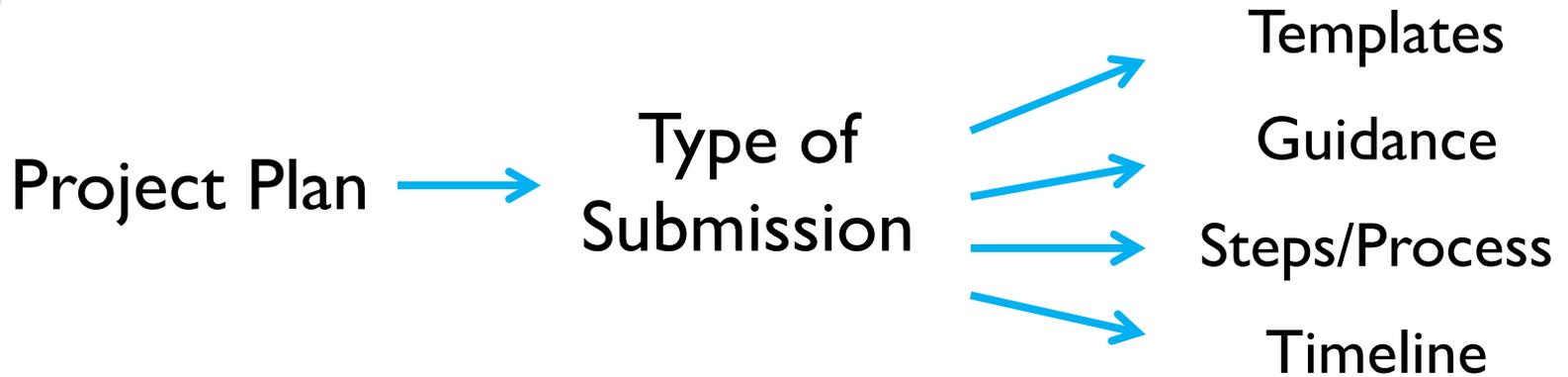




# NIH Fast Track Process

## Overview of Generic Clearances

# Types of PRA Clearance Requests



## Types of Submissions:

- **Generic Clearance (Regular and Fast-Track)**
- New (Full Generic and Full Regular)
- Revisions
- Extensions
- Reinstatement (With or without change)
- Violations of currently approved clearances
- “Bootlegs” (Existing data collections without OMB No.)
- Emergency (Extensions and Approvals)



# What is a Generic Clearance?

- A plan for conducting more than one collection of information using very similar methods.
- Considered only when the agency is able to demonstrate that there is a need for multiple, similar collections, but the specifics of each collection cannot be determined until shortly before the data are to be collected.
- OMB currently recognizes two types of generic clearances: **Regular and Fast Track**

# What Collections are/are not Covered under a Generic Clearance?

In general, currently, the only projects OMB approves for generic clearance are:

- Simple customer satisfaction surveys where the results will be used for internal NIH purposes only, and
- Studies concerning formative and cognitive research, needs assessments, feasibility studies, and in limited instances process evaluations.

Projects that OMB will NOT approve for generic clearance (regular or fast track) include:

- Most evaluations , and
- Scope of data collection efforts are unknown

# Processing Generic Clearances

OMB approves all Generic Clearances via a 2-step process:

**Step One:** Approval of overall request (aka) Umbrella/Parent Request.

- General approach and methodology approved
- Survey methods, concept, etc and burden are submitted and approval is given for a 3-year period.

*Regular Gen. 4-6 months vs. Fast-track Gen 6-8 weeks*

**Step Two:** Approval of the specific generic sub-studies under the overall request. This step can take 1-3 months from the time the specific request is created and submitted to the IC PRA contact through to its approval.

*Regular sub-study 1-3 months vs. Fast-track Sub-study 2-3 weeks*



# Regular Generic Clearance Sub-study Timeline

- **Step One:** Package created by PI. Includes: cover memo or mini-supporting statement, generic clearance form, survey instruments and any additional supporting documents (invitation letters, flyers, scripts, etc.)
- **Step Two:** Program PI or IC PRA contact sends package to PCB for review
- **Step Three:** PCB reviews within 5 to 10 business days
- **Step Four:** PCB submits final request into ICRAS (HHS PRA Database)
- **Step Five:** HHS reviews in 2-3 days
- **Step Six :** OMB reviews within 1 month
- **Step Six:** OMB responds to PCB with an action
- **Step Seven:** When approved the clearance must have the same OMB number and expiration date as the original “umbrella/parent” approval.



# NIH Fast Track Process

## The Fast Track Generic Clearance Process

# What is a Fast Track Request?

- A Fast Track (FT) request is a type of generic clearance request. The Fast Track clearance process is designed for a wide range of information collections that focus on the awareness, understanding, attitudes, preferences, or experiences of customers or other stakeholders (e.g., delivery partners, co-regulators, and potential customers) relating to existing or future services, products, or communication materials.
- If the information collection meets the requirements as approved by OMB/OIRA, the program can submit a request for OMB approval for a Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (the formal name for the Fast Track clearances). It is as simple as completing a short form (found on PCB website) once your clearance has been established and submit the collection to OIRA for approval.



