DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

SEP 18 2013

MEMORANDUM FOR MAYO CLINIC
ATTN: JONATHAN J. OVIATT
CHIEF LEGL OFFICER AND CORPORATE SECRETARY,
INSTITUTIONAL OFFICIAL

FROM: AFMSA/SGE-C
Research Oversight & Compliance Division
7700 Arlington Blvd. Ste. 5151
Falls Church, VA 22042-5151

SUBJECT: Approval of AF Issued Renewal of DoD Addendum to the Department of Health and Human Service's Federalwide Assurance (FWA) Number 00005001

References: (a) 32 CFR 219, Protection of Human Subjects
(b) 10 USC 980, Limitation on Use of Humans as Experimental Subjects
(c) AFI 40-402, Protection of Human Subjects in Research
(d) DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

On behalf of the Air Force Surgeon General, your DoD Addendum to the above FWA is approved. Your institution's assigned DoD Addendum number and covered human research are as follows:

DoD Number	**Research Covered**
F50420	**"All DoD-Supported Human Research Protocols Performed by this Institution".**

This Addendum must be updated regularly subject to a change in signatory official. For its uninterrupted continuation, this Addendum must be renegotiated with AFMSA/SGE-C prior to its expiration, which is **16 Aug 2018**.

Please maintain a copy of the attached approved Addendum with your research records.

In order to comply with this Addendum, you must provide to this office a copy of all continuing review reports submitted to the IRB in addition to the reports required by the above references.

Thank you for your cooperation in this matter. Please feel free to contact me at 703-681-6277 or afmsa.sge.c@pentagon.af.mil for additional assistance.

JAMES BENJACK, Lt Col, USAF, BSC
Director, Research Oversight & Compliance Division

Attachment: DoD Addendum **#F50420**

MAYO CLINIC

200 First Street SW
Rochester, Minnesota 55905
507-284-2511

Office for Human Research Protection
Institutional Review Board
507-266-2284, Fax 507-538-0051

Department of Defense
Human Research Protection Program

DEPARTMENT OF DEFENSE (DOD) ADDENDUM TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICE'S (DHHS) FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS

This Addendum is for non-DoD Institutions that already have an FWA approved by DHHS and will be engaged in DoD-supported human subject research.

Part 1
INSTITUTION INFORMATION

A. Purpose of DoD Addendum

[ ] New
[**X**] Renewal for DoD Addendum Number: ~~F504020~~ F50420 (K1 SGE-C)

B. Institution Information

Name: Mayo Clinic
DHHS FWA Number: FWA00005001
Description of the Institution: Mayo Clinic is a large medical center with campuses in Arizona, Florida, and Rochester, MN. Types of research performed include social, behavioral, educational, investigational drugs, investigational devices and chart reviews. The research is funded by government grants and contracts; commercial entities; private foundations and non-profit organizations; gifts and donations; and Mayo Clinic funds.

C. Scope

This Addendum applies to DoD-supported human research protocols performed by this institution.

D. Effective Date

This Addendum is effective as of the date the approval document is signed by the DoD Component Designated Official and expires on the date listed in the approval document.

Part 2
DOD REQUIREMENTS

In addition to the requirements identified in the Institution's FWA, this institution assures it shall comply with the following laws, regulations, and guidance when conducting, reviewing, approving, overseeing, supporting, or managing DoD-supported research with human subjects:

- Title 32 Code of Federal Regulations Part 219 (32 CFR 219), Department of Defense Regulations, "Protection of Human Subjects"
- Title 45 Code of Federal Regulations Part 46, (45 CFR 46) Department of Health and Human Services Regulations, "Protection of Human Subjects," Subparts B, C, and D as made applicable by DoDD 3216.02
- Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- DoD Instruction (DoDI) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research"
- Title 10 United States Code Section 980 (10 USC 980), "Limitation on Use of Humans as Experimental Subjects"
- DoDD 3210.7, "Research Integrity and Misconduct"
- DoD Instruction (DoDI) 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs"

Part 3
DOD COMPONENT REQUIREMENTS

The institution assures it shall also comply with DoD Component requirements for the research protocol(s) sponsored by that DoD Component. The requirements for each DoD Component are listed below. DoD Components may require that other research, not specifically identified by 32 CFR 219, also comply with the terms of this Addendum (32 CFR 219.101(d)).

