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It starts with **you**.
And ends with benefits for your patients.
Joint replacement by the numbers:

Hospital participation is the key.

To meet our goal of capturing 90% of all adult hip and knee arthroplasties, the AJRR needs participation from as many hospital sites as possible. As an AJRR participant, you benefit from a completely objective, evidence-based measure of total joint performance and survivorship, including information focused on continuous quality improvement.

AJRR participation by state:
Over 750,000 knee and hip replacements are performed each year in the U.S. — up to 12% of these procedures may face future revision.

Joint registries have demonstrated up to a 50% reduction in revision rates after registry initiation.

If the U.S. revision rate were cut by just 2%, we could realize savings of over $65 million.

The AJRR has a simple, straightforward process for hospitals to contribute data on primary and revision hip and knee arthroplasties to the registry. The process involves documenting procedures in your hospital’s electronic medical record system, then submitting results through AJRR’s secure online portal.

The AJRR converts and compiles data into its own aggregate format, and produces comparative reports individualized by hospital site, surgeon, procedure, implant, manufacturer, or other value-added criteria.

Initially, the AJRR is gathering Level I data (the minimum amount of patient, procedural and implant data) from hospitals, but the registry will soon expand to include Level II, Level III, and Level IV data.

A menu of reporting options is available from general (aggregate) reports on procedures, survivorship, and patient demographics to customized reports that offer detailed, value-added information.

Learn more today: www.ajrr.net
The success of the American Joint Replacement Registry places these results within our reach. So better outcomes depend on you.

Invaluable benefits to patients, surgeons and hospitals.

More than a data repository, the AJRR provides a wide range of actionable information and reporting that helps improve patient care and hospital management.

- **Improved patient follow-up and intervention.** The AJRR helps orthopaedic surgeons identify patients who need follow-up evaluation, and when—increasing patient safety and quality of care.

- **Informed clinical decision-making.** The registry provides up-to-the-minute performance data to help orthopaedic surgeons and hospitals make fully-informed decisions on procedures and implants.

- **Better quality control.** Site-specific performance reports from the AJRR are designed to help hospitals identify potential cost-savings, and improve overall quality and patient safety.

- **Early detection and an improved product.** Comparative reports provide a comprehensive and independent method for manufacturers to evaluate and track performance throughout a product’s lifecycle.

- **Increased leverage with payers.** The registry helps surgeons and hospital sites gain leverage with payers by providing objective, evidence-based support for clinical decision-making.
Critical choices should be well informed.

The increasing awareness of total joint replacement procedures, product recalls, and the pace of problem identification have placed a significant burden on orthopaedic surgeons and hospitals. **Your choices today are critical to ensuring a favorable outcome.**

The American Joint Replacement Registry (AJRR) is a not-for-profit organization that enhances patient safety, improves the quality of care, and helps reduce the cost of care. Modeled on similar, successful programs in other countries, the AJRR was established as a collaboration between orthopaedic surgeons, implant manufacturers, payers, medical societies, and other organizations.
The goal of the AJRR is simple, but critical:

to collect data on total joint replacement primary and
revision procedures in the U.S.—and use evidence-based
performance and survivorship data to improve the
quality of care.

Speak to your hospital administrators about
the importance and benefits of tracking joint
replacement procedures for everyone involved.

Sign up to lead AJRR data collection
efforts at your hospital.

Encourage your colleagues and
administrators at affiliated hospitals to participate
in the AJRR.

It all starts with you—so get
started today. www.ajrr.net

Register    Report    Results

better outcomes
WHAT IS THE AJRR?

The American Joint Replacement Registry (AJRR) is a multi-stakeholder, independent, not-for-profit organization with diverse national constituents. The AJRR’s goal is to optimize patient outcomes through collection of data on all primary and revision total joint replacement procedures in the U.S. The mission of the registry is to enhance patient safety, improve quality of care, and reduce the cost of care.

