Supporting Statement A

for

electronic Prior Approval Submission System (ePASS)

National Heart, Lung, and Blood Institute
Division of Extramural Activities
Office of Grants Management

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Table of contents

A.1 Circumstances Making the Collection of Information Necessary

The National Heart, Lung, and Blood Institute (NHLBI) is planning to develop an information system that will support the electronic submission and tracking of certain requests that are submitted in accordance with existing NIH Prior Approval policies.

The National Institutes of Health (NIH) is the leading supporter of biomedical research in the world. Most of this research is performed by institutions outside of NIH in response to grant or contract applications that are awarded by NIH grants and contracts offices. At the time of submission the applicant assures and certifies to the Federal Government full compliance with all applicable Federal laws, regulations and policies. The policies and procedures that are generally applicable to NIH grants are set forth in the NIH Grants Policy Statement. Section 8.1.2 *Prior Approval Requirements* is the area of policy most relevant to this request for OMB clearance to develop an electronic system that will support an electronic business model for submitting prior approval requests.

Recipients of NIH awards are allowed a certain degree of latitude to make adjustments to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities. If NIH approval is required, it must be requested of - and obtained in writing from - the awarding Institute or Center's Grants Management Officer (GMO) in advance of the change or obligation of funds. The NHLBI is planning to develop an electronic system that will receive and track the business process for these requests. The Authorized Organizational Representative (AOR) initiates the request to NIH, thus making the collection of this information necessary.

The burden on both the external AOR and internal NIH staff to request, monitor, and respond to prior approvals is not insignificant. Annually, the 24 NIH institutes and centers (ICs) with funding authority award over 65,000 grants across all funding mechanisms. It is estimated that approximately 20% of grant awards will request some type of prior approval in a year. The third largest institute at NIH, the National Heart, Lung, and Blood Institute (NHLBI), awarded over 4700 grants in FY 2013 and is seeking OMB clearance to develop a portal, ePASS (electronic Prior Approval Submission System), that will support an electronic business process for the submission of prior approval requests. It is anticipated that ePASS will be fully integrated by eRA for use by all NIH Institutes and Centers in the future. The portal would not be used to initiate questions to the grantees, nor is it collecting or soliciting information from the public or our stakeholders.

A.2 Purpose and Use of the Information Collection

Administrative officials are already submitting – and NIH is already collecting – information related to prior approval requests via e-mail or hard copy letters. These requests would now be collected and tracked in ePASS in electronic format specific to the type of prior approval being requested. The grantee will initiate a request for a certain action as required by NIH policy: use of unobligated balances/carryover, change of principal investigator, change of effort, Training Grant (NRSA) waivers, significant rebudgeting, additional no cost extensions, and change of scope. These are all prior approvals as required by the NIH Grants Policy Statement as referenced earlier. (In addition, the NHLBI plans to use ePASS for requests to support other pre-submission approvals required by NIH policy, such as requests to submit an R13 Conference Grant application or an application with direct costs greater than $500K.) Each type of request requires specific points to be addressed as part of the justification in order to generate a review and response from NIH. The template provided by ePASS along with links to the relevant NIH policies will ensure that all specific points are addressed and documented in the official grant file.

A.3 Use of Information Technology and Burden Reduction

All information is submitted via the internet, tracked in ePASS, and automatically forwarded to the official grant file for documentation of the action. The system will ensure that authorized individuals at the recipient organization are submitting requests and that the appropriate NIH staff is receiving the requests. Both internal and external authorized users will be able to track the status and history of requests.

There will be significant security procedures in place for the use of ePASS. Use of the system will require NIH Commons credentials for the AORs (see template in appendix) and NIH network credentials for appropriate federal staff. The request information submitted to NIH will be maintained on protected NIH servers as is other eRA grant information and will be visible as appropriate to the users for tracking purposes. As with other NIH processes that have transitioned from paper to electronic (such as grants applications and requests for change of recipient institution), this method of collection is

considered to be the least burdensome to the recipient and the least burdensome to NIH personnel who will receive, track, and review the requests. A Privacy Impact Assessment was completed for the database and it included in this clearance package.

