EXECUTION COPY
Version: NEALS CIRB/MCTA Pilot Project Sites
Revised: September 2016

NEALS Central IRB

Institutional Review Board ("IRB") Authorization Agreement

Names and Federalwide Assurance ("FWA") Numbers of Institutions Providing IRB Review:

THE BRIGHAM AND WOMEN'S HOSPITAL, INC. ("BWH") - FWA #484

THE GENERAL HOSPITAL CORPORATION d/b/a MASSACHUSETTS GENERAL HOSPITAL ("MGH") - FWA #3136

Name and FWA of Institution Relying on the Designated IRBs:

INSERT FULL LEGAL NAME OF, ABBREVIATION FOR, AND FWA # OF RELYING SITE: E.G., ABC MEDICAL CENTER, INC. ("**ABC**") - FWA # **XXXX**

Other Parties:

PARTNERS HEALTHCARE SYSTEM, INC.

Terms of Agreement

I. Background

The IRBs of MGH and BWH (collectively known as the "Partners Human Research Committee" or "PHRC") have been selected by the Northeast ALS Consortium ("NEALS") to serve as the central IRB ("Central IRB") for select NEALS studies. As of the Effective Date of this Agreement, the IRBs of MGH and BWH are registered with the Office for Human Research Protections ("OHRP"), and MGH and BWH each maintain an OHRP-approved FWA. In addition, as of the Effective Date, MGH and BWH, as part of Partners HealthCare System, are fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. ("AAHRPP"). MGH and BWH shall notify **ABC** promptly in writing if their FWAs are threatened, terminated, or expire or if their accreditation status changes during the term of this Agreement.

NEALS is a non-profit group of researcher institutions (each a "NEALS Member") who collaboratively conduct clinical research in Amyotrophic Lateral Sclerosis and other motor neuron diseases. The Neurological Clinical Research Institute ("NCRI") at MGH is the Clinical Coordinating Center for NEALS research studies (the "NCRI CCC") and also operates the Data Coordinating Center for the studies (the "NCRI DCC"). **ABC** is a NEALS Member participating in the pilot of a Central IRB process (the "NEALS cIRB Pilot") for specific NEALS research studies.

This Institutional Review Board Authorization Agreement ("Agreement") is to: (1) establish the PHRC (hereafter referred to as the Central IRB) as the IRB of record for **ABC** with respect to select human subject research studies conducted by **ABC** through NEALS (the "Clinical Studies") and (2) to set forth the respective authorities, roles, and responsibilities of each party in such arrangement.

This Agreement does not preclude any party from participating in any other IRB authorization agreements that it may have or enter into with other entities, including others of the parties, for human subject

research other than the Clinical Studies for which **ABC** relies upon review by the Central IRB under this Agreement. This Agreement is between the undersigned parties only and does not include any other FWA-holding entities with which **ABC** is affiliated or has an IRB reliance relationship.

This Agreement meets federal requirements for designation of another institution's IRB as the reviewing IRB, as set forth in the OHRP document *Terms of the Federalwide Assurance* current as of June 2011. This Agreement will be kept on file at each signatory institution and will be provided to OHRP or other federal agencies upon request.

II. General Terms

1. Agreement Scope. The Officials signing below agree that **ABC** will rely on the Central IRB, in accordance with the terms and conditions set forth in this Agreement, for review and continuing oversight of select studies conducted by **ABC** as a NEALS Member, subject to the eligibility requirements set forth in Section II.2 of this Agreement below.

2. Eligibility.

   a. In general: **ABC**'s eligibility for participation in this Agreement is contingent on (i) its status as a NEALS Member participating in the NEALS cIRB Pilot; (ii) its maintenance of a current, OHRP-approved FWA; and (iii) its provision of a complete, satisfactory NEALS Member IRB Information Sheet to the Central IRB (via the NCRI CCC).

   b. Specific Clinical Studies: The process for ceding IRB review of specific Clinical Studies is set forth in a Central IRB / NEALS document entitled "The Central IRB Reliance Process SOP" (the "Reliance SOP"). Only Clinical Studies for which both **ABC** and the Central IRB have agreed that IRB review will be provided by the Central IRB in accordance with the Reliance SOP will be included in this Agreement.