Department of the Army

- AR 70-25 Use of Volunteers as Subjects of Research, 25 January 1990
- AR 40-38, Clinical Investigation Program, 1 September 1989
- AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, 4 January 1991

Department of the Navy

- SECNAVINST 3900.39D of 6 November 2006

Department of the Air Force

- Air Force Instruction 40-402, Protection of Human Subjects in Research

Office of the Secretary of Defense for Personnel and Readiness

- HA Policy 05-003

Part 4
INSTITUTION RESPONSIBILITIES

The complete list of requirements for compliance is provided above in Part 2, DoD Requirements; Part 3, DoD Component Requirements; and in the institution's FWA. A select list of responsibilities of the Institutional Official, IRB, and Investigators are identified below. This partial list is taken from the regulations and guidance listed in Parts 2 and 3. The institution should communicate with the DoD organization supporting the research to ensure the institution and their IRB are in compliance.

- Conduct initial and continuing research ethics education for personnel who are engaged in human subject research (e.g., who review, approve, oversee, or manage research)
- Document determination by a designated Institutional Official (other than investigators) whether research meets criteria for exemption
- Ensure new research and substantive scientific amendments to approved research shall undergo scientific review and that the review is considered by the IRB
- Ensure additional protections for military research subjects to minimize undue influence
- Explain to subjects any provisions for medical care for research-related injury
- Report unanticipated problems, adverse events, research-related injury, and suspensions or terminations of research
- Appoint a Medical Monitor when necessary
- Safeguard for research conducted with international populations
- Protect pregnant women, prisoners, and children
- Comply with DoD limitations on research where consent by legally authorized representatives is proposed
- Comply with DoD limitation on exceptions from informed consent (e.g., 10 USC 980, 45 CFR 46, and 21 CFR 50)
- Comply with limitations on dual compensation for U. S. military personnel
- Follow DoD requirements for additional review for DoD-sponsored survey research or survey research within DoD
- Address and report allegations of non-compliance with human research protections
- Address and report allegations of research misconduct
- Follow procedures for addressing financial and other conflicts of interest
- Prohibit research with prisoners of war (POW)
- Comply with all provisions for research with human subjects using investigational test articles (drugs, device, and biologics)
- Follow recordkeeping requirements
- Support oversight by the sponsoring DoD Component (which may include DoD Component review of the research and site visits)

Part 5
DESIGNATION OF IRB(S) THAT WILL REVIEW DOD-SUPPORTED RESEARCH

All of the IRBs supporting the institution do not need to be listed in Tables 1 and 2. List only those IRBs that will review DoD-supported research.

A. IRB(s) that are Part of this Institution

In Table 1, identify each IRB that is organizationally part of this institution and can review DoD-supported research under this Addendum to the FWA (the IRBs should also be listed on the FWA). For each IRB listed in Table 1, the IRB Chair must sign this Addendum in Part 6. When requested by the DoD-sponsor, attach the membership list for each IRB listed (in accordance with 45 CFR 46); see Table 3 for an example.

Table 1. IRB(s) within the Institution

IRB Name or Number	**DHHS IRB Registration Number (8 digits)**
1. Mayo Foundation IRB #1 – IRB – C	IRB00000020
2. Mayo Foundation IRB #2 – Blue Friday	IRB00003294
3. Mayo Foundation IRB # 3 - Thursday	IRB00003295
4. Mayo Foundation IRB #6 – Wednesday	IRB00005256

B. IRB(s) that are not Part of this Institution

In Table 2, identify each IRB that is not associated with this institution and can review DoD-supported research under this Addendum to the FWA. For each IRB listed in Table 2, attach the DoD Institutional Agreement for IRB Review (or an equivalent agreement). When requested by the DoD-sponsor, attach the membership list for each IRB listed (in accordance with 45 CFR 46); see Table 3 for an example.

