

IC: _____			
ANNUAL INTRAMURAL SELF ASSESSMENT OF MANAGEMENT CONTROLS			
PERIOD OF REVIEW: FY2007			
<i>SCIENTIFIC STAFF COVERED BY ASSESSMENT: All Scientific Staff with IPD from Senior Investigator to Student (including Contract Staff)</i>			
<u>Program and Project Planning Management</u>			
A. Protection of Human Subjects and Standards for Clinical Research			
		Yes	No
1	Do you have access to a duly constituted IRB, established in accordance with the NIH Policy Manual 3014 - NIH Human Research Protection Program? NIH Policy Manual 3014 - NIH Human Research Protection Program		
1a.	Are the IRB records maintained in accordance with the NIH Policy Manual 3014 - NIH Human Research Protection Program? (http://www1.od.nih.gov/oma/manualchapters/intramural/3014/) NIH Policy Manual 3014 - NIH Human Research Protection Program		
1b.	Where? (Bg. # _____, Room # _____)		
1c.	Secured by whom? Name: _____		
2	Has your IC received any allegations of non-compliance with the NIH Policy Manual 3014 - NIH Human Research Protection Program? (http://www1.od.nih.gov/oma/manualchapters/intramural/3014/)		
2a.	If yes, please explain: _____		
3	How many new protocols has your IRB reviewed during FY2007? #:		
3a.	How many new protocols has your IRB disapproved or deferred/tabled during the period of review? #:		
4	How many of the following types of protocols are active in your IC?		

	Research: Clinical Trial: Screening:		
	Research: Natural History/Epidemiology: Training:		
5	Were all patients seen in your IC Clinical Program covered by a written, active protocol? If NO, please describe situations to justify such exceptions:		
6	Who at your IC has oversight responsibility to assure that patients sign and receive copies of informed consent documents? Name and phone number:		
7	Were all IRB annual continuing reviews completed within 30 days of their scheduled review?		
8	Does your IRB follow the NIH standard operating procedures in accordance with NIH Policy Manual 3014 - NIH Human Research Protection Program? NIH Policy Manual 3014 - NIH Human Research Protection Program		
8a.	Are all new protocols evaluated for suitability of enrollment of minorities, children and women?		
8b.	Has the IRB identified, on continuing reviews, any protocols with unsatisfactory enrollment of minorities, children and women?		
8c.	If YES, how many:		
8d.	What action was taken?		
9	Are all clinical protocols including natural history and epidemiology subjected to critical scientific review before being sent to the IRB?		
9a.	Who reviews:		
10	Do you assure that all new scientific staff in your IC complete the OHSR computer-based training program protecting human research subjects at the NIH? OHSR CBT program		
10a.	How many staff have not completed this program:		
10b.	Please explain:		
10c.	Have all of your IRB members taken the Computer-Based Training (CBT) for NIH IRB members (http://ohsr.od.nih.gov/irb_cbt/)		

	IRB Members CBT		
11	Do you involve your IC Clinical Director in determining and allocating resources for clinical research?		
12	Have you and your Clinical Director implemented the NIH Standards for Clinical Research within the NIH Intramural Research Program? NIH Standards for Clinical Research		
13	Do all PIs on clinical protocols distribute to associate investigators the "Guide to Prevention of Conflict of Interest in Clinical Research? (http://www.nih.gov/campus/irnews/guidelines.htm) Guide to Prevention of Conflict of Interest in Clinical Research		
13a	If PIs do not distribute, how is the Guide distributed?		
14	Are potential conflicts of interest resolved before IRB members are appointed?		
15	Are all stored human samples with patient identifiers recorded in a database or other tracking system?		

