RESOLUTION AGREEMENT

I. Recitals

- 1. Parties. The Parties to this Resolution Agreement ("Agreement") are:
- A. The United States Department of Health and Human Services, Office for Civil Rights ("HHS"), which enforces the Federal standards that govern the privacy of individually identifiable health information (45 C.F.R. Part 160 and Subparts A and E of Part 164, the "Privacy Rule"), the Federal standards that govern the security of electronic individually identifiable health information (45 C.F.R. Part 160 and Subparts A and C of Part 164, the "Security Rule"), and the Federal standards for notification in the case of breach of unsecured protected health information (45 C.F.R. Part 160 and Subparts A and D of 45 C.F.R. Part 164, the "Breach Notification Rule"). HHS has the authority to conduct compliance reviews and investigations of complaints alleging violations of the Privacy, Security, and Breach Notification Rules (the "HIPAA Rules") by covered entities and business associates, and covered entities and business associates must cooperate with HHS compliance reviews and investigations. See 45 C.F.R. §§ 160.306(c), 160.308, and 160.310(b).
- B. The Brigham and Women's Hospital, Inc. ("BWH"), which is a covered entity, as defined at 45 C.F.R. § 160.103, and therefore is required to comply with the HIPAA Rules. BWH is a major teaching hospital of Harvard Medical School. BWH is part of Brigham and Women's Health—which includes 150 outpatient practices with over 1,200 physicians.

HHS and BWH shall together be referred to herein as the "Parties."

2. Factual Background and Covered Conduct.

On January 26, 2015, HHS initiated a compliance review of BWH based on information contained in a *Boston Globe* article dated January 12, 2015. The article indicated BWH permitted ABC News to film a medical documentary program at BWH. On February 13, 2015, HHS notified BWH of HHS' review of BWH's compliance with the Privacy Rule. Prior to the filming, which took place from October 2014 to January 2015, BWH reviewed and assessed patient privacy issues related to the filming and implemented various protections regarding patient privacy, including providing the ABC film crew with the same HIPAA privacy training received by BWH's workforce.

However, despite such efforts, HHS's investigation indicated that the following conduct occurred ("Covered Conduct")

A. Based on the timing of when BWH received some written patient authorizations, BWH impermissibly disclosed the PHI of patients to ABC employees during the production and filming of a television program at BWH (See 45 C.F.R. § 164.502(a)).

- B. Despite the various patient privacy protections that were put in place by BWH, BWH failed to appropriately and reasonably safeguard its patients' PHI from disclosure during a filming project conducted by ABC on its premises in 2014 and January 2015. (See 45 C.F.R. § 164.530(c)).
- 3. No Admission. This Agreement is not an admission of liability by BWH.
- 4. No Concession. This Agreement is not a concession by HHS that BWH is not in violation of the HIPAA Rules and not liable for civil money penalties.
- 5. <u>Intention of Parties to Effect Resolution</u>. This Agreement is intended to resolve HHS Transaction Number: 15-202247 and any violations of the HIPAA Rules related to the Covered Conduct specified in paragraph 1.2 of this Agreement. In consideration of the Parties' interest in avoiding the uncertainty, burden, and expense of formal proceedings, the Parties agree to resolve this matter according to the Terms and Conditions below.

II. Terms and Conditions

- 6. <u>Payment</u>. HHS has agreed to accept, and BWH has agreed to pay HHS, the amount of \$384,000.00 ("Resolution Amount"). BWH agrees to pay the Resolution Amount on the Effective Date of this Agreement as defined in paragraph II.14 by automated clearing house transaction pursuant to written instructions to be provided by HHS.
- 7. Corrective Action Plan. BWH has entered into and agrees to comply with the Corrective Action Plan ("CAP"), attached as Appendix A, which is incorporated into this Agreement by reference. If BWH breaches the CAP, and fails to cure the breach as set forth in the CAP, then BWH will be in breach of this Agreement and HHS will not be subject to the Release set forth in paragraph II.8 of this Agreement.
- 8. Release by HHS. In consideration of and conditioned upon BWH's performance of its obligations under this Agreement, HHS releases BWH from any actions it may have against BWH under the HIPAA Rules arising out of or related to the Covered Conduct identified in paragraph 1.2 of this Agreement. HHS does not release BWH from, nor waive any rights, obligations, or causes of action other than those arising out of or related to the Covered Conduct and referred to in this paragraph. This release does not extend to actions that may be brought under section 1177 of the Social Security Act, 42 U.S.C. § 1320d-6.
- 9. Agreement by Released Parties. BWH shall not contest the validity of its obligation to pay, nor the amount of, the Resolution Amount or any other obligations agreed to under this Agreement. BWH waives all procedural rights granted under Section 1128A of the Social Security Act (42 U.S.C. § 1320a-7a) and 45 C.F.R. Part 160 Subpart E, and HHS claims collection regulations at 45 C.F.R. Part 30, including, but not limited to, notice, hearing, and appeal with respect to the Resolution Amount.
- 10. <u>Binding on Successors</u>. This Agreement is binding on BWH and its successors, heirs, transferees, and assigns.