Table 2. IRB(s) not part of this Institution

IRB Name or Number	**DHHS IRB Registration Number (8 digits)***	**Name of the Institution Providing the IRB**	**DoD Assurance Number of the Institution***	**DHHS FWA Number of the Institution***
1. IORG0000460	IRB00000781	NCI Adult CIRB		
2. IORG0000460	IRB00004296	NCI Pediatric CIRB		
3.				
4.				

* If applicable.

Part 6
INSTITUTIONAL AGREEMENT

A. Official Legally Authorized to Represent the FWA Institution (i.e., signed the FWA)

Acting in an authorized capacity on behalf of this institution and with an understanding of the institution's responsibilities under it's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature:  Date: 9-7-13

Name: Jonathan J. Oviatt
Rank/Grade: N/A
Institutional Title: Chief Legal Officer and Corporate Secretary, Institutional Official
Telephone number: 507-284-8707
FAX number: 507-284-0929
Mailing Address: Mayo 11
200 First Street SW
Rochester, MN 55905
Email address: joviatt@mayo.edu

B. Chair(s) of the IRB(s) that are part of the Institution and listed in Table 1

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature:  Date: 8/28/2013

Name: R. Scott Wright, MD
Institutional Title: Professor of Medicine, College of Medicine; Cons-Cardiol Noninv
Telephone number: 507-266-3626
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: wright.scott@mayo.edu

Name(s) or Number of IRB:

Co-Chair

5. Mayo Foundation IRB #6 – Wednesday	IRB00005256

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: Date: 8/28/2013

Name: Yves Ouellette, MD, Ph.D.
Institutional Title: Assistant Professor of Pediatrics, College of Medicine; Cons-Ped Sub Spec
Telephone number: 507-284-6437
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: Ouellette.yves@mayo.edu

Name(s) or Number of IRB:

Co -Chair

5. Mayo Foundation IRB #6 – Wednesday	IRB00005256

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: Date: 9/22/13

Name: Gary Schwartz, MD
Institutional Title: Professor of Medicine, College of Medicine;Cons-Nephrology
Pager number: 507-284-7649
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: gschwartz@mayo.edu

Name(s) or Number of IRB:

Co-Chair

Mayo Foundation IRB # 3– IRB Thursday	IRB00003295

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: Rita Basu Date: 8/29/2013

Name: Rita Basu, MD
Institutional Title: Professor of Medicine, Mayo Clinic
Telephone number: 507-538-2146
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: basu.rita@mayo.edu

Name(s) or Number of IRB:

Co-Chair

Mayo Foundation IRB #3 -Thursday	IRB00003295

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: Joseph K Lobl, MD Date: 8/30/13

Name: Joseph Lobl, MD
Institutional Title: Assistant Professor of Emergency Medicine, College of Medicine; Cons-Emerg Med SVCS
Telephone number: 507-284-6669
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: lobl.joseph@mayo.edu

Name(s) or Number of IRB:

Chair

2. Mayo Foundation IRB #2 – Blue Friday	IRB00003294

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature:  Date:

Name: Eugene Kwon, MD
Institutional Title: Professor of Immunology and Urology, College of Medicine; Cons-Med/Surg Urol
Telephone number: 507-266-8734
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: kwon.eugene@maypo.edu

Name(s) or Number of IRB:

Vice - Chair

2. Mayo Foundation IRB #2 – Blue Friday	IRB00003294

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: Date:

Name: Bart L. Clarke, MD
Institutional Title: Assistant Professor of Medicine, College of Medicine; Cons-Eno Res
Telephone number: 507-284-7968
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: Clarke.bart@mayo.edu