B. RULES COVERING INVOLVEMENT OF INTRAMURAL SCIENTIST AND USE OF INTRAMURAL FACILITIES IN NIH-FUNDED EXTRAMURAL PROJECTS			
		Yes	No
1	Do you notify your scientists of the requirements involving collaborations or serving as consultants on an NIH grant?		
2	Are intramural scientists in your IC who are listed on a grant application as collaborating, or serving as consultants on an extramural NIH grant, submitting to you a copy of the letter of collaboration for advanced approval? Extramural collaboration cover-memo		
3	Are you notifying the grants management office of the appropriate IC about collaborations involving your intramural scientists, that are such a substantial part of a grant application that it may need to be changed to a cooperative agreement (U01)?		
4	Have you approved of any significant use of NIH intramural facilities by Guest Researchers or Special Volunteers supported by extramural NIH funds, i.e., SBIR, or other Federal granting agency?		
4a	If YES, how often:		
4b	Was the grants management office of the IC (or other Federal granting agency) informed?		

C. BOARD OF SCIENTIFIC COUNSELOR (BSC) REVIEWS			
		Yes	No
1	Do you distribute the "Orientation Guidelines for Boards of Scientific Counselors" to all regular Board of Scientific Counselor members, and Ad Hoc consultants? Orientation Guidelines for Boards of Scientific Counselors		
2	Has any Principal Investigator/laboratory/branch gone un-reviewed for more than four years?		
2a.	If YES, please justify non-review:		
3	For each laboratory reviewed during the period of review, were all tenured senior investigators and all tenure-track investigators reviewed?		
3a.	If NO, please justify non-review:		
4	Do you report to the BSC your actions in response to their recommendations?		
4a.	Were any recommendations by the BSC not addressed by the Scientific Director?		
4b.	Does someone from your IC report on the BSC evaluation of intramural research to the IC National Advisory Council annually?		
5	Do you have reviewers with clinical research expertise on your BSC?		
5a.	Are clinical protocols reviewed by your BSC or a subgroup of your BSC?		
6	Do you provide your BSC with lists of fellows who have left your IC since the last review, along with the position that they have taken?		
7	Is your BSC reviewing and commenting on the quality of the mentoring provided by each PI to his/her trainees?		
8	Is your BSC reviewing and commenting on the quality of the mentoring received by each tenure-track investigator?		

D. ANIMAL CARE AND USE (answer with assistance of ACUC chair)		Yes	No
1	Does your IC have a properly constituted ACUC or access to a properly constituted ACUC (under a formal contractual agreement) that meets regularly to review Animal Study Proposals (ASP)?		
1a.	Is there a nonaffiliated community member appointed to your ACUC (or the ACUC that supports your IC under a formal contractual agreement)?		
1b.	How many Animal Study Proposals were approved on the first round _____; tabled for revision or re-review _____ ?		
1c.	How many Animal Study Proposals were disapproved _____ ?		
2	Were there any animal-related incidents (include ASP or investigator privileges revoked or suspended) required to be reported to OLAW during FY2007?		
2a.	If YES, please explain:		
3	Does a system exist to verify that all appropriate staff receives introductory and triennial refresher training in the care and use of animals (e.g., PI & Animal Users Course)? OACU refresher training		
4	Have all projects that require NIH Institutional Biosafety Committee (IBC) approval been reviewed and approved by the IBC prior to the initiation of animal work?		
4a.	Have all projects that require NIH Division of Radiation Safety (DRS) approval been reviewed and approved by the DRS prior to the initiation of animal work?		
5	Does a system exist to assure that staff having direct contact with animals, their viable tissues, body fluids, wastes, or living quarters are enrolled in the Animal Exposure Surveillance Program (AESP)?		
6	Were any major/significant deficiencies found during the ACUC semi-annual program review or inspection of your animal facilities?		
6a.	Describe the resolution of these deficiencies:		