# What is a Fast Track Request?

Within five business days of OIRA's receipt of the submission, OIRA will raise with your agency any questions, concerns, or issues that OIRA has identified with the submission. If OIRA does not respond within the 5 business days, then OIRA will notify your agency that OIRA has approved the collection, and your agency may proceed with the collection under the OMB-issued control number for the approved Fast Track generic clearance.



# What Types of Activities are Covered by the Fast Track Process?

As a general matter, the following kinds of collections fall under the Fast Track Process:

- a. Comment cards or complaint forms;
- b. Focus groups;
- c. One-time or panel discussion groups;
- d. Moderated, un-moderated, in-person, and/or remote-usability studies;
- e. Testing of a survey or other collection to refine questions;
- f. Post-transaction customer surveys (e.g., by call centers);
- g. On-line surveys; and
- h. Customer satisfaction qualitative surveys (e.g., those designed to detect early warning signs of dissatisfaction with agency service delivery).

# What Kinds of Collections are Generally **NOT** eligible for the Fast Track Process?

Examples of collections that would generally **not** fall under the Fast Track Process are:

- (a) surveys that require statistical rigor because they will be used for making significant policy or resource allocation decisions;
- (b) collections whose results are intended to be published;
- (c) collections that impose significant burden on respondents or significant costs on the Government;
- (d) collections that are on potentially controversial topics or that raise issues of significant concern to other agencies;
- (e) collections that are intended for the purpose of basic research and that do not directly benefit the agency's customer service delivery; and
- (f) collections that will be used for program evaluation and performance measurement purposes.



# Processing an IC Specific Fast Track Generic Clearance

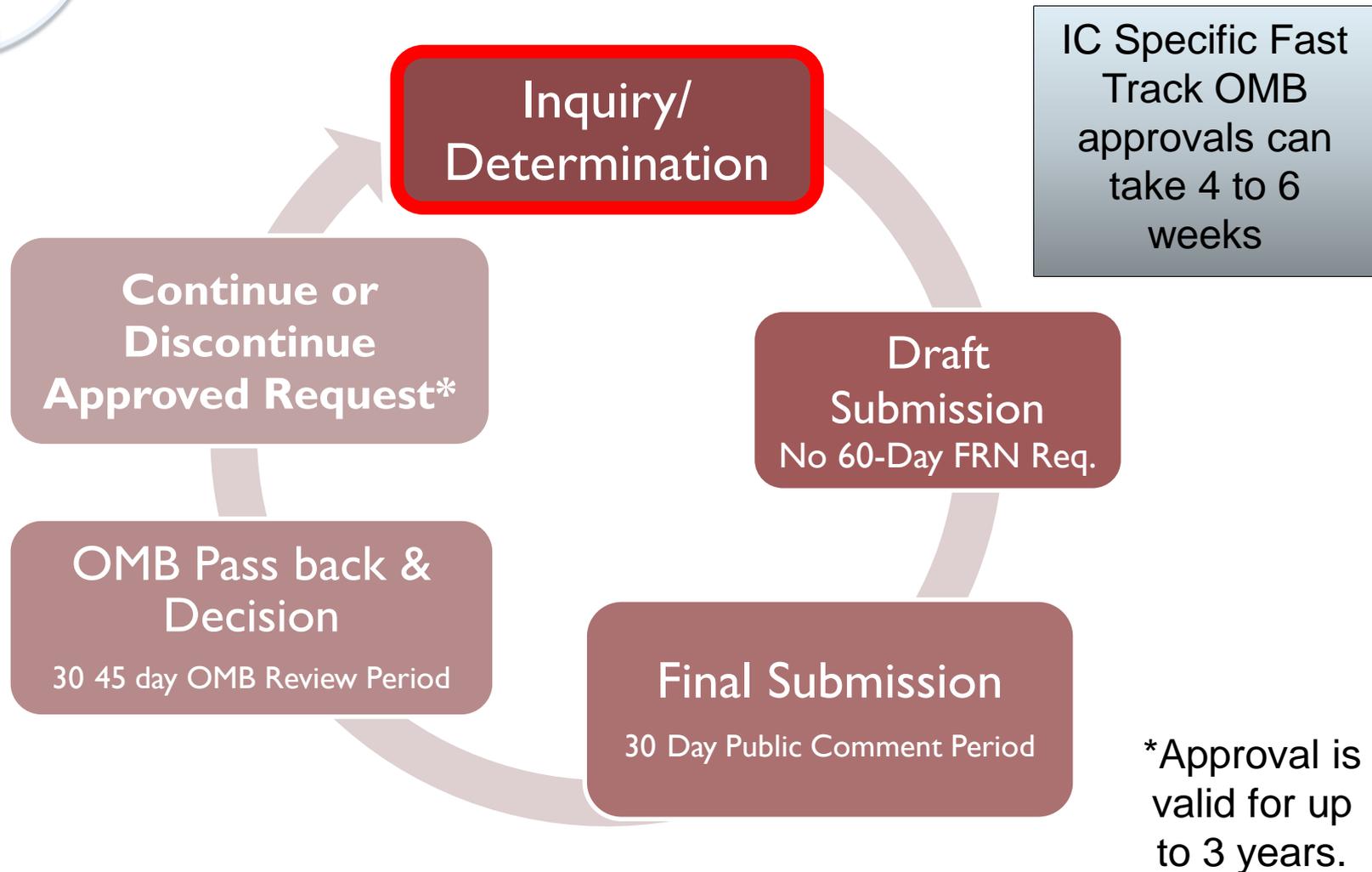
In order to submit using this mechanism, please make sure what you propose fits the justification explained in the approved supporting statement. If it does, please submit the Fast Track generic request template along with the survey instrument, focus group guidance, interview scripts, etc. and any other supporting materials ( i.e. consent forms (if applicable), invitation and thank you letters/email, brochures etc.) for OMB review and action.