   The Reliance SOP indicates the categories of information, including information about **ABC**s' local research context, and the timeframes and documentation for providing such information to the Central IRB, that will be required from **ABC** and its investigators on a protocol-by-protocol basis in order for the Central IRB to provide review of a Clinical Study under this Agreement. Without limiting anything in the Reliance SOP, the eligibility of any specific Clinical Study for inclusion in this Agreement shall be contingent on **ABC**'s provision of complete information necessary to inform the Central IRB of **ABC**'s local research context as relevant to that Clinical Study. Such information shall include specific requirements of state or local laws, regulations, policies, standards or other factors applicable to **ABC** or the Clinical Study, as well as the conflict of interest information and relevant requirements of other local ancillary committee reviews described in Section III.4 of this Agreement.

   c. Obligation to Update Information. **ABC** will provide written notification to the Central IRB (via the NCRI CCC) promptly upon any material changes to the information provided on its NEALS Member IRB Information Sheet or otherwise about its site, its human research program, or the local research context in connection with this Agreement or any Clinical Study.

3. Permanent Authority of Central IRB. Once the parties have designated the Central IRB as the IRB of record for a Clinical Study pursuant to this Agreement, the Clinical Study will remain under the Central IRB's oversight authority for the life of **ABC**'s participation in the Clinical Study. For avoidance of doubt, **ABC** may suspend or terminate its participation in a Clinical Study at any time. In the event that **ABC**'s participation in a Clinical Study ceases for such reason or any other reason, the parties will work together to determine the effect of such cessation on the human subject research activities being conducted at the time.

4. NCRI CCC Role; SOPs; Contact Persons; Communications. MGH, through the NCRI CCC, shall manage and coordinate the operations of the parties' IRB authorization relationship established by this Agreement, including communications with the Central IRB.

On behalf of the Central IRB, NCRI will maintain NEALS specific standard operating procedures ("SOPs") applicable to all sites participating in the NEALs cIRB Pilot (collectively, "Pilot Study Sites") to govern certain details of the IRB authorization relationship referenced generally in this Agreement. The SOPs will be made available to **ABC** via the NEALS website. The NCRI CCC will promptly notify **ABC** of any material amendments to the SOPs referenced in this Agreement.

The NCRI CCC and **ABC** will each identify to one another a designated contact-person or liaison who will communicate on its behalf with respect to matters concerning implementation of this Agreement, and each will notify the other promptly if its contact-person changes. The contact information for such persons will be posted on the NEALS website and shall be used for all communications, reports and notices required or contemplated by this Agreement other than those specifically noted in Section VII.2 or otherwise delineated in the SOPs referenced herein. Although the parties contemplate that most day-to-day communications with the Central IRB under this Agreement and the SOPs will occur via the NCRI CCC, nothing herein shall prohibit **ABC** and the Central IRB from communicating directly with one another if necessary regarding any matter related to this Agreement. Contact information for Central IRB representatives will be included on the NEALS website.

III. Obligations Regarding IRB Review/Decisions

1. FWA; Central IRB Review in Accordance with FWA. **ABC** will maintain a current, approved FWA with OHRP for the duration of this Agreement. **ABC** will notify the Central IRB (via the NCRI CCC) promptly in writing if its FWA is threatened, terminated, or expires for any reason.

The Central IRB will perform initial review and continuing oversight of the Clinical Studies included in this Agreement in accordance with the human subjects protection requirements of **ABC**'s OHRP-approved FWA and the federal regulations and ethical principles referenced therein. Review by the Central IRB will take into account the requirements of the local research context identified by **ABC** pursuant to the Reliance SOP and Sections II.2(b) and III.4 of this Agreement. **ABC** shall provide a copy of its FWA to the Central IRB (via the NCRI CCC) with the NEALS Member IRB Information Sheet and thereafter upon any material change or renewal. Material change includes, but is not limited to, a change in the components of **ABC** that are covered under the FWA.