7	Has the IC veterinarian, or other source, reported to you or the IC ACUC any instances of facility management deficiencies that would threaten AAALAC accreditation?		
7a	Describe the resolution of these deficiencies:		
8	Do you meet with the ACUC Chair twice a year to review your IC Animal Care and Use program?		
9	Does your ACUC Chair or Vice Chair attend meetings of the NIH Animal Research Advisory Committee on a regular basis?		
10	Did the ACUC review IC animal(s) activities in shared/central facilities?		
10a.	Were all noted deficiencies corrected to the ACUC's satisfaction?		
10b.	Did one or more members of the ACUC conduct visits during FY2007 to all IC areas where animal activities are performed?		
11	Did all new ACUC members receive their required training?		
12	Were all scientific staff, including students, Guest Researchers, Special Volunteers and contractors who work with animals, identified and enrolled in AESP (or equivalent program) and given required training?		
13	Do you provide support for the ACUC to have a coordinator?		
14	Do you provide funding for your ACUC chair and/or other ACUC members to attend ACUC oriented or continuing education courses and/or workshops, e.g., OLAW Workshops or PRIM & R Meetings?		
15	Are co-investigators and users provided sufficient opportunity to acquire training and experience in animal procedures associated with IC ASPs? Co-investigator is defined as individuals (other than the PI) who perform animal activities described in any particular protocol.		

16	Does the ACUC fulfill its responsibilities regarding oversight of animal activities performed at contract sites, as outlined in NIH Policy Manual 3040-3?		
	NIH Policy Manual 3040-3		
17	Does the ACUC assure that staff members who work with awake behaving nonhuman primates have received all necessary training and achieved competency in those procedures, as outlined in NIH Policy Manual 3044-2?		
	NIH Policy Manual 3-44-2: Protection of NIH Personnel Who Work with Nonhuman Primates		

E. SCIENTIFIC MISCONDUCT		Yes	No
1	Does your organization use approved NIH procedures to define misconduct and to report allegations? A Guide to Handling Scientific Misconduct Allegations		
1a.	Has each member of your scientific staff been provided a copy of the publication: "A Guide to the Handling or Scientific Misconduct Allegations in the Intramural Research Program at the NIH?" A Guide to Handling Scientific Misconduct Allegations		
2	Is research ethics/scientific conduct training, using case discussions, provided by the IC yearly? The following are required to take the training (no counts required as in previous years):		
	Senior Investigators		
	Investigators		
	Senior Scientists/Senior Clinicians		
	Research Fellows/Clinical Fellows		
	Staff Scientists/Staff Clinicians		
	Senior Research Assistants/Research Assistants		
	Post-baccalaureate Fellows		
	Graduate Students		
	Technical IRTAs		
	Contract staff		
2a	Have all new Intramural staff taken the "Research Ethics" online course? Research Ethics Training		
3	Do you have a designated IC official responsible for receiving allegations of scientific misconduct? Name and phone number:		
4	Did the designee receive any allegations during the period of review?		
4a.	Were all of these allegations addressed?		
4b.	Were all such allegations brought to the attention of the Agency Intramural Research Integrity Officer (AIRIO) in the Office of Intramural Research?		
5	What was the disposition of the allegation(s): Proceeded to inquiry stage?		

5b.	Proceeded to investigation stage?		
6	Were any allegations of inappropriate authorship raised during the period of review?		
6a.	If YES, how many:		
7	Have research resources (equipment, personnel, and space) been diverted to prohibited activities (i.e., violations of the Antideficiency Act)?		
7a.	If YES, please describe corrective action taken:		
8	Do you inform personnel that unauthorized removal of government records, equipment, and laboratory reagents is illegal (e.g., removal of government property without a duly authorized loan agreement or property pass)?		
8a.	Are you aware of any incidents of illegal removal of government property in FY2007?		
8b.	If YES, please describe corrective action taken:		
8c.	Are all intramural staff aware of restrictions associated with removing research materials and equipment from the lab upon departure from NIH?		
	Departure memo		