We do not know all of the factors that influence the success of a total joint replacement. The AJRR includes all patient types, not just Medicare. With an estimated 90 percent capture rate, the registry will provide more comprehensive orthopaedic knowledge have the potential to identify problems before they are discovered by public health agencies. More than a data repository, the AJRR provides a wide range of actionable information and reporting that helps improve patient care and hospital management. The AJRR will specifically help with:

- Improved patient follow-up and intervention
- Informed clinical decision-making
- Better quality control
- Early detection and an improved product
- Increased leverage with payers

CURRENT GOALS

- Eliminate need for manual data entry at hospitals through electronic interfaces
- Expand registry staff to accelerate hospital enrollment to expand the number institutions reporting data
- Finalize and complete AJRR policies and procedures for data reporting to leverage input from the multi-stakeholder AJRR community
- Engage governmental agencies, medical societies and the Public Advisory Board to ensure the AJRR remains current in the requirements to and goals of improving patient outcomes

AJRR MILESTONES

In 2009 the American Academy of Orthopaedic Surgeons (AAOS) and industry leaders approved conceptual and financial support for the AJRR.

- May 2009 – Kick-off meeting held in New York
- June 2009 – AJRR officially incorporated as a Not For Profit organization
- June 2009 – Obtained independent Institutional Review Board (IRB) approval, waiver of informed consent and HIPAA waiver of authorization certifications
- September 2009 – Workgroups formed
- February 2010 – AJRR board ratified by the AAOS
- November 2010 – AJRR received 501 (c)(3) status
- December 2010 – Business Plan finalized and approved by Board of Directors
- March 2011 – Initiated pilot program involving 15 diverse pilot hospital sites
- March - July 2011 – Successful data transmission and collection from pilot sites
- July 2011 – Completed data trial, lessons learned and review

JOINT REPLACEMENT BY THE NUMBERS

- Over 750,000 knee and hip replacements are performed each year in the U.S. Up to 12% of these procedures may face future revision.
- Joint registries have demonstrated up to a 50% reduction in revision rates after registry initiation and identification of best practices.
- If the U.S. revision rate were cut by just 2%, Medicare could realize savings of over $65 million.
AJRR Board of Directors

David G. Lewallen, MD, Chairman, Mayo Clinic
William J. Maloney, MD, Vice-Chairman, Stanford Hospital & Clinics
Thomas C. Barber, MD, Kaiser Permanente
Kevin J. Bozic, MD, MBA, University of California San Francisco
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E. Anthony Rankin, MD, Providence Hospital
Eric Rugo, MBA, Stryker Orthopaedics
Steven H. Stern, MD, United Healthcare
Patience H. White, MD, MA, Arthritis Foundation

AJRR Staff

Caryn D. Etkin, PhD, MPH, Director of Research
Susan E. Hobson, MPH, Research Associate
Jeffrey P. Knezovich, CAE, Executive Director
Randolph R. Meinzer, Director of Information Technology
Steven Hamada, Senior Software Engineer
Hannelore Venable, Administrative Assistant
Currently the AJRR is collecting Level I data

**Patient-related data**
- Name (Last, First)
- Date of Birth
- Social Security Number
- Diagnosis (ICD-9 or ICD-10)
- Gender
- Race/Ethnicity *(optional)*

**Hospital-related data**
- Name
- Address
- Hospital NPI

**Surgeon-related data**
- Name
- Surgeon NPI

**Procedure-related data**
- Type (ICD-9)
- Date of Surgery
- Laterality
- Implants

It is the goal of the AJRR to enable its software to accept Level II, Level III and Level IV data in early 2013.