2. Informed Consent Form. The Central IRB will provide an approved study-wide informed consent form for each Clinical Study included under this Agreement. The form will indicate areas where **ABC** may add language or otherwise customize the form for its own site. Any modifications will be subject to approval by the Central IRB, which will then provide a final approved consent form to **ABC** for use at its site.

3. HIPAA; Form of Authorization. The Central IRB will perform the determinations required by the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations (collectively, "HIPAA") with respect to the mechanisms for permitting the use and disclosure of Protected Health Information ("PHI") for the Clinical Studies included in this Agreement, namely authorization and waivers of authorization for use and disclosure of PHI as applicable. When an authorization will be used, the Central IRB will also provide as part of the approved informed consent form for an included Clinical Study a model form of authorization for use and disclosure of PHI. Such model form of authorization shall explicitly permit PHI to be used and shared by and with Partners HealthCare

System, Inc. ("Partners"), the Central IRB, MGH, BWH, and all Pilot Study Sites and their investigators participating in a Clinical Study as necessary for conducting, reviewing, and overseeing the Clinical Study (including investigation and evaluation of events) as contemplated by the protocol and this Agreement.

Subject to the approval of the Central IRB and NCRI, **ABC** may elect to require its own form of HIPAA authorization to be used instead of the Central IRB model authorization form. In such cases, **ABC** will ensure that its form of authorization explicitly permits PHI to be used and shared by and with Partners, the Central IRB, MGH, BWH, and all Pilot Study Sites and their investigators participating in a Clinical Study as necessary for conducting, reviewing, and overseeing the Clinical Study (including investigation and evaluation of events) as contemplated by the protocol and this Agreement.

If it becomes necessary in connection with a Clinical Study for the parties to access and share PHI in any way not covered by the existing authorization or waiver of authorization, then the parties will work together to determine any additional steps necessary to ensure that the required information is shared in a HIPAA-compliant manner. Each party shall maintain, use and disclose PHI accessed from the others pursuant to this Agreement in compliance with HIPAA, including but not limited to the security provisions thereof, and all other laws and regulations applicable to such party.

Each party shall be independently responsible for its own HIPAA compliance and obligations (for example, minimum necessary requirements, or accounting of disclosures of PHI made pursuant to a waiver of authorization) in connection with the Clinical Studies included in this Agreement other than the initial determinations regarding mechanisms for use and disclosure of PHI referenced in this Section III.3.

4. Local Research Context: State/Local Law; Conflicts of Interest; Other Local Ancillary Committee Reviews.

a. In connection with each Clinical Study reviewed under this Agreement, and in accordance with the specific requirements and timeframes set forth in the Reliance SOP, **ABC** shall perform its own analysis of any specific requirements of state or local laws, regulations, policies, standards or other factors applicable to **ABC** or the Clinical Study, and shall include any relevant requirements or results of such analysis that would affect its conduct of the Clinical Study as part of the information provided to the Central IRB under the Reliance SOP and Section II.2(b) of this Agreement.

b. In connection with each Clinical Study reviewed under this Agreement, and in accordance with the specific requirements and timeframes set forth in the Reliance SOP and the NCRI document entitled "The Conflict of Interest and Financial Disclosure Requirements SOP" (the "Conflict of Interest SOP"), **ABC** shall perform its own investigator conflict of interest analysis under its relevant policies, and as part of the information provided to the Central IRB under the Reliance SOP and Section II.2(b) of this Agreement shall include:

i. A report of any investigator financial conflict of interest determination ("FCOI Report") made by **ABC** according to the Public Health Service regulations on Promoting Objectivity in Research, 42 CFR Part 50, Subpart F (the "Public Health Service Regulations");
ii. Any additional information pertaining to the nature and management of reported FCOIs that is specified in 42 CFR § 50.605(b)(3), or that is required by the Central IRB, or that **ABC** has determined to be necessary to address financial interests of its investigators relating to the Clinical Study.