F. ADMINISTRATIVE PROCEDURES		Yes	No
1	Do you have a mechanism to notify all new staff of the requirement to complete the NIH Online Orientation Program? (http://orientation.nih.gov) NIH Orientation		
1a.	Has someone been designated to follow up and ensure that everyone completes this training?		
2	Do you distribute copies of the following to all new scientific staff: NIH Guide to Training and Mentoring? NIH Guide to Training and Mentoring		
2a.	Guidelines for the Conduct of Research? Guidelines for the Conduct of Research		
2b.	Guidelines for the Conduct of Research Involving Human Subjects at the NIH? Guidelines for the Conduct of Research Involving Human Subjects at the NIH		
3	Who is responsible in your IC to ensure that dual payment of personnel does not occur? Name and phone number:		
3a.	Were there instances during FY2007 when personnel have been paid under two systems?		
3b.	If YES, please describe:		
4	Do you have a procedure for clearance of manuscripts, as specified by the Board of Scientific Directors? (Procedures should contain elements as found in: Publications and Meeting Abstracts Clearance)		
5	Are all contract workers (CWSs, CWAs, and CWTs) hired as specified in: Policy for Use of Contract Workers to Support Scientific Functions in the IRP		
5a	Are appointments of contract workers (CWSs, CWAs, and CWTs) reported to OIR as specified? Policy for Use of Contract Workers to Support Scientific Functions in the IRP		
6	How many of your IC laboratories requiring Clinical Laboratory Improvement Act (CLIA) certification to conduct diagnostic tests were identified:		
6a	Applied for certification:		
6b	Received certification:		

7	Do you inform all new personnel, including trainees, about the Government-wide restrictions regarding:		
7a	Human fetal tissue procurement? Human fetal tissue procurement restrictions		
7b	Human embryonic stem cell research? NIH Update on Existing Human Embryonic Stem Cells		
7c	Do you have a procedure in place to ensure the OIR is notified of every purchase of human embryonic stem cell lines? Checklist and Request for Permission to Acquire Human Embryonic Stem Cells		
8	Have you developed formal checkout procedures (i.e., checklist, database, or clearance form) for departing staff?		
8a	Are departing staff aware of the rules regarding transfer of government property? Required Permissions and Procedures for Transporting Materials When Leaving an NIH Laboratory		
9	Are your researchers encouraged to use the on-line application system to fill post-baccalaureate, summer and post-doctoral positions? OITE Training Website		
10	Have all staff been informed of restrictions associated with the use of NIH letterhead to write letters of reference?		
11	Have you worked with your CIO and CIT to verify that all mission-critical databases and systems are backed up in case in an event that would interrupt normal operations?		

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<u>Health and Safety of Intramural Personnel</u>			
		Yes	No
1	Does the IC have a safety and health committee?		
1a.	Who serves as Chair? Name of individual and phone number:		
2	Is there an established mechanism for reporting safety and health concerns to IC management?		
3	Is there a mechanism established to track required corrective actions?		
4	Have all IC laboratory personnel who work with potentially hazardous materials completed the appropriate training courses required by the NIH, "Laboratory Safety at the NIH" and "Working Safely with HIV or Other Bloodborne Pathogens at the NIH"?		
4a.	Have personnel who have contact with patients or biological specimens completed the training course "Bloodborne Pathogen Control Training"?		
4b.	Did personnel with occupational exposure to bloodborne pathogens receive annual refresher training (in compliance with the OSHA Bloodborne Pathogen Standard)?		
	Safety Courses		
5	Have any work-related accident/injury/infectious disease cases occurred during FY2007?		
5a.	What steps were taken to resolve the specific (and future) problem's?		
6	Have all staff in your IC who use radionuclides completed the appropriate Radiation Safety Training?		
	Radiation Safety Course		

6a.	Have any users in your IC had their privileges to use radionuclides suspended for failure to take the radiation safety refresher training, security violations, or other violations of rules governing the use of radionuclides?		
6b.	If YES, how many:		
7	Have you appointed a Controlled Substances Program Coordinator and alternates in your program?		
7a.	Has he/she developed a list of all Controlled Substances Custodians? NIH Policy for Handling and Safeguarding of Controlled Substances for Nonhuman Use		
7b.	Have new Custodians received proper training?		
7c.	Does your Coordinator make random checks of laboratories that store controlled substances to ensure that the materials are appropriately secured?		
7d.	Has the required inventory of controlled substances been conducted in FY2007?		
8	Are all packages containing hazardous materials, including dry ice, that are shipped from your labs packaged according to applicable rules and regulations?		
9	Who in your Intramural Research Program is responsible for assuring all new scientific staff, including all students and trainees, have taken the required training courses?		
10	Does your Institute conduct research with Select Agents? Usage of Select Agents		
10a.	Are all Select Agents registered with the Select Agent Program in the Division of Occupational Health and Safety?		
10b.	Have all employees who have access to Select Agents received the required Security Clearance?		
11	Has, or is, your Intramural Research Program worked/working with ORS on a Continuity of Operations Plan including identification of relevant IC key contracts?		