A.4 Efforts to Identify Duplication and Use of Similar Information

Staff at NHLBI examined institute and NIH data sources to determine if existing systems were available to provide the function proposed for ePASS and none were identified. Since ePASS will replace the current e-mail and paper ways in which the recipient submits these requests, there will be no duplication or similar use of information.

A.5 Impact on Small Businesses or Other Small Entities

Only small businesses that are conducting research on funded NIH grants would potentially need a request for Prior Approval. The procedure and the burden associated with Prior Approval requests for small businesses that are conducting research would be the same as for other research organizations. The electronic template-driven process with links to the associated NIH policies should streamline the experience for small businesses or other inexperienced organization. Any negative impact on small businesses or other small entities is anticipated to be negligible.

A.6 Consequences of Collecting the Information Less Frequently

The information collected with the on-line template is a onetime collection associated with a specific Prior Approval request for an individual research project. Prior Approval requests are submitted as necessary in order to fulfill compliance requirements. There are no associated deadlines, although requests are generally made during an active project period.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances related to the electronic Prior Approval requests.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

An announcement was placed in the Federal Register, Document Number 2014-27762, November 24, 2014, Page 69865 for public comment on this data collection system, thereby providing the research community with the opportunity to provide input into the proposed ePASS system. One comment was received (Attachment 2) which was supportive and additional screenshots (Attachment 1) were provided to further demonstrate the grantee side of the ePASS portal.

A.9 Explanation of Any Payment of Gift to Respondents

Not applicable; we do not pay applicants to submit a Prior Approval request.

A.10 Assurance of Confidentiality Provided to Respondents

The legal authority to collect this information is granted under 42 U.S.C Sections 232, 281 and 285 of the Public Health Service Act. This package has been reviewed and has been determined that the Privacy Act will apply, please see Attachment 3. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0036, (http://oma.od.nih.gov/public/ms/privacy/pafiles/0036.htm) covering "Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH." The NIH System of Record Notice was previously published in the Federal register on September 26, 2002, Volume 67, No 187, page 60742.

A.11 Justification for Sensitive Questions

No sensitive questions will be asked and no Personally Identifiable Information (PII) will be collected.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

OMB approval is requested for 3 years. There are no costs to respondents other than their time.

The total estimated annualized burden hours are 470.

A.12 – 1 ESTIMATES OF HOUR BURDEN

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Hour Burden
NHLBI Grantees	940	1	30/60	470
Totals	940			470

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

Estimates are taken from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes291069.htm). Respondents can range from Physicians to Administrative Assistants.

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondents	Hourly Wage Rate	Respondent Cost
NHLBI Recipients (AORs)	940	1	30/60	$40	$37,600

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record

A.13 - 1 Estimate of Other Total Cost to Develop the Electronic Prior Approval Submission System (ePASS)

Capital/Start-up Cost for ePASS	Amount	Operational/Maintenance and Purchase Components	Amount
Process Leaning Activities	37,000	Trouble-shooting and monitoring fees	N/A
System Build (including, Front End Requirements Definition & Development 350 Story Points)	840,000		
ETL License Cost	0		
ETL Tool Support	18,000		
Database and Web Service Build	8,400		
Infrastructure Setup	5,700		
TOTAL . . .	909,100	TOTAL . . .	N/A

Estimate of Other Total Cost to Develop ePASS: $909,100

A.14 Annualized Cost to the Federal Government

The average annualized cost of monitoring the project by NHLBI is estimated at $80,000. This estimate is itemized in the following table:

Personnel	Amount	GS Grade and Step	% Time	Cost
Chief, OGM	1	15-10	2%	$3,000
Specialists, OGM	15	13-5	5%	$77,000
Total				$80,000

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16 Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish any information collected for any requests requiring NIH prior approval. Metrics on the overall types of requests and response times may be used on a routine basis to ensure efficient service when prior approval must be requested by research organizations.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

Not Applicable. We are not seeking a waiver of this requirement.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Not Applicable.