The Central IRB will have the authority to impose additional prohibitions or conflict management requirements, including any requirements of the funding entity or entities, that are more stringent or restrictive than what **ABC** has implemented and that are necessary for the Central IRB to approve the Clinical Study. Absent extraordinary circumstances, the Central IRB will not disapprove prohibitions or conflict management requirements of **ABC** that are more stringent or restrictive than what the Central IRB requires. **ABC** will provide to the Central IRB, and will require its investigators to cooperate with any request for, further information deemed necessary by the Central IRB for these determinations. The Central IRB will apply its standard policies regarding confidentiality of review information to disclosures and other information submitted to it regarding conflicts of interest.

c. In connection with each Clinical Study reviewed under this Agreement, and in accordance with the specific requirements and timeframes set forth in the Reliance SOP, **ABC** shall perform its own other local ancillary committee reviews as applicable and required by its policies (such as nursing review, radiation safety, pharmacy and any others), and shall include any relevant requirements or results of such reviews that would affect its conduct of the Clinical Study as part of the information provided to the Central IRB under the Reliance SOP and Section II.2(b) of this Agreement.

d. It shall be the sole responsibility of **ABC** to identify and interpret the requirements of its applicable state or local laws, regulations, policies, and ancillary review processes as are relevant to specific Clinical Studies, and to communicate such requirements to the Central IRB.

5. Notification of Central IRB Decisions; Minutes. The Central IRB (via the NCRI CCC) will notify **ABC** of its review decisions regarding included Clinical Studies, of applicable continuing review deadlines, and of subsequent IRB-reviewed and approved changes in an included Clinical Study affecting **ABC** or affecting all participating Pilot Study Sites, in accordance with the procedures described in the Reliance SOP. Relevant minutes of the Central IRB's meetings pertaining to an included Clinical Study will be made available to a designated official of **ABC** via a secure login-in / password-protected portal on the NEALS website.

6. Acceptance of and Cooperation with Central IRB Decisions; Requests for Protocol Exceptions or Amendments. **ABC** will accept the decisions and requirements of the Central IRB with respect to the Clinical Studies included in this Agreement. **ABC** will also require that its investigators cooperate in the Central IRB's continuing review process and cooperate with all other requirements of the Central IRB and of the NCRI CCC related to this Agreement.

The principal investigator at **ABC** may submit requests to the Central IRB for an amendment or exception to the protocol for a Clinical Study in accordance with the criteria and requirements described in the Reliance SOP. No changes to the research activities shall be initiated by **ABC** or its investigators without prior approval by the Central IRB unless necessary to eliminate apparent immediate hazards to subjects.

IV. Compliance and Commencement of Clinical Studies

1. Compliance Responsibilities of the NEALS Member and Its Investigators. **ABC** shall remain responsible in connection with the Clinical Studies included in this Agreement for its own compliance, and for ensuring compliance by its investigators and research staff (including, but not limited to, physicians, research nurses, coordinators, data managers, or other members of the research team), with:

- the determinations, policies, and procedures of the Central IRB and of NCRI for the NEALS cIRB Pilot (including the SOPs);
- the terms of **ABC**'s OHRP-approved FWA;

- 21 CFR Parts 50, 54, 56, 312, and 812 and 45 CFR Part 46 (collectively, the "Federal Research Regulations"), HIPAA, and all other applicable international, federal, state, and local legal requirements;
- the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"); and
- relevant policies, procedures, and documents of **ABC** for conducting human subject research and for obtaining and complying with requirements of local ancillary committee review as applicable.

ABC is responsible for educating and training its investigators and research staff to perform human subject research, for maintaining documentation of all required training and of up-to-date relevant credentialing and privileging for such individuals (as applicable), and for ensuring that its investigators and research staff are informed of and for requiring compliance with all obligations of cooperation, compliance, and reporting under this Agreement.

Without limiting any of the foregoing, **ABC** will require its principal investigator and any co-investigators overseeing a Clinical Study included in this Agreement to sign the Commitment Statement for Investigators attached as Exhibit A hereto and incorporated by reference herein before commencing the Clinical Study. Copies of signed Commitment Statements shall be maintained at **ABC** and provided to the Central IRB upon request.

2. Commencement of Clinical Studies. **ABC** and its investigators and research staff shall not commence human subject activities on any Clinical Study until the NCRI CCC provides written permission to **ABC** to do so.

3. Enforcement. **ABC** shall institute appropriate local oversight mechanisms to ensure that it can meet its obligations under this Section IV and this Agreement.

