Supporting Statement A for:

Generic Clearance to Support Programs and Administrative Operations at the National Cancer Institute (NCI)

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ATTACHMENTS

This is a request for a generic submission that would be used for administrative and program-related submissions. Administrative submissions are defined as information collections (ICs) wherein the primary content is used for administrative purposes (e.g., an application) or to monitor, measure, manage or improve a program. These ICs may involve little if any, subsequent analysis and/or the use of descriptive statistics. Some ICs are forms used to source and aggregate contact information, history, preferences, opinions, and/or other data that does not necessitate further inquiry but allow the respondents to maintain contact, indicate preferences, and respond to data calls of information that has not already been collected. Other ICs may be program-related requests for the purpose of program monitoring, performance measurement, and improving or assessing the effectiveness of the program. This submission is the result of two years of analysis at the National Cancer Institute (NCI) which has demonstrated that more often than not, the potential and actual Paperwork Reduction Act (PRA) bootlegs that occur are administrative in nature, not research based. Additionally, NCI program staff who have submitted sub-projects that have been reviewed and returned by OMB, have contributed ideas and comments to this request. And finally, input and collaborations have been sought regarding this submission with program staff from different divisions and offices at NCI and PRA Liaisions at a variety of other National Institutes of Health (NIH) Institutes. Along with the analysis, NCI's ongoing education and outreach effort has increased the awareness and the need for a generic submission that covers administrative and program-related information collections. NCI's current scope for administrative generic sub-projects is non-existent and this submission would fill that gap.

A. Justification

A1. Circumstances Making the Collection of Information Necessary

Established under the National Cancer Institute Act of 1937, the National Cancer Institute (NCI) is the Federal Government's principal agency for cancer research and training. The Public Health Service Act, Section 410 (42 USC § 285) elucidates NCI's mission as "the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer." The National Cancer Act of 1971 further broadened the scope and responsibilities of the NCI and created the National Cancer Program. Over the years, legislative actions have added information dissemination mandates, as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice, to the NCI mission. In keeping with all of its legislative mandates, the NCI includes official components that comprise the Office of the Director, intramural and extramural research,

and management organizations critical to conducting, funding and supporting the goals to prevent, treat, and eradicate cancer. The mission of NCI's Office of Management and Policy Compliance (OMPC) is to design and conducts management analyses and provides coordination and expertise for submissions to the Office of Management and Budget throughout the Institute.

The Institute's research focus is not confined to the generation of major genetic, immunological, histological, pharmaceutical, and radiological advancements, but also includes investigations of related health sciences and investigations of smaller scale. Disciplines such as bioinformatics, survey research, communications, and health administration help ensure that:

- The research addresses the cancer needs of the US population;
- Findings are communicated in a clear and timely manner to clinicians, and cancer patients and their families; and
- The NCI infrastructure operates at the level needed to support and adapt to rapidly-evolving scientific findings, and
- Maintains the NCI as a world leader in all areas of cancer research.

This generic clearance will enable the Institute to more efficiently conduct selected administrative projects necessary for the achievement of program[1] objectives. Sample objectives that require OMB approval would include forms and applications related to program and administrative operations, management and policy compliance. It is important is to ensure that NCI's administrative support is targeted and streamlined and works in conjunction with the research efforts of both the intramural and extramural scientists. For effective administrative support, strategic and funding objectives need to be monitored, managed and reported. There are

[1] A program is defined as is a set of planned, systematic activities that uses managed resources to achieve goals that meet needs of identified individuals or groups. A program operates in a specific context, results in documentable outputs, outcomes and impacts, follows an assumed system of beliefs, and has specific resources with investigable costs and benefits (D.B. Yarbrough, L.M. Shulha, R.K. Hopson, & F.A. Caruthers (2011). Joint Committee on Standards for Educational Evaluation. The Program Evaluation Standards, 3rd Edition, p. xxiv).

times where program monitoring and performance measurement could be conducted to ensure the program's objectives are met and the quality in which this occurred. Many different types of program monitoring and assessment sub-projects can be envisioned based on previous requests and proposals. **Attachment 1** includes an array of examples of potential administrative sub-projects that could be submitted under this generic clearance within the next year.