Name(s) or Number of IRB:

Co - Chair

1. Mayo Foundation IRB #1 -- IRB - C	IRB00000020

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: Date: 8/23/2013

ERROR WJT 2 Sept, 2013

Name: Irene Meissner, MD
Institutional Title: Professor of Neurology, College of Medicine; Cons- Neurology
Telephone number: 507-284-6337
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: imeissner@mayo.edu

Name(s) or Number of IRB:

Co - Chair

1. Mayo Foundation IRB #1 – IRB - C	IRB00000020

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: Date: 21 August 2013

Name: William J. Tremaine, MD
Institutional Title: Professor of Medicine, College of Medicine; Cons- GI
Telephone number: 507-284-7919
FAX number: 507-538-0051
Institution: Mayo Clinic
Email address: tremaine.william@mayo.edu

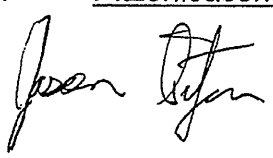
Name(s) or Number of IRB:

Dr Tremaine is the medical director for Mayo Clinic IRB and is an alternate for any chair or co-chair.

4. Mayo Foundation IRB #6 – Wednesday	IRB00005256
3. Mayo Foundation IRB #3 - Thursday	IRB00003295
2. Mayo Foundation IRB #2 – Blue Friday	IRB00003294
1. Mayo Foundation IRB #1 – IRB - C	IRB00000020

C. Primary Contact - Human Research Protection of the FWA Institution

Name: Jason Pitzen
Institutional Title: Administrator Research Ops
Telephone number: 507-266-2473
FAX number: 507-538-0051
Email address: Pitzen.Jason@mayo.edu

Signature:  Date: 8/22/2013

FWA #: **FWA00005001**
Institution: **Mayo Clinic**
Expires: **08/16/2018**

OMB No. 0990-0278
Approved for use through June 30, 2014

Federalwide Assurance (FWA) for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: **Mayo Clinic**

City: **Rochester** State/Province: **MN** Country: **USA**

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)	
Mayo Clinic	ROCHESTER	MN	A
Mayo Clinic - Methodist Hospital	ROCHESTER	MN	A
Mayo Clinic Arizona	SCOTTSDALE	AZ	A
Mayo Clinic Jacksonville	JACKSONVILLE	FL	A
Mayo Clinic - Saint Marys Hospital	ROCHESTER	MN	A
Gold Cross Ambulance Service	ROCHESTER	MN	A
MFMER, d.b.a. Air Medical Transport	ROCHESTER	MN	A
Mayo Clinic Florida d/b/a Mayo Clinic Hosp	Jacksonville	FL	A
MFER d.b.a. Mayo Clinic Pharmacy	Rochester	MN	A
Charter House, Inc.	Rochester	MN	A
Mayo Regional Practices - AZ d.b.a. Thunderbird Clinic	Scottsdale	AZ	A
Mayo Regional Practices- AZ d.b.a. Arrowhead Clinic	Fountain Hills	AZ	A
Mayo Family Clinic NW	Rochester	MN	A
Mayo Family Clinic Kasson	Kasson	MN	A
Mayo Family Clinic NE	Rochester	MN	A
Mayo Clinic Radiation Therapy Facility	Northfield	MN	A

National Cancer Institute
Central IRB Initiative

Authorization Agreement/Division of Responsibilities
Between the NCI Central Institutional Review Board and the Signatory Institution

Authorization Agreement

A. **Name of Organization Providing IRB Review:** National Cancer Institute Central Institutional Review Board (CIRB)

NCI CIRB's Organization Number: IORG0000460
Adult CIRB IRB Registration Number: IRB00000781
Pediatric CIRB IRB Registration Number: IRB00004296

B. **Name of Signatory Institution Relying on the NCI CIRB:** *Mayo Clinic*

Signatory Institution's OHRP Federalwide Assurance (FWA) Number: *FWA00005001*

1. **A Signatory Institution's "Component Institution" is defined by the NCI CIRB as meeting all of the following criteria:**
   a. the Component Institution operates under a different name than the Signatory Institution but the Signatory Institution has legal authority for the Component Institution;
   b. the FWA number for the Component Institution is the same as the Signatory Institution;
   c. the local context considerations of the Component Institution are the same as the Signatory Institution;
   d. the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution; and
   e. the conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.