V. Obligations Upon Commencement of a Clinical Study

1. Reporting to Central IRB. The standards, time frames and procedures for reporting by Pilot Study Site investigators to the Central IRB of

- unanticipated problems (including adverse events)
- injuries to subjects
- protocol deviations/violations
- changes initiated without prior Central IRB approval to eliminate apparent immediate hazards to subjects
- complaints
- non-compliance and
- cessation of research activities by an investigator or a Pilot Study Site

determined, discovered or learned by them in connection with the conduct of a Clinical Study are set forth in a document entitled "The Central IRB Reporting SOP" (the "Reporting SOP"). It is anticipated that **ABC**'s principal investigator or his/her designee for a Clinical Study will perform the reporting for that study, as outlined in the Reporting SOP. **ABC** will require its investigators to report information on such events occurring in connection with its site to the Central IRB in accordance with the requirements of the Reporting SOP. In any instance in which the **ABC** principal investigator is the subject of the report (for example, apparent non-compliance by the principal investigator), **ABC** will make the report called for by the Reporting SOP through other institutional representatives.

2. Central IRB Determinations and Notifications Regarding Events. The Central IRB will review reports of events provided to it under Section V.1 of this Agreement and the Reporting SOP and, after completion of any investigations conducted by the parties as described in Section V.3, will make determinations regarding such events and any appropriate remedial actions. The Central IRB (via the NCRI CCC,) will notify **ABC**'s principal investigator promptly in writing of:

    - determinations by the Central IRB of unanticipated problems involving risks to subjects or others or serious or continuing non-compliance based on such reports;
    - other unanticipated problems, injuries to subjects, external safety monitoring reports, complaints, and serious or continuing non-compliance first discovered or learned by the Central IRB in connection with the conduct of a Clinical Study by **ABC**;
    - unanticipated problems, injuries to subjects, external safety monitoring reports, complaints, and serious or continuing non-compliance determined, discovered, or learned by the Central IRB in connection with the conduct of the Clinical Study by another Pilot Study Site if such discovery or determination regarding the other site affects subject safety or the conduct of the Clinical Study at all participating Pilot Study Sites; and
    - any suspension or termination of Central IRB approval of an included Clinical Study and of remedial actions required of **ABC** or its investigators by the Central IRB or NCRI CCC in response to any of the events described in Sections V.1 and V.2 of this Agreement.

3. Investigations and Remedial Actions; Cooperation. **ABC** will conduct its own investigations, as necessary, of events described in Sections V.1 and V.2 pertaining to its site or investigators. The Central IRB and NCRI CCC will provide information and reasonable assistance as requested by **ABC** in conducting its investigation. Notwithstanding any investigation conducted by **ABC**, the Central IRB or the NCRI CCC or their designee(s) may conduct, direct, or require additional investigation of such events. **ABC** will cooperate with and require its investigators' cooperation with any inquiry, investigation or audit by the Central IRB, NCRI CCC, NCRI DCC, or any government authority into such events. Such cooperation will include, but is not limited to, providing access to or copies of research records and related information, conferencing or meeting with Central IRB or NCRI CCC or NCRI DCC representatives upon request, permitting reasonable on-site audits of **ABC**'s facilities in accordance with applicable policies of **ABC** for facility and on-site records access, providing copies of any documents or reports furnished to **ABC** by government authorities or provided by government authorities to **ABC**, and helping to carry out and enforce remedial action if reasonably indicated. Such remedial action may include suspension or termination of IRB approval of a Clinical Study or termination of participation by **ABC** or its investigators in designated Clinical Studies or in specific research activities. **ABC** may also take further action where appropriate to deter and remedy deficiencies; however, to the extent there is a conflict between remedial actions sought to be taken by the parties, the more stringent of the remedial actions shall apply. Any findings of fact made by any party in its own investigation shall be shared promptly with the other parties. No party shall be required to share internal communications or reports to the extent such are protected by attorney-client privilege or other applicable privileges.