- 11. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 12. No Additional Releases. This Agreement is intended to be for the benefit of the Parties only and by this instrument the Parties do not release any claims against or by any other person or entity.
- 13. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.
- 14. Execution of Agreement and Effective Date. The Agreement shall become effective (i.e., final and binding) upon the date of signing of this Agreement and the CAP by the last signatory (Effective Date).
- 15. Tolling of Statute of Limitations. Pursuant to 42 U.S.C. § 1320a-7a(c)(1), a civil money penalty ("CMP") must be imposed within six years from the date of the occurrence of the violation. To ensure that this six-year period does not expire during the term of this Agreement, BWH agrees that the time between the Effective Date of this Agreement and the date the Agreement may be terminated by reason of BWH's breach, plus one-year thereafter, will not be included in calculating the six (6) year statute of limitations applicable to the violations which are the subject of this Agreement. BWH waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the covered conduct identified in paragraph I.2 that is filed by HHS within the time period set forth above, except to the extent that such defenses would have been available had an administrative action been filed on the Effective Date of this Agreement.
- 16. <u>Disclosure</u>. HHS places no restriction on the publication of the Agreement. In addition, HHS may be required to disclose material related to this Agreement to any person upon request consistent with the applicable provisions of the Freedom of Information Act, 5 U.S.C. § 552, and its implementing regulations, 45 C.F.R. Part 5.
- 17. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
- 18. <u>Authorizations</u>. The individual(s) signing this Agreement on behalf of BWH represent and warrant that they are authorized by BWH to execute this Agreement. The individual(s) signing this Agreement on behalf of HHS represent and warrant that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

For The Brigham and Women's Hospital, Inc.

| Elizza GNasel | 1/6/18 |
|---------------------|--------|
| Elizabeth Mabel, MD | Date |
| President | |

For Department of Health and Human Services

Susan M. Pezzullo Rhodes, Regional Manager Office for Civil Rights, New England Region

Date

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Appendix A

CORRECTIVE ACTION PLAN

BETWEEN THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

THE BRIGHAM AND WOMEN'S HOSPITAL, INC.

I. Preamble

The Brigham and Women's Hospital, Inc. (hereinafter known as "BWH") hereby enters into this Corrective Action Plan ("CAP") with the United States Department of Health and Human Services, Office for Civil Rights ("HHS"). Contemporaneously with this CAP, BWH is entering into a Resolution Agreement ("Agreement") with HHS, and this CAP is incorporated by reference into the Resolution Agreement as Appendix A. BWH enters into this CAP as part of consideration for the release set forth in paragraph II.8 of the Agreement.

II. Contact Persons and Submissions

A. Contact Persons

BWH has identified the following individuals as authorized representatives and contact persons regarding the implementation of this CAP and for receipt and submission of notifications and reports:

Debra Torosian HIM Director and Privacy Officer The Brigham and Women's Hospital, Inc. 1153 Centre Street Boston, MA 02130

and

Robert G. Martin
Senior Legal Counsel
Partners HealthCare System, Inc.
Office of the General Counsel
399 Revolution Drive, Ste 660
Somerville, MA 02145

HHS has identified the following individual as its authorized representative and contact person with whom BWH is to report information regarding the implementation of this CAP:

Susan M. Pezzulio Rhodes, Regional Manager Office for Civil Rights, New England Region U.S. Department of Health and Human Services JFK Federal Building, Room 1875
Boston, MA 02203

Email: susan.rhodes@hhs.gov Telephone: (617) 565-1347 Facsimile: (617) 565-3809

BWH and HHS agree to promptly notify each other of any changes in the contact persons or the other information provided above.

B. Proof of Submissions.

Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, including certified mail, overnight mail, or hand delivery, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

III. Effective Date and Term of CAP

The Effective Date for this CAP shall be calculated in accordance with paragraph II.14 of the Agreement ("Effective Date"). The period for compliance ("Compliance Term") with the obligations assumed by BWH under this CAP shall begin on the Effective Date of this CAP and end on the date HHS approves the Implementation Report specified at paragraph VI unless HHS has notified BWH under section VIII hereof of its determination that BWH breached this CAP. In the event of such a notification by HHS under Section VIII hereof, the Compliance Term shall not end until HHS notifies BWH. Except that after the Compliance Term ends, BWH shall still be obligated to comply with the document retention requirement in section VII.