**Level II**
e.g., Patient risk factors/co-morbidities (ICD-9), PQRI measures, surgical approaches, prophylaxis, ASA score

**Level III**
e.g., SF-12, SF-36, HOOS, KOOS, WOMAC, Oxford Hip and Knee Scores, Knee Society Knee Scoring System, Harris Hip Score, AAOS Hip and Knee Core Scale

**Level IV**
Radiographic Images
Hospital Staff Roles

Surgeon Champion

What is a surgeon champion?
A surgeon champion is an orthopaedic surgeon at your institution who will:
• Promote the AJRR to institutional stakeholders;
• Assist in educating local staff and surgeon colleagues about the importance of the national registry to improve patient care;
• Provide ongoing feedback to the AJRR to assist in improving and evolving the information used to analyze outcomes;
• In partnership with administration, appoint a staff champion to work with the AJRR.

Why participate in the AJRR?
As surgeons, you are interested in improving patient care and reducing your revision rates. The AJRR will serve as the national database for tracking revisions and providing surgeons with valuable annual reports they can use to compare their performance to their peers on both the local and national levels.

Staff Champion

What is a staff champion?
A staff champion can be any employee at your institution involved with orthopaedic procedures who:
• Serves as the contact point for the AJRR;
• Works with the local institution to facilitate agreement signoff;
• Coordinates the list of users;
• Coordinates the training;
• Becomes the AJRR expert at the site;
• Provides feedback to the AJRR in relation to how the site is doing with data entry, any issues, etc.

Essentially, the staff champion is responsible for guiding the AJRR cause and enrollment process throughout the hospital.
Surgical Department

Why participate in the AJRR?
The AJRR is committed to finding the best ways to tap into data already being captured in the operating room and in your Electronic Medical Record (EMR) system. Any additional data points that have to be manually entered are of the utmost value to the surgeon and the hospital for upholding quality and tracking revisions. The AJRR values your time and attention to detail. The goal is to seamlessly integrate into your workflow and draw as much data as possible from already existing sources.

Your role in the AJRR
Depending on how your institution wishes to contribute information to the AJRR, you may:
• Assist in entering data into the AJRR web form;
• Collect data to be entered by other staff members;
• Assist in training participants.

Legal

Why participate in the AJRR?
As the hospital legal representative, you are interested in knowing how the AJRR will protect your patients’ privacy. You may also be interested in our agreements and ensuring that they address federal and local requirements for privacy. By participating in the AJRR, you are facilitating your hospital’s ability to measure outcomes related to total joint replacement resulting in improved patient care.

Your role in the AJRR
• Review the Business Associate Agreement (BAA) and Participation Agreement;
• Work with administration to ensure that local concerns are addressed;
• Provide feedback to the AJRR for legal discussions;
• Ensure that the appropriate institutional signatures are provided;
• Ensure that the appropriate institutional staff has reviewed the AJRR information.

AJRR Note
AJRR legal agreements cannot be modified on a per hospital basis. As the AJRR will be involved with hundreds and potentially thousands of hospitals, it is not feasible for us to manage individualized agreements. Along these lines, we are not able to sign individual hospital agreements.

The AJRR does accept comments on our agreements. Comments on agreements will be reviewed and updated by legal counsel on an annual basis to address hospital concerns.
Hospital Staff Roles

Risk Managers

Why participate in the AJRR?
As a hospital risk manager, you are interested in knowing how the AJRR will protect the data, especially Protected Health Information (PHI). The AJRR has the appropriate systems and processes in place to address all federal and local regulations from Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology (HITECH) perspectives.

Your role in the AJRR
• Possibly serve as a member of the agreement review team;
• Review AJRR White Papers on privacy and security;
• Work with the local institution to review elements of the AJRR data acquisition process;
• Review the AJRR policies and procedures for data transparency.

IT Professionals

Why participate in the AJRR?
As an IT professional, you are interested in knowing how the AJRR will collect data from your hospital without disrupting the systems already in place. The AJRR is committed to gathering data using the least invasive process. The easiest technique is to interface directly with your EMR system and pull data directly from the source. This will help your administrators avoid duplicative efforts and reduce error rates when submitting data. As the AJRR expands to capture Level II and III data, your hospital will be able to track outcomes and truly measure how patient care is being improved.