Two sub-projects are being simultaneously proposed within the scope of this generic:

1) a survey to assess grantee's outcomes after an Innovative Molecular Analysis Technologies (IMAT) grant is awarded (**Attachments 3**), and

2) applications to enroll in two Division of Cancer Epidemiology and Genetics (DCEG) training programs (**Attachments 4**).

Feedback from NCI scientists throughout the division of extramural research indicated that sub-studies often were not done or delayed due to limitations of scope of the current generic clearances. A needs assessment with current and potential PRA/OMB submitters for the OMPC found that small-scale studies that sought to assess the effectiveness of administrative processes were often abandoned due to falling outside the defined scopes of the generics, or deemed as not worth the time and effort for OMB review. In addition, it found that some small projects were not conducted due to the wait for a vacancy in a submission bundle in one of the generic clearances.

Additionally, outside influences support the adoption of performance measurement and program monitoring throughout the government. In OMB Circular M-12-14 dated May 18, 2012, it is recommended that agencies have officials who are responsible for program evaluations and:

- can develop and manage the agency's research agenda,
- provide input to program leaders on program management, and

- to refine program performance measures.

Therefore, the OMPC seeks to create a generic clearance to collect administrative and program-related information to fulfill NCI's needs providing a mechanism for projects that fall outside the scope of the current generic clearances. The information collections under this generic clearance will be conducted by NCI administrators to ensure that division, office, and center objectives are met. Additionally, the sub-projects under this generic clearance will conform to the criteria determined by the Office of Management and Budget which states that generic clearances are "considered only when the agency is able to demonstrate that there is a need for multiple, similar collections, but that the specifics of each collection cannot be determined until shortly before the data are to be collected." Furthermore, proposed projects will be low in total burden hours, non-controversial in nature, and are not performed with the intent to provide information for a report to Congress or influence[2] policy decisions.

A2. Purpose and Use of the Information

Administrative submissions are defined as information collections (ICs) wherein the primary content is used for administrative purposes (e.g., an application) or to monitor, measure, assess or improve a program. Some ICs are forms used to source and aggregate contact information, history, preferences, opinions, and/or other data that does not necessitate further inquiry but allow the respondents to maintain contact, indicate preferences, and respond to data calls of information that has not already been collected. Other ICs may be program-related requests for the purpose of monitoring, improving or assessing the effectiveness of the program. Information collections that are part of this generic clearance would be contextual based, not

[2] As defined in OMB and DHHS, "Guidelines for Ensuring the Quality of Information Disseminated to the Public," "influence" means that agency can reasonably determine that dissemination of the information will have, or does have, a clear and substantial impact on important public policies or important private sector decisions."

generalizable, and the information would be used internally, to make decisions about on-going monitoring or improving a part of the program, or the program as a whole.

Recommendations and management support may include assessing a program prior to starting a program, mid-way through, or at the conclusion of a program. A generic sub-project may include a systematic and objective inquiry that results in recommendations to improve, continue, or terminate either parts or a full program. Sub-projects may be formative and feasibility projects in which parts of a program, or a pre-testing of a full program, is used for program monitoring or performance measurement.

Examples of the types of information collections that could be included under this generic clearance include: compiling mailing list for respondents to receive information from NCI based on their preferences/interests; collecting demographic information of website users to a particular website so that the website can be tailored to meet their needs and demographic; and collecting information from grantees or contractors which may include questions used to monitor their progress, self-report their scientific advances, or information required by a federal policy or program. The sub-projects that involve monitoring grantees progress will provide information that will help to understand how investigators use the resources provided by the program and form collaborative relationships. This information can be used to improve the use of resources in the future and to help the program office to create methods to more effectively encourage collaboration between awardees. The promotion of successful collaborative relationships is particularly important for multi-disciplinary research programs. Similar information may be collected in a program assessment to target the most effective and efficient use of program resources.