IV. Time

In computing any period of time prescribed or allowed by this CAP, all days referred to shall be calendar days. The day of the act, event, or default from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day which is not one of the aforementioned days.

V. Corrective Action Obligations

BWH agrees to the following:

A. Policies and Procedures

- 1. BWH shall develop, maintain, and revise as necessary, its written policies and procedures to address the Covered Conduct specified in paragraph I.2 of the Agreement to comply with the Federal standards that govern the privacy and security of individually identifiable health information (45 C.F.R. Parts 160 and 164, Subparts A, C, and E, the Privacy and Security Rules) (collectively "Policies and Procedures"). BWH's Policies and Procedures shall include, but not be limited to, the minimum content set forth below:
- a. A specific prohibition on the use or disclosure of PHI for photography, video recording, or audio recording, that is not otherwise permitted or required by the Privacy Rule and HHS Guidance, before a valid authorization is obtained from the patient who is the subject of the PHI sought to be disclosed or his or her representative.
- b. A process for evaluating and approving any requests from the media to film on BWH's facilities in areas that are not otherwise generally accessible to the public (i) to ensure that appropriate safeguards are in place to protect against impermissible uses or disclosures of PHI and incidental disclosures of PHI and (ii) to ensure that BWH obtains a compliant authorization from each individual whose PHI may be accessible to the media, before allowing third parties to have access to patients' PHI and treatment areas or other areas of BWH where PHI will be accessible in written, electronic, oral, or other visual or audio form.
- c. Identification of BWH personnel or representatives who workforce members, agents, or business associates may contact in the event of any inquiry or concern regarding compliance with HIPAA in relation to these activities.
- d. A requirement that a BWH workforce member actively monitor all photography, video recording, and audio recording conducted on BWH's facilities by the media, in areas that are not otherwise generally accessible to the public, for purposes not related to medical treatment or a health care operation to ensure compliance with the Privacy Rule and BWH Policies and Procedures.
- e. Internal reporting procedures requiring all workforce members to report to the designated person or office at the earliest possible time any violations of the Policies and Procedures. Such procedures shall require BWH to promptly investigate and address all reports received in a timely manner.
- f. Application of appropriate sanctions (which may include retraining or other instructive corrective action, depending on the circumstances) against members of BWH's workforce, including supervisors and managers who fail to comply with the Policies and Procedures.
- 2. BWH shall provide such Policies and Procedures to HHS within 60 days of the Effective Date for review and approval. Upon receiving any recommended changes to such Policies and Procedures from HHS, BWH shall have 60 days to revise such Policies and Procedures accordingly and provide the revised Policies and Procedures to HHS for review and approval.

3. BWH shall, in accordance with BWH's applicable administrative procedures, finalize and officially adopt the Policies and Procedures within 90 days of receipt of HHS' approval.

B. Distribution and Updating of Policies and Procedures

- 1. BWH shall distribute, in accordance with BWH's applicable administrative procedures, the Policies and Procedures identified in section V.A. to all members of the workforce within 90 days of HHS approval of such Policies and Procedures, and to new members of the workforce within 30 days of their beginning of service. After the Policies and Procedures are finalized and adopted per section V.A.3, all workforce members will receive training on the Policies and Procedures as part of orientation training for new members of the workforce and as part of annual training for all workforce members, at the subsequent regularly scheduled rollouts of new annual training and orientation training, pursuant to BWH's applicable administrative procedures.
- 2. BWH shall assess, update, and revise, as necessary, the Policies and Procedures identified in section V.A. at least annually (and more frequently if appropriate).

C. Reportable Events.

During the Compliance Term, BWH shall, upon receiving information that a workforce member may have failed to comply with its Policies and Procedures, as approved per section V.A.3., promptly investigate this matter. If BWH determines, after review and investigation, that a member of its workforce has failed to comply with the Policies and Procedures approved by HHS under section V.A.3, BWH shall report such events to HHS as provided in section VI.A.5. Such violations shall be known as Reportable Events. The report to HHS shall include the following information:

- 1. A complete description of the event, including the relevant facts, the persons involved, and the provision(s) of the Policies and Procedures implicated; and
- 2. A description of the actions taken and any further steps BWH plans to take to address the matter to mitigate any harm, and to prevent it from recurring, including application of appropriate sanctions against workforce members who failed to comply with the Policies and procedures as approved per section V.A.3.