Your role in the AJRR
• Act as “IT Champion” at your hospital;
• Review AJRR privacy and security provisions;
• Provide feedback to the AJRR on automated data submission;
• Assist in the development of automated interfaces to the AJRR to minimize the burden on clinical staff.
Hospital Staff Roles

Hospital Administration

Why participate in the AJRR?
As hospital administrators, you are interested in improving quality through the use of objective measures. Key to any improvement process is establishing those measures which indicate progress toward your goals. What a better way to improve quality than by reducing the number of revisions at your hospital? AJRR annual data reports will allow you to do so with ease. As the AJRR begins to collect Level II and III data, your hospital will be able to track outcomes and truly measure how patient care is being improved upon. The national data set that AJRR is building will be able to provide you with the reports you need to get the job done.

Your role in the AJRR
Depending on your institution’s process, you may be involved with the BAA and Participation Agreement signoff. The AJRR appreciates your ongoing support for our national effort along with your colleagues and other interested parties.

Clinical Researchers

Why participate in the AJRR?
As clinical researchers, you are interested in using AJRR national data to support your studies. The AJRR will serve as the data system for tracking revisions nationally. The AJRR provides clinical researchers with valuable reports which they can use to compare with other data sets or to use in a local research project or study.

Your role in the AJRR
• Be a candidate for staff champion;
• Facilitate data submission to the AJRR working with your management to identify the least invasive method for data submission;
• Provide feedback to the AJRR on report formats, data entry validation, and error proofing the data entry system.

Once the AJRR begins collecting Level II and III data, hospital staff involved with the AJRR will have access to more detailed, custom reports that will allow them to view patients’ successes over their lifetime. What a better way to study outcomes than by measuring them against the national sampling. AJRR will put all of the information into simple reports that staff can use to compare with or supplement data at the local or national level, show improved quality of care, and reduced revision rates.
Frequently Asked Questions

General

Q. What is the goal of the AJRR?
A. The goal of the AJRR is to collect Level I Data Elements (see Level I Data Elements Definitions on page 19) from as many hospitals as possible to create survivorship curves and track revisions to improve quality.

Q. How is the AJRR funded?
A. The AJRR receives private support from its many stakeholders (surgeons, orthopedic societies, industry, hospitals, payers, and the public at large). For a complete list of donors, please visit the AJRR website www.ajrr.net and click on “Contributors”.

Q. What is the economic incentive to participate?
A. Other national joint replacement registries such as the Swedish Hip Arthroplasty Register have proven that monitoring survivorship reduces revision rates. A reduction in revisions translates into fewer costs for many of the stakeholders involved. In addition, the overall cost to the public at large is reduced.

Q. Who engage at my hospital to start the process of signing up for AJRR?
A. We suggest you first identify a surgeon champion and staff champion to assist with the enrollment process. The staff champion, generally an orthopedic nurse or other orthopedic staff member, will serve as the main point person at your hospital. S/he will introduce the project to the IT department, bring the project before the Institutional Review Board and communicate with your legal department about the two agreements (see Hospital Staff Roles). The Surgeon Champion should ideally be kept updated on the enrollment process as it evolves. As such, this person should intervene if concerns or issues arise regarding enrollment. The Surgeon Champion should also inform his/her surgeon colleagues of registry participation.

Q. What types of reports will be available to us, how frequently, and at what cost?
A. During the startup phase of the registry the AJRR will provide free procedural metrics to participating organizations based on the data submitted. Sites will be required to make a request to the AJRR for additional reports. Once the AJRR has acquired sufficient procedural data to derive statistically sound observations, the AJRR will provide annual reports to participating institutions allowing the facility to compare quality metrics to similar de-identified institutions. The AJRR will request a small fee to cover preparation of the annual reports. The AJRR will also accept requests for custom reports based on the national data set. Fees for annual and custom reporting have not yet been established.