The information included in administrative progress reports can also be used for performance measurement and program monitoring. Specifically, the administrative information being gathered will be used to monitor the progress of grants and or contracts. An example may be a supplemental request to previously approved forms such as the Research Performance Progress Report (RRPR) (OMB#0925-0002). Other sub-projects may request the information in a more program specific format. This information is necessary to ensure that funding recipients are on track to reach program goals and that the requirements and intent of the Request for Application/Funding Opportunity Announcement are being met. Evidence of failure to meet program goals may be used by program staff to initiate discussions with investigators regarding ways to adjust their collaboration or research plans to improve their ability to meet program goals. Frequent reporting creates multiple opportunities for adjustments to prevent serious shortcomings. It also provides and opportunity for investigators to learn from each others experiences. An excellent performance by awardees is used to identify areas that could benefit from shared activities and inform best practices.

In summary, these are forms and applications that allow NCI to obtain results in a rapid fashion to guide development or implementation of larger projects, inform program direction, provide administrative functions, and to be used internally for program management purposes. This generic will not include outcome program evaluations that may use inferential statistics for analysis and include randomized control trials. Additionally, any proposal to conduct a program evaluation that will affect public policy or guide major funding decisions will be submitted as a full submission, rather than a sub-project.

A.3. Use of Improved Information Technology and Burden Reduction

To enable NCI to meet their objectives, forms and applications related to program and administrative operations and policy compliance must keep up with rapidly evolving technologic trends and advances, as well as uses in the marketplaces of research investigators and health care professionals. The use of electronic data collection forms, such as computer-assisted telephone interview (CATI), computer-assisted personal interview (CAPI) and audio and computer-assisted self-interview (ACASI), and online/web forms, permits efficient data collection and avoids the need for hard copies, stamps, and travel. When at all possible, technology will be employed to minimize the burden on the respondents.

All sub-projects will be referred and assessed for a Privacy Impact Assessment (PIA) by the NCI Privacy Act Coordinator. If it is determined a PIA is needed, the program staff with work with the NCI Privacy Act Coordinator to draft and publish a PIA to ensure the privacy and security of the data.

A4. Efforts to Identify Duplication and Use of Similar Information

Currently, there are four approved generic clearances at NCI that facilitate scientific research endeavors:

- A Generic Submission for Formative Research, Pretesting and Customer Satisfaction of NCI's Communication and Education Resources (0925-0046, Expiry Date 5/31/2016),
- Questionnaire Cognitive Interviewing and Pretesting (0925-0589, Expiry Date 4/30/2014),
- Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NCI) (0925-0642, Expiry Date 9/30/2014), and
- A Generic Submission for Theory Development and Validation (0925-0645, Expiry Date 12/31/2014).

Additionally, there are two other generic clearances for specific programs at NCI: Technology Transfer Center (TTC) Customer Satisfaction Surveys (0925-0633, Expiry Date 4/30/2014), and Office of Advocacy Relations (OAR) Formative Research, Pretesting, Stakeholder Measures and Advocate Forms (0925-0641, Expiry Date 9/30/2014). The latter two will not be discussed further since they are center-specific and designed to meet very specific needs of a particular program.

The four generic clearances listed above collect information that has a range with a broad scope. NCI generic clearances have conducted formative research, pre-testing, questionnaire development, pilot testing, usability studies, customer satisfaction surveys, in-depth interviews (IDI's), focus groups, and cognitive interviewing for a variety of respondents including the general public, cancer advocates, researchers, physicians, other health care providers, and students. At this time, only one approved generic clearance has the scope to approve administrative sub-studies and that is the OAR generic, which is specific to forms and applications related to advocates. It is felt that this generic submission will fill a need that exists at NCI.