D. Training

1. All members of BWH's workforce whose job function involves reviewing and approving any access or filming by media, who work with the media, including BWH's Privacy Officer, BWH's Security Officer, and members of BWH's Office of General Counsel, shall receive training on BWH's Policies and Procedures, including the specific items referenced in section V.A, within 90 days of the implementation of the Policies and Procedures, or within 60 days of when they become a member of the workforce of BWH.

- 2. At a minimum, training shall cover all of the topics that are necessary and appropriate for each member of the workforce identified in paragraph V.D.1 to carry out that workforce member's function within BWH.
- 3. Each workforce member identified in paragraph V.D.1 shall certify, in electronic or written form, that he or she has received and understands the required training. The training certification shall specify the date on which training was received. All course materials shall be retained in compliance with section VII.
- 4. BWH shall review the training at least annually, and, where appropriate, update the training to reflect changes in Federal law or HHS guidance, any issues discovered during internal or external audits or reviews, and any other relevant developments.
- 5. BWH shall not provide access to PHI to any workforce member identified in paragraph V.D.1 if, after the applicable timeframe in paragraph V.D.1 has expired, that workforce member has not signed or provided the written or electronic certification required by paragraph V.D.3.

VI. Implementation Report

- A. <u>Implementation Report</u>. Within 120 days after the receipt of HHS' approval of the policies and procedures required by section V.A., BWH shall submit a written report to HHS summarizing the status of its implementation of the requirements of this CAP. This report, known as the "Implementation Report," shall include:
- 1. An attestation signed by an owner or officer of BWH attesting that the Policies and Procedures are being implemented, and have been distributed to all appropriate members of the workforce;
- 2. A copy of all training materials used for the training required by this CAP, a description of the training, including a summary of the topics covered, the length of the session(s) and a schedule of when the training session(s) were held:
- 3. An attestation signed by an owner or officer of BWH attesting that applicable members of the workforce have completed the initial training required by this CAP and have executed the training certifications required by section V.D.3.;
- 4. An attestation signed by an owner or officer of BWH attesting that BWH has complied with the obligations of this CAP;
- 5. A summary of Reportable Events (defined in section V.C) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events; and

6. An attestation signed by an owner or officer of BWH stating that he or she has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VII. Document Retention

BWH shall maintain for inspection and copying, and shall provide to HHS, upon request, all documents and records relating to compliance with this CAP for six (6) years from the Effective Date.

VIII. Breach Provisions

BWH is expected to fully and timely comply with all provisions contained in this CAP.

A. Timely Written Requests for Extensions

BWH may, in advance of any due date set forth in this CAP, submit a timely written request for an extension of time to perform any act required by this CAP. A "timely written request" is defined as a request in writing received by HHS at least ten (10) days prior to the date such an act is required or due to be performed.

B. Notice of Breach of this CAP and Intent to Impose Civil Monetary Penalty.

The parties agree that a breach of this CAP by BWH constitutes a breach of the Agreement. Upon a determination by HHS that BWH has breached this CAP, HHS may notify BWH of: (1) BWH's breach; and (2) HHS' intent to impose a civil money penalty ("CMP") pursuant to 45 C.F.R. Part 160, or other remedies for the Covered Conduct set forth in paragraph I.2 of the Agreement and any other conduct that constitutes a violation of the HIPAA Privacy, Security, or Breach Notification Rules ("Notice of Breach and Intent to Impose CMP").

C. BWH's Response.

BWH shall have 60 days from the date of receipt of the Notice of Breach and Intent to Impose CMP to demonstrate to HHS' satisfaction that:

- 1. BWH is in compliance with the obligations of the CAP that HHS cited as the basis for the breach:
 - 2. The alleged breach has been cured; or
 - 3. The alleged breach cannot be cured within the 60-day period, but that:
 - (a) BWH has begun to take action to cure the breach;
 - (b) BWH is pursuing such action with due diligence; and

(c) BWH has provided to HHS a reasonable timetable for curing the breach.

D. Imposition of CMP.

If at the conclusion of the 60-day period, BWH fails to meet the requirements of section VIII.C. of this CAP to HHS' satisfaction, HHS may proceed with the imposition of a CMP against BWH pursuant to 45 C.F.R. Part 160 for any violations of the Covered Conduct set forth in paragraph 1.2 of the Agreement and for any other act or failure to act that constitutes a violation of the HIPAA Rules. HHS shall notify BWH in writing of its determination to proceed with the imposition of a CMP.

For The Brigham and Women's Hospital, Inc.

Elizabeth Nabel MD

President

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Date

For Department of Health and Human Services

Sue Angullo Parelio Susan M. Pezzullo Rhodes, Regional Manager

Office for Civil Rights, New England Region

9/6/18 Date