Q. How many staff/surgeons can have access to AJRR at a hospital site?
A. The AJRR can support multiple users based on the hospital’s request. The AJRR does recommend that the hospital limit the number of users in an effort to minimize the possibility of errant access to Protected Health Information (PHI). Physicians requesting access to their Institutions’ data or AJRR de-identified data for research purposes must make a formal request to the AJRR to gain access to the de-identified data and will be charged a research fee to cover access to the AJRR data system and associated training on the research tool kits. Requests for an institution’s extracted data set, for example .CSV files for import into excel or other research tools, will be fulfilled within one month of the request.
Frequently Asked Questions

Data and IT

Q. Is AJRR collecting data on a hospital-by-hospital basis?
A. Yes, the AJRR will only contract with hospitals and hospital networks, not individual surgeons or clinics.

Q. Is the AJRR system automated?
A. The AJRR has selected a software system that has the capability to automate data exchanges. The AJRR can accept extracted Level I electronic data for inclusion in the registry. The AJRR recommends a teleconference between the AJRR technical staff and hospital IT staff to agree on the method for electronic data exchange. In the near future, the AJRR will be establishing fully automated interfaces to accept electronic information directly from any hospital’s IT systems. Additionally, the AJRR is defining the requirements for electronically extracting information from UB-04 administrative claim forms and continuity of care documentation.

Q. Who will input the data at each hospital?
A. For those sites electing to enter data manually via a web form, nurses, physician assistants, residents, device representatives, a hospital administrator or data-entry clerk may enter the data.

Q. How will the AJRR prevent errors and ensure that all cases are entered?
A. It is the responsibility of the institutions to enter all cases. The AJRR software system includes field by field data entry error checks, where appropriate drop down selection lists, and random sampling data validation to minimize user errors. The AJRR employs both software and human reviews to ensure the data is valid and accurate prior to allowing the information to be used for analysis.

Q. How often should data be submitted?
A. Data should be submitted whenever the hospital collects it, either in real time or after the surgeries. Minimally the AJRR recommends that participating sites contribute procedural information on a monthly basis.

Q. Can the web form be customized for each individual hospital?
A. No, the AJRR intends to keep the mode of data entry uniform for all hospital participants. The forms can include specific institutional customizations such as the surgeon list and local users of the system.

Q. Who is AJRR’s independent data warehouse provider?
A. The AJRR utilizes a Health Insurance Portability and Accountability (HIPAA) compliant data hosting center to ensure privacy and security. The hosting center was selected based on its ability to use the appropriate procedures and policies that will ensure HIPAA compliance and it also must have a SAS 70 (II) certification.

Q. Does the AJRR plan to sell registry data to a third party?
A. No, the AJRR has no immediate plans to sell information to a third party. It is a goal of AJRR to provide reports that focus on improving the quality of implants and implant procedures.

Q. Will the AJRR be able to link to the Social Security Administration to auto-populate fields?
A. No, not at this time.
Frequently Asked Questions

**IRB**

**Q. Do we need to obtain informed consent from patients?**

**A.** No, hospitals do not need to inform patients of the registry to get consent. The registry was designed for quality improvement purposes and as such, was able to get a waiver of informed consent and authorization from a commercial IRB (see below) to provide blanket coverage for all U.S. hospitals. However, if an individual hospital would like to offer patients the option to consent; they are welcome to do so.

**Q. Will the hospital Institutional Review Board (IRB) have to review this project first?**

**A.** Each hospital or local/academic IRB is different. If your hospital already has its own registry or is sending data to a local registry, the process may take less time due to the fact that a similar data collection protocol has already been reviewed. However, you should expect that your institution’s IRB will have to review the AJRR protocol first. This protocol was approved with a “Waiver of Consent” by the Western IRB (http://www.wirb.com). It will be important to follow-up with the IRB regularly so that the AJRR project stays on their agenda.