   List the Signatory Institution's Component Institution(s) by name:
   1. *Mayo Clinic, Rochester, MN*
   2. *Mayo Clinic-Methodist Hospital, Rochester, MN*
   3. *Mayo Clinic Arizona, Scottsdale, AZ*
   4. *Mayo Clinic Jacksonville, Jacksonville, FL*
   5. *Mayo Clinic - Saint Mary's Hospital, Rochester, MN*
   6. *Gold Cross Ambulance Service, Rochester, MN*
   7. *MFMER, d.b.a. Air Medical Transport, Rochester, MN*
   8. *Mayo Clinic Florida d/b/a Mayo Clinic Hospital, Jacksonville, FL*
   9. *MFER d.b.a. Mayo Clinic Pharmacy, Rochester, MN*
   10. *Charter House, Inc., Rochester, MN*
   11. *Mayo Regional Practices - AZ d.b.a Thunderbird Clinic, Scottsdale, AZ*
   12. *Mayo Regional Practices - AZ d.b.a Arrowhead Clinic, Fountain Hills, AZ*

2. **A Signatory Institution's "Affiliate Institution" is defined by the CIRB as meeting all of the following criteria:**
   a. the local context considerations of the Affiliate Institution are the same as the Signatory Institution;
   b. the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution; and
   c. the conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.

Authorization Agreement/Division of Responsibilities
Between the NCI Central Institutional Review Board and the Signatory Institution

List the Signatory Institution's Affiliate Institution(s) by name:

1. *None*

C. Authorization

The review performed by the NCI CIRB will meet the human subject protection requirements of *Mayo Clinic's* OHRP-approved FWA. The NCI CIRB will follow written procedures for reporting its findings and actions to appropriate officials at *Mayo Clinic*. Relevant minutes of CIRB meetings, and supporting documents, are available to the Signatory Institution via the NCI CIRB website at any time. *Mayo Clinic* remains responsible for ensuring compliance with the NCI CIRB's determinations and with the terms of the Signatory Institution's OHRP-approved FWA. This document should be kept on file at the Signatory Institution and at the CIRB Operations Office and must be provided to OHRP upon request.

The Officials signing below agree that the NCI CIRB provides IRB review as described in the *"Division of Responsibilities between the NCI CIRB and the Signatory Institution"* for *Mayo Clinic* and all Component and Affiliate Institutions.

This document will go into effect upon the signature of the Signatory Institution and the NCI.

Name and Title of Signatory Official for the Signatory Institution:

Jonathan J. Oviatt
Name

Chief Legal Officer & Corporate Secretary
Title

Signature

July 30, 2013
Date

Name and Title of Signatory Official for NCI:

Jeffrey S. Abrams, M.D.

Name

Acting Director for Clinical Research
Division of Cancer Treatment and Diagnosis
National Cancer Institute

Title

Signature

8/6/2013
Date

Send 2 originals to the NCI CIRB Operation Office:

NCI CIRB Operations Office
c/o The EMMES Corporation
401 N. Washington Street, Suite 700
Rockville, MD 20850

Division of Responsibilities

The responsibilities of the NCI CIRB are to:

1) Maintain an NCI CIRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
   a) Post the roster of NCI CIRB membership on the public side of the NCI CIRB website;

2) Conduct initial, amendment, and continuing review of studies as well as review of any other study-specific documents submitted by the Study Chair to the NCI CIRB;