As the focal point for Institute-wide PRA/OMB submissions, the OMPC staff receives all specific information collection submissions for full and generic clearances. As such they are apprised of efforts in progress and thus uniquely positioned to identify similar information collection efforts and avoid duplication. In addition, the individual NCI offices and centers perform an internal review of proposed information collections as a preliminary step in avoiding duplication. Though five generics already exist at NCI, none of the existing generics allow for administrative information collections (such as an application or listserv), performance

measurement and program monitoring. In the past, OMB has approved generic clearances for program monitoring and performance measurement for a variety of agencies including:

- Public Diplomacy Evaluation Office: Performance Measurement, Evaluation and Public Diplomacy Program Surveys (State/AFA) –
  OMB No. 1405-0158, Expiration Date 9/30/2011

- Consolidated State Performance Report (Part 1 and Part II) (ED/OESE) –
  OMB No. 1810-0614, Expiration Date 7/31/2015

- FTC Administrative Activities (FTC) –
  OMB No. 3084-0047, Expiration Date 2/28/2015

The purposes of the above mentioned information collections includes: strategic planning, improve program management and design, assess the quality and efficacy of a program, report on program performance, support/guide funding decisions, monitor implementation of a program, and inform policy and monitor compliance.

A5. Impact on Small Businesses or Other Small Entities

The target groups for these requests would include, but are not limited to: grantees, researchers/investigators, fellows, general public, and owners of small businesses such as independently-owned medical practices or health insurance agencies. It may be possible that small businesses or other small entities would participate in an information collection. As such, the sub-projects would be conducted in a manner that reduces the burden of time and effort, by keeping the forms brief. Additionally, if a small business or other small entity is part of the population sample, the program staff for the individual sub-projects will provide justification for participation of small businesses.

A6. Consequences of Collecting the Information Less Frequently

The majority of sub-projects to be conducted through this generic are planned as information collections from a single contact with participants. Sub-projects that involve the

completion of a progress report may require frequent collections to judge prgogress toward meeting program goals or to suggest solutions to those having difficulty meeting program goals. This includes assisting investigators in identifying collaborative partners and study topics, when necessary. When instances occur that multiple contacts will be made, the submitter for the individual sub-studies will make provisions for the additional contact and provide justification in terms of more meaningful results.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

NCI recognizes the requirement of OMB review as a mechanism to reduce burden on information collection participants and will ensure that information collections conducted under this generic clearance will comply with 5 CFR 1320.5. Investigators of specific sub-projects will provide indication of and justification for exceptions to these guidelines.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on May 23, 2013, Volume 78, p. 30930. One public comment was received on May 24, 2013 stating that the agency should spend more money on funding prevention research. An email response was sent on May 28, 2013 stating, "Your comments were received and they will be taken into consideration."

The program staff who have written the previous full generics at NCI, as well as program staff who have submitted sub-projects that have been reviewed and returned by OMB, have contributed ideas and comments to this request. Additionally, NCI has sought out collaborations and input regarding this submission with program staff and PRA Liaisions at a variety of other NIH Institutes.

A9. Explanation of Any Payment or Gift to Respondents

There will be few if any sub-projects that would use an incentive to motivate participation. If an incentive is planned, the sub-project will justify the need in the mini-SSA at the time of the request. Specifically, incentives may be used in situations where hard-to-find population or highly specialialized respondents are needed to improve or maintain the quality of the survey data, or in studies that impose exceptional burden on respondents (e.g., asking highly sensitive questions).

A10. Assurance of Confidentiality Provided to Resondents

In keeping with human subjects research protections, the information collections conducted under this generic clearance will take steps to guarantee that all personally indentifiable information (PII), and all data collected, are secure and private. PII will only be collected to the extent necessary. Respondents will be informed of security through explanatory text on the cover of forms and applications. In addition, respondents will be advised of the purpose of the information collection, the use of information collection, NCI sponsorship, and that their participation is voluntary and that they may choose to discontinue or have their name and/or related information withdrawn at any time. In instances where it is possible, information will be presented in aggregate form, without links to the identity of individual participants.

It may be necessary for some information collections to retain name and contact information collected on a form or application to be used to contact potential respondents. In these instances, the rationale for retention of PII will be fully explained. Most of the information collections to be conducted under this clearance are considered exempt from IRB review at NIH. NCI investigators will submit a request for exemption to the NIH Office of Human Subjects Research (OHSR). However, if it is determined that the information collection involves non-

exempt activities, the investigator is required to submit the information collection for review by the NCI Special Studies Institutional Review Board for approval.