4. Reports to Sponsors and Oversight Authorities. In the event of any required reporting to sponsors/funding agencies, OHRP, FDA, and/or other oversight authorities of unanticipated problems involving risks to subjects or others, serious or continuing non-compliance, and suspension or termination of IRB approval in connection with the Clinical Studies included in this Agreement, **ABC** and the Central IRB will work together to determine which one of them will make the report. The party making the report will provide the other parties with an opportunity to review and comment on a draft of such report before it is sent to the sponsor/oversight authority, and will copy the other parties' institutional official(s) and designees identified in Section VII.2 of this Agreement on the

final report. Nothing in this Agreement shall prevent any party from making its own additional report to such entities. In such event, the party making the additional report will provide the other parties with an opportunity to review and comment on the draft report before it is sent to the sponsor/oversight authority, and will copy the other parties' institutional official(s) and designees identified in Section VII.2 of this Agreement on the final report.

5. Recordkeeping. **ABC** will instruct its investigators to maintain records of all human subjects research and related activities conducted under this Agreement for at least seven (7) years after completion of the research, and longer if required by law, the sponsor, or **ABC**'s institutional policies. Upon request, **ABC** shall provide a copy of such records to the Central IRB, and to others if legally required.

VI. Termination

1. Term. This Agreement shall become effective on the last date signed below ("Effective Date") and shall continue for the duration of and until the cessation of **ABC**'s participation as a NEALS Member or as a Pilot Study Site, provided that the Agreement is not earlier terminated as provided in Section VI.2 below.

2. Termination. Either Partners, MGH, or BWH, on the one hand, or **ABC**, on the other, may terminate this Agreement for cause upon fourteen (14) days prior written notice to the other party(ies) as provided in Section VII.2. Cause may include, but is not limited to, breach of the Agreement by a party that is not cured to the reasonable satisfaction of the non-breaching party(ies) within said fourteen (14)-day notice period, and in the case of MGH and BWH evidence of material changes in any information provided by **ABC** referenced in Section II.2 of this Agreement. In the event that any party's FWA is threatened, terminated, or expires, or in the case of MGH/BWH if their AAHRPP accreditation status changes, the other party(ies) may terminate the Agreement immediately.

3. Effect of Expiration or Termination; Survival. In the event of any termination of this Agreement, the parties will work together to determine the effect of such termination on any Clinical Study(s) and associated research activities being conducted under the Agreement at the time of termination. In the event of any expiration or termination of this Agreement, **ABC** will remove the Central IRB from the list of designated IRBs on its FWA (if it had included the Central IRB on this list) and will notify the Central IRB (via the NCRI CCC) that this has been done.

   Sections III.3 (paragraphs 3 and 4), III.4(b) (last sentence), IV.1, IV.3, V., VI.3, VII.2, VII.3 and Exhibit A of this Agreement will survive any expiration or termination of the Agreement. Section VII.1 will survive any expiration or termination of the Agreement to the extent specified therein.

VII. Other

1. Insurance. During the term of this Agreement, each party shall maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its respective activities under this Agreement. If such coverage is on a "claims made" basis, then the party shall maintain adequate tail insurance or comparable continuing coverage for three (3) years following expiration or termination of this Agreement. Upon request of another party, each party shall provide a certificate or equivalent documentation of its relevant coverage. If **ABC** is an instrumentality of a state government, documentation that **ABC** has self-funded liability coverage or relies upon the applicable law of its state to limit its liability as an instrumentality of such state government constitutes documentation of coverage hereunder.

2. Notices. Any notices to the undersigned institutional parties required under Section VI.2 of this Agreement or copies of final reports referenced under Section V.4 shall be delivered by hand, by facsimile, by overnight carriers (such as FedEx or UPS), or scanned and emailed, or by first-class mail, postage prepaid and addressed as follows:

If to MGH/BWH/Partners:

Harry W. Orf, Ph.D
Senior Vice President for Research
Massachusetts General Hospital
55 Fruit Street – BUL-2-240E
Boston, MA 02114
Phone: 617-724-9079
Fax: 617-724-3377
E-mail: *horf@partners.org*

with copies to: Daniela Grasso Walker
Sr. Project Manager
Massachusetts General Hospital
Neurological Clinical Research Institute
165 Cambridge St – Suite 600
Boston, MA 02114
Phone: 617-726-0842
E-mail: *dgrasso@partners.org*

and

Maria E. Sundquist
Assistant Director
Partners Human Research Office
116 Huntington Avenue – Suite 1002
Boston, MA 02116
Phone: 617-424-4101
Fax: 617-424-4199
E-mail: *msundquist@partners.org*

and

Paul J. Anderson, M.D., Ph.D.
Chief Academic Officer
Brigham and Women's Hospital
75 Francis Street – SM-6-652B
Boston, MA 02115
Tel: 617-525-1202
Fax: 617-525-1310
E-mail: *panderson@partners.org*

If to **ABC**:

[***List name/degree, title, address, phone, fax number, email; with copies to…***]

3. Miscellaneous. This Agreement may be amended only by a written agreement signed by authorized representatives of all parties. If any provision of this Agreement shall be held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected thereby. The failure of a party to insist upon the performance of any of the terms of this Agreement shall not be construed to be a waiver or relinquishment of any of the terms of the Agreement or of the whole Agreement. All the titles and headings contained in the Agreement are inserted only as a matter of convenience and reference

and do not define, limit, extend, or describe the scope of this Agreement or the intent of any of its provisions. This Agreement is not assignable in whole or in part, and any attempt to do so shall be void.

[The remainder of this page is intentionally left blank.]

The Institutional Officials signing below agree that **ABC** will accept and rely on the review and approval by the Central IRB of Clinical Studies included in this Agreement, according to the terms and conditions set forth herein.

EXECUTED BY AUTHORIZED INSTITUTIONAL OFFICIALS

The Brigham and Women's Hospital, Inc.

_____ Date: _____
Name: Paul J. Anderson, M.D., Ph.D.
Institutional Title: Chief Academic Officer

The General Hospital Corporation d/b/a Massachusetts General Hospital

_____ Date: _____
Name: Harry W. Orf, Ph.D
Institutional Title: Senior Vice President for Research

Partners HealthCare System, Inc.

_____ Date: _____
Name: P. Pearl O'Rourke, M.D.
Institutional Title: Director of Human Research Affairs

INSERT FULL LEGAL NAME OF RELYING ENTITY
E.G., ABC MEDICAL CENTER, INC.

_____ Date: _____
Name:
Institutional Title:

Exhibit A
Commitment Statement for Investigators

As an investigator at **ABC**, I, _____, would like to participate in research for which review and continuing oversight is provided by the Partners Human Research Committee ("Central IRB") as provided in the NEALS IRB Authorization Agreement (the "Agreement") between The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH"), The Brigham and Women's Hospital, Inc. ("BWH"), Partners HealthCare System, Inc. ("Partners") and **INSERT FULL LEGAL NAME OF RELYING ENTITY, E.G., ABC MEDICAL CENTER, INC.** ("**ABC**"). I understand that one of the conditions of my participation in such research is my acknowledgement and acceptance through this Commitment Statement of my responsibilities under the Agreement and applicable laws, regulations, ethical guidelines, and other policies and principles, as described herein. Capitalized terms not defined in this Commitment Statement shall have the meaning ascribed to them in the Agreement.

A. Overview

1. I acknowledge that I have read the Agreement and the Central IRB's and NEALS' SOPs and other policies, procedures, and documents for conducting NEALS research. I understand and hereby accept my responsibilities for satisfying the intent and procedures in these documents and policies, for fully complying with them, and for protecting the rights and welfare of human research subjects involved in research conducted under the Agreement.

2. I will comply with the requirements of **ABC**'s OHRP-approved Federalwide Assurance, the Federal Research Regulations, HIPAA, and any other international, federal, state, or local laws or regulations as they may relate to research covered by the Agreement.

3. I will abide by determinations of the Central IRB and will accept its final authority and decisions. I will further abide by other policies, procedures, and decisions of NEALS and **ABC** as they may apply.

B. Reporting

1. I will report to the Central IRB proposed changes in research activities under the Agreement in accordance with the requirements described in the Central IRB / NCRI Reliance SOP. No changes shall be initiated without prior Central IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.