3) Conduct review of local context considerations:
   a) as outlined in the following Worksheets: the Annual Signatory Institution Worksheet About Local Context for NCI CIRB Review, the Annual Principal Investigator Worksheet About Local Context, and the Study-Specific Worksheet About Local Context;

4) Conduct review of potential unanticipated problems and/or serious or continuing noncompliance when the Signatory Institution or other entity reports an incident, experience, or outcome to the CIRB. This review includes the following step:
   a) report any unanticipated problem and/or serious or continuing noncompliance determination to OHRP, the FDA, and the NCI Signatory Official;

5) Conduct review of individual Adverse Event Reports for studies without a Data and Safety Monitoring Board (DSMB) or equivalent monitoring body;

6) Post all study-specific documents related to CIRB reviews to the restricted access side of the CIRB website;
   a) Notify research staff and institutional designees of all CIRB actions, per written procedures, via institution-specific correspondence, broadcast emails, and access to the restricted area of the CIRB website;

7) Notify the Signatory Institution immediately if there is ever a suspension or restriction of the CIRB's authorization to review a study; and

8) Post the NCI CIRB Standard Operating Procedures on the public side of the CIRB website.

The responsibilities of the Signatory Institution are to:

1) Comply with the NCI CIRB's requirements and directives;

2) Report to the NCI CIRB the names of any Component or Affiliate Institutions that rely on the Signatory Institution's IRB.
   a) Component Institutions are defined by the NCI CIRB as meeting all of the following criteria:
      - the Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the Component Institution;
      - the FWA number for the Component Institution is the same as the Signatory Institution;

- the local context considerations of the Component Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context;
- the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context; and
- the conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.

b) Affiliate Institutions are defined by the NCI CIRB as meeting all of the following criteria:

- the local context considerations of the Affiliate Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context;
- the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context; and
- the conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.

3) Ensure the safe and appropriate performance of the research at the Signatory Institution and at all Components and Affiliates. This includes, but is not limited to:
   a) ensuring the initial and ongoing qualifications of investigators and research staff;
   b) overseeing the conduct of the research;
   c) monitoring protocol compliance;
   d) maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
   e) providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and
   f) investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence, experience, or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance. When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, the institution must provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences;

   NOTE: As part of ensuring safe and appropriate performance of research the Signatory Institution has the authority to observe any aspect of the research process including observing the consent process. The CIRB retains the authority to direct this to be done when necessary.

4) Provide updates in a timely manner to the NCI CIRB whenever a Signatory Institution Principal Investigator is no longer the responsible party for a study under the purview of the NCI CIRB;

5) Notify the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review;

6) Complete and submit the Annual Institution Worksheet About Local Context, the Annual Investigator Worksheet About Local Context, and any other worksheets/forms required by the NCI CIRB for participation;

7) Decide on a study-by-study basis whether to open the study through the NCI CIRB or to conduct its own local IRB full Board review. Indicate the decision to open a study through the NCI CIRB by submitting a Study-Specific Worksheet About Local Context;

8) In the local consent form:
   a) incorporate NCI CIRB-approved boilerplate language into the NCI CIRB-approved model consent form;

   NOTE: Including HIPAA Authorization language as part of boilerplate language is permitted. The CIRB does not approve the HIPAA Authorization language as it does not function as a Privacy Board however the CIRB will accept HIPAA Authorization language when submitted as part of the boilerplate.

   b) make no language changes to the consent form with the exception of NCI CIRB-approved boilerplate language;
   c) obtain NCI CIRB approval of changes to the boilerplate language prior to implementation; and
   d) obtain NCI CIRB approval of translations of the consent form prior to implementation;

9) Maintain a regulatory file for each study under NCI CIRB purview as per local institution and sponsor policy; and

10) Conduct full board review of any study enrolling prisoners, since the NCI CIRB is not constituted to review studies enrolling prisoners.