A11. Justification for Sensitive Questions

Information collections may contain sensitive questions, most of a moderate nature. Factors such as income, age, education, race, gender are critical to characterizing various groups of people. Each sub-project will provide a description of sensitive questions and justification for their use.

A12. Estimates of Annualized Burden Hours and Costs

It is impossible to provide a precise estimate of burden hours and costs associated with this clearance as sub-projects will vary widely by number of respondents and average time per response. However, it is estimated that approximately 20,000 respondents will be asked to participate in generic sub-projects, with the average instrument taking approximately 50 minutes to complete (though the range may be anywhere from 5 to 90 minutes), which amounts to approximately 16,667 burden hours total over three years. The total burden hours for sub-projects submitted under this generic will be low (generally not to exceed 1,000 hours per request) unless it is clearly justified in the sub-project.

Additionally, two sub-projects are being simultaneously proposed with this full generic. The Post-award Survey of NCI Innovative Molecular Analysis Technologies (IMAT) Grantees is a 90 minute survey of 400 respondents, which amounts to 600 burden hours (**Attachments 3**). The second sub-project are applications to enroll in two Division of Cancer Epidemiology and Genetics (DCEG) training programs (**Attachments 4**). The two applications are estimated to amount to 525 burden hours.

Table A12-1. Estimate for Burden Hours over Three-Year Approval Period

Category of Respondents	Number of Respondents	Frequency of Responses	Average Time per Response (in hours)	Total Burden Hours
Individuals, Households, Private Sector, State Government, Local Government, Tribal Government, or Federal Government	20,000	1	50/60	16,667
Total	20,000			16,667

Based on the Bureau of Labor Statistics for May 2011, the mean hourly wage for all occupations is $21.74 (Table A12-2). This would amount to $271,750 over the course of three years.

Table A12-2. Estimate for Costs to Respondents over Three-Year Approval Period

Category of Respondents	Burden Hours	Hourly Wage Rates	Total Wage Rate
Individuals, Households, Private Sector, State Government, Local Government, Tribal Government, or Federal Government	16,667	$21.74	$362,340.58
Total			$362,340.58

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

No costs are anticipated.

A14. Annualized Cost to the Federal Government

The anticipated cost to the Federal Government is approximately $500,000 over the course of three years; this amounts to an annualized cost to the Federal Government of approximately $166,667. This is calculated by taking an estimated average of $25,000 per project over 20 projects during 3 years. These are an estimated costs since this request has not

been formally approved in the past; future submissions will have a more accurate accounting. The actual total cost to the Federal Government will be reported on every sub-project. As certified by the responsible program staff, the costs to collect the information will be low for the Federal Government. These costs are comprised of: operational expenses (e.g., equipment, overhead, printing, postage and support staff), contractor payments and any other expenses that are necessary to collect the information approved under this generic clearance.

A15. Explanation for Program Changes or Adjustments

This is a new, generic collection of information.

A16. Plans for Tabulation and Publication and Project Time Schedule

Generally, administrative sub-projects will not involve analysis. However, if analysis of a few questions is involved it will typically include frequencies, cross tabulations, and measures of central tendancy to yield descriptive statistics of demographic variables. These sub-studies will not involve inferential statistical analyses and parametric tests. The findings gleaned from the sub-projects are intended to be used by program staff to dissesimate information about the program, make decisions on the continuation of grants, report scientific advances that have been identified by grantees and other similar activities.

Results from information collections may be presented in reports and briefs for the NCI Division, Offices and Centers, NIH, or HHS. Additionally, some information depending on the content (e.g., listing of scientific advances per grantee or institution) may be released to the public through website, email or a newsletter. The respondents will be informed of the plans to release and the specific release plans will be requested in the individual sub-project submissions for OMB review (**Attachment 2**).

Project timelines will vary according to funding priorities within each DOC. Individual projects will depend on the number of respondents and the complexity or length of the form or application. Administrative information collection time periods can range from 1 month to 3 years. Should the administrative collection of information plan on continuing after the expiry date of the full generic, the program staff will submit another request to continue to collect the information.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

All forms will display the OMB number and expiration date.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act submissions are requested.