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<u>Recruitment, Appointment, Retention, and Evaluation of Scientific and Technical Personnel</u>		
A. Tenure Track		
		Yes No
1	Are NIH Tenure Program guidelines distributed to all tenure-track investigators?	<input checked="" type="checkbox"/> <input type="checkbox"/>
2	Is there a process for competitive selection of the most highly qualified internal and external candidates into the tenure-track or tenure positions?	<input checked="" type="checkbox"/> <input type="checkbox"/>
2a.	Do you have a plan to enhance the diversity of your workforce?	<input type="checkbox"/> <input type="checkbox"/>
2b.	Are all ads forwarded to the Office of Intramural Training and Education for inclusion in their website (http://training.nih.gov) as required?	<input type="checkbox"/> <input type="checkbox"/>
2c.	Are positions advertised in scientific journals with broad circulation?	<input type="checkbox"/> <input type="checkbox"/>
2d.	Are positions advertised in journals targeted to women and under-represented minorities (African American, Hispanic, Native American) and disabled?	<input type="checkbox"/> <input type="checkbox"/>
2e	Did the selection(s) improve the race or gender balance of your tenure-track and tenured staff?	<input type="checkbox"/> <input type="checkbox"/>
		<input checked="" type="checkbox"/> <input type="checkbox"/>
		<input type="checkbox"/> <input type="checkbox"/>
		<input type="checkbox"/> <input type="checkbox"/>

B. Women and Minority Scientists (With assistance of IC Intramural Administrative Officer and IC EEO Officer)			
		Yes	No
1	Does the IC Woman Scientist Advisor (WSA) attend all Lab/Branch Chiefs' meetings?		
2	On each tenure-track or tenure search committee is there an:		
	EEO representative?		
	WSA or designee?		
	Under-represented minority scientist?		
	DDIR representative?		
3	Are you comparing salaries for tenured, tenure-track and staff scientists/clinicians on a yearly basis to ensure that there are no disparities with respect to gender or minority status?		

C. Evaluation of Scientific and Technical Personnel		Yes	No
1	Does the Scientific Director review the progress annually of all:		
1a.	Pre-doctoral trainees?		
1b.	Post-doctoral fellows?		
1c.	Tenure-track scientists in a meeting with the tenure-track investigator? Philosophy and Practices for Tenure Track Investigators		
2	In what manner does the Scientific Director review the progress of the Investigator? (Specify which category or categories):		
2a.	One-on-one?		
2b.	Group meeting?		
2c.	Meeting with Lab/Branch Chief?		
2d.	Other? Please indicate method of review:		
3	Does the Scientific Director review Staff Scientists/Staff Clinicians prior to renewal or every four years?		
4	In what manner does the Scientific Director review the progress of Staff Scientists/Staff Clinicians? (Specify which category or categories)		
4a.	One-on-one?		
4b.	Group meeting?		
4c.	Meeting with Lab/Branch Chief?		
4d.	Other? Please indicate method of review:		
5	Was each post-doctoral fellow who remained at the NIH for more than five years sent a memorandum from the supervisor describing the proposed career course (in accordance with the 5-yr/8-yr rule)? 5-8 Year Rule		
5a.	Were copies of all such memoranda provided to the DDIR?		