## Processing an IC Specific Fast Track Generic Clearance (Con't)

- Although similar to a regular submission, the fast track request process has been streamlined.
- The 60-day FRN is already published by OMB.
- Both the 30-day FRN and the supporting statements are easy to fill out forms. The PI/IC only fills out the highlighted sections.
- OMB normally approves shortly after the 30-day public comment period.

# Initial IC Specific Fast Track Clearances PRA Submission Cycle



# Sub-study Submission Materials

## Regular -

- Mini-Supporting Statement OR
- Justification Memo

## Fast Track –

- Two-page form with minimal text

## Checklist for all Generic Sub-studies

- Include all Final Instruments, Scripts, Emails, Letters, etc.
- IRB/OHSRP review is included
- Do not use “Confidential,” instead use secure or private
- Screenshots **must be** included if electronic
- Justify Incentives
- Race/Ethnicity questions must be in the format of Directive 15.

# “Fast Track” Generic Clearance Sub-study Timeline

- **Step One:** Package created by PI. Includes: template, survey instrument, and any additional supporting documents (invitation letters, flyers, scripts, etc.)
- **Step Two:** PI/IC sends package to PCB for review
- **Step Three:** PCB reviews within 3 to 5 business days.
- **Step Four:** PCB submits final request into ICRAS (HHS PRA Database)
- **Step Five:** HHS reviews in 1-2 days
- **Step Six :** OMB reviews and approves on or before 5 days of receiving request.
- **Step Six:** OMB responds to PCB with an action
- **Step Seven:** When approved the clearance must have the same OMB number and expiration date as the original approval.



# NIH –Wide Fast Track Generic Clearance (OMB # 0925-0648)

The Project Clearance Branch has obtained an NIH Wide fast-track generic clearance. This clearance can be used by ICs and OD offices who do not have plans for more than a few submissions per year, otherwise the I/C can obtain their own fast track clearance. We have several ICs offices that have obtained IC specific FT clearances.

ICs that currently have Fast Track Clearances include: (NCI) 0925-0642; (NICHD) 0925-0643; (NIMH) 0925-0650; (NINR) 0925-0653; and (NIDA) 0925-0655.

# Differences: Regular v. Fast Track

- Content, scope & purpose
  - **Regular** - challenge.gov/contest, theories testing, formative research, pilot household interviewing, forms, or testing survey methodology
  - **Either** - customer satisfaction survey
  - **Fast Track** - confirm content, scope and purpose fit within Fast Track guidelines
- Incentives, if used, then amount?
  - **Regular** - no hard guidelines, but often questioned. Justified on a case by case basis
  - **Fast Track** - a limit on the amount of incentive
    - In the case of in-person cognitive laboratory and usability studies, up to \$40 may be provided as an incentive.
    - For in-person focus groups, an incentive up to \$75 may be provided.

# Additional PRA/OMB Resources

## NIH Project Clearance Branch

[http://odoerdb2-1.od.nih.gov/nih/policies/project\\_clearance/pcb.htm](http://odoerdb2-1.od.nih.gov/nih/policies/project_clearance/pcb.htm)

## New Fast Track Process Memo (Guidance Memo) 2011

[http://nih-extramural-intranet.od.nih.gov/nih/policies/project\\_clearance/omb\\_memo\\_061511.pdf](http://nih-extramural-intranet.od.nih.gov/nih/policies/project_clearance/omb_memo_061511.pdf)

## PRA/OMB Guidance for Generic Clearances 2010

[http://www.whitehouse.gov/sites/default/files/omb/assets/inforg/PRA\\_Gen\\_I\\_CRs\\_5-28-2010.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/inforg/PRA_Gen_I_CRs_5-28-2010.pdf)



# Lessons Learned & PRA-OMB Questions?