2. I will report to the Central IRB unanticipated problems, subject injuries, protocol deviations/violations, complaints, non-compliance and cessation of research activities as contemplated in the Agreement and in accordance with the Central IRB / NCRI Reporting SOP.

C. Other Responsibilities

1. A designated principal investigator for **ABC** ("Site Principal Investigator") will assume overall administrative responsibility for all aspects of each research study approved under the Agreement.

2. I will attend any training and educational sessions required by **ABC** or the NCRI CCC before conducting any research under the Agreement. I will attend other educational and training sessions that **ABC** deems appropriate and will be responsible for reviewing updated information from **ABC**, the NCRI CCC and the Central IRB regarding the conduct of research under the Agreement.

3. I understand that the Central IRB and NEALS have designated documents and procedures for conducting and reviewing research under the Agreement, and I agree to use/follow such documents and procedures, unless both **ABC** and the NCRI CCC specifically agree otherwise before the Central IRB reviews and approves the research.

4. Except where informed consent and HIPAA authorization have been formally waived by the Central IRB, I will seek, document, and maintain records of informed consent and HIPAA authorization from each prospective subject or his or her legally authorized representative as required by applicable federal regulations.

5. I acknowledge and agree to cooperate in the Central IRB's responsibility for initial and continuing IRB reviews and approvals, record keeping, reporting, and certification. I will timely provide all necessary information for progress reports used in the Central IRB's continuing review process. I will maintain records of all human subjects research and related activities conducted under the Agreement for at least seven (7) years after completion of the research, and longer if required by law, by the sponsor, or by **ABC**'s policies.

6. I will provide the Central IRB, the NCRI CCC, the NCRI DCC, and **ABC** with all information that they deem appropriate to assist them in carrying out their responsibilities under the Agreement, including but not limited to my name, the study/ies in which I am participating, the name of the Site Principal Investigator for the study/ies, the start and end dates of the study/ies, and pertinent study records.

7. I will communicate constructively with representatives of the Central IRB, the NCRI CCC, the NCRI DCC, and **ABC**, with other investigators, and with human subjects as a means of maintaining a high level of awareness regarding the protection of the rights and welfare of the subjects.

8. If I conduct research under the Agreement involving an investigational new drug, biologic or device subject to FDA regulations I will comply with all investigator (or investigator-sponsor, if appropriate) responsibilities described in 21 CFR Parts 312 and 812 or successor provisions.

9. I will not commence human subject activities on any study under the Agreement until the NCRI CCC provides written permission to **ABC** to do so. Provision of any emergency medical care without prior full board review is permitted under applicable federal regulations. However, research data may not be used from such interventions.

10. I will cooperate with any inquiry by the Central IRB, the NCRI CCC, the NCRI DCC, their designees, or any government authority into research compliance in a study in which I participate under the Agreement, including but not limited to providing research records and related information and conferencing or meeting with Central IRB / NCRI CCC / NCRI DCC research representatives upon request. In the event I am deemed to have failed to comply with the Agreement, I agree to take action(s) that the Central IRB, NCRI, the NCRI DCC and **ABC** deem appropriate, including but not limited to termination of my participation in designated research activities.

I understand that it is my personal responsibility to abide by the Federal Research Regulations, HIPAA, research billing requirements, applicable state and local laws, applicable Central IRB / NEALS and **ABC** policies, and this Commitment Statement and the Agreement, and that in the event of serious or continuing non-compliance with any of these requirements, **ABC** and/or the Central IRB may report such non-compliance to OHRP, other federal departments or agencies that sponsor the research or have jurisdiction over it (such as the FDA), the sponsor of the research, and institutional officials as

appropriate. I understand that my primary responsibility is to the well-being of research subjects and that their interests take precedence to the research.

Investigator Signature:_____ Date:_____

Name:_____

Title:_____

Address:_____

_____

_____

Phone:_____

Fax: _____

Receipt of signed Commitment Statement acknowledged by:

INSERT FULL LEGAL NAME OF RELYING ENTITY
E.G., ABC MEDICAL CENTER, INC.

By:_____ Date of receipt:_____

Name:_____

Title:_____