6	Have you established mechanisms to provide appropriate technical supervision for all scientific contractor staff?		
7	Are procedures in place to ensure that clinical fellows in ACGME accredited programs are placed on the appropriate performance plan? Clinical Fellow's Performance Plan: 602		

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		Women	Men	Total Minority*	Under- Represented Minority**	Total		
	Provide the following data:							
1	Total number of tenured scientist on board as of September 30, 2007.							
1a.	Total number of scientists acquiring tenure in FY2007							
1b.	Outside recruitment							
1c.	Tenured from within NIH							
1d.	Approved via Central Tenure Committee							
1e.	Approved via SBRS Policy Board							
2	Total number of tenure-track scientists on board as of September 30, 2007.							
2a.	Total number of scientists appointed to tenure-track positions in FY2007							
2b.	Outside recruitment							
2c.	Selected from within NIH							
2d.	Selected from within IC							
3	Total number of promotions (or salary increases greater than 4% in Title 42/SBRS) of tenured scientists in FY2007							
4	Total number of Staff Scientists on board as of September 30, 2007							
5	Total number of Staff Clinicians on board as of September 30, 2007							
	*African-American; Hispanic; Native American (American Indian/Alaskan Native); Asian/Pacific Islanders							
	**African-American; Hispanic; Native American (American Indian/Alaskan Native)							

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<u>Conflict of Interest</u>		
		Yes
		No
1	Have you encountered any violation(s) of conflict of interest statutes and Office of Government Ethics regulations involving intramural scientific staff? Ethical Conduct: Sourcebook	
1a.	If YES, please explain:	
1b.	Did all intramural staff take the NIH ethics training modules?	
1c.	Were all outside activities reviewed by the IC DEC and the NIH Ethics Advisory Committee (NEAC) as required by position type?	
2	Are you forwarding all appropriate outside activity requests [top 5 (IC Director, Dep. Dir., Scientific Director, Clinical Director and Extramural Director), greater than 10K, and awards] to NIH Ethics Advisory Committee ?	
3	Are your Clinical Director's protocols in your IC reviewed by your IC IRB?	

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<u>Technology Transfer</u>		
		Yes No
1	Do you have a process within your IC to assist scientists in the identification of inventions and a process to advise them of their obligation to file an Employee Invention Report (EIR)?	<input type="checkbox"/>
		<input type="checkbox"/>
2	Do you have a process in place within your IC to evaluate Employee Invention Reports (EIRs)?	<input type="checkbox"/>
		<input type="checkbox"/>
3	Were any EIRs not forwarded through the IC review process and on to the NIH Office of Technology Transfer because of lack of funds to pursue patents in the future?	<input type="checkbox"/>
		<input type="checkbox"/>
4	Does a documented procedure exist to screen publications for patentable inventions prior to public disclosure (journals, press releases, abstracts, CRISP summaries)?	<input type="checkbox"/>
		<input type="checkbox"/>
5	Does a documented procedure exist to reduce potential for public disclosure of invention due to a seminar or talk?	<input type="checkbox"/>
		<input type="checkbox"/>
6	Was there any assignment of invention rights to inventors during the period of review?	<input type="checkbox"/>
		<input type="checkbox"/>
7	Do you have safeguards in place to assure that no conflict of interest situation will arise in the employee's performance of official duties from invention assignments to an employee or from other personal interest in a patent from an invention not owned by the U.S. Government?	<input type="checkbox"/>
7a.	If YES, please describe safeguard or situation:	<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>

8	Has the IC encountered any intellectual property complications or problems that could have been avoided by appropriate use of a MTA or CRADA?		
8a.	If YES, explain:		
9	Is there an IC policy regarding the processing and use of MTAs and CRADAs?		
10	Is there an IC process in place to ensure that all fellows working on CRADA-related projects are aware of the agreement and possible restrictions related to research collaborations and future employment opportunities?		
11	Does your IC have procedures in place to ensure IC scientists are not being inappropriately limited in publication rights, waiving intellectual property rights or violating confidentiality and/or conflict of interest rules?		
12	Does your IC have an internal resource person or a service center contact person for technology transfer issues?		
12a.	Name of person and phone number:		
13	Is there an IC process in place to ensure that all fellows, Guest Researchers, Special Volunteers and other non-employees working on technology transfer matters do not represent themselves as government employees or engage in negotiations and other matters as if they represented the government?		
14	Are Pre- and Post-doctoral Fellows/GR/SV notified of their responsibility to report and assign to the government any invention that occurs while working in a NIH facility or within the scope of official duties, whether or not the invention was made with government resources?		
15	Do you notify all Scientific Staff to take the online Technology Transfer course? Technology Transfer Training Course		