**Q. What kind of training has the AJRR staff had on Protected Health Information (PHI)?**

**A.** The AJRR staff has been trained in HIPAA privacy and security through the Collaborative Institutional Training Initiative (CITI). The AJRR is also establishing policies on which employees will have access to information. In general, only those employees involved with information validation or quality metrics and reporting will have access to PHI. All AJRR HIPAA policies and procedures are based on CRF45 Part 164 and “Security Standards for the Protection of Electronic Protected Health Information,” 45 CFR Part 160 and Part 164, Subparts A and C.
Legal
Thank you for your interest in the American Joint Replacement Registry (AJRR). We understand that hospital attorneys may have questions about our legal agreements. While we appreciate your comments, the AJRR Board of Directors has decided not to accept any changes to our existing documents, except as necessary to permit compliance with state law requirements. This decision is based on the fact that we will be contracting with hundreds of hospitals across the country, and it will not be feasible to negotiate and manage different agreements with each hospital. However, in the summer of 2011 and then again during the 4th quarter of 2011, AJRR went through a substantial review process with feedback from over a dozen hospitals, including our pilot sites. Our attorney reviewed all of those comments and revised the 2012 agreements to incorporate many of them into AJRR standard participation and business associate/data use agreements. We plan to follow the same process in making annual updates to our agreements for 2013. So, we are happy to accept your comments and revisions and consider them in the next round of updates to our standard agreements.

Q. What is the rationale for collecting PHI?
A. The AJRR will have to collect PHI, including Social Security numbers, in order to identify and track patients that may receive their revision procedures at a different location from their original procedure. This allows revisions to be linked back to the original procedure. Without PHI, tracking of implants on a national scale is simply not possible. The AJRR is participating in the Food and Drug Administration Unique Device Identification (UDI) initiative, which may provide the opportunity to eliminate some of the PHI the AJRR needs to collect in the future.

Q. What are AJRR’s notification requirements in the event of a breach of unsecured PHI?
A. As the AJRR Business Associate Agreement (BAA) provides in Section 3.2, the AJRR will report promptly to participants any breach of unsecured PHI. Any breach will be reported no later than 5 calendar days after discovery, which is well before the 60-day Health Insurance Portability and Accountability (HIPAA) breach notification requirement.

Q. In the event of a breach, is there shared liability?
A. Yes, please see section 5(c) of the BAA.

Q. Is the data submitted discoverable? Can it be subpoenaed?
A. The data is potentially discoverable and can be subpoenaed. But, we believe it is unlikely that the AJRR will receive such a subpoena or that any PHI would in fact be subject to discovery in state or federal court. Illinois law, which should apply to any state-based subpoena or discovery request, provides strong protection against discovery of AJRR data. At the federal level, the rules of evidence require the courts to weigh the value of the data in a particular case against the intrusion into patient privacy. In previous registry cases, the federal courts have declined to grant access to patient identifiable information. AJRR would vigorously oppose any subpoena of AJRR data.

Q. Will hospital/surgeon indemnification be offered?
A. AJRR’s participation and BA/DUA agreements have mutual indemnification provisions in which cross indemnifications are granted by the parties. AJRR’s indemnification of participants is necessarily limited to reflect shared nature of our interests and the need to limit AJRR’s risk to ensure the viability of the registry.
Q. What will the participation and report fees be? (as mentioned in the Participation Agreement)
A. During the startup phase of the registry AJRR will provide free procedural metrics to participating organizations based on the data submitted. Sites will be required to make a request to AJRR for reports. Once AJRR has acquired sufficient procedural data to derive statistically sound observations, it will provide annual reports to participating institutions allowing the facility to compare quality metrics to similar de-identified institutions. AJRR may request a small fee to cover preparation of the annual reports. The AJRR will also accept requests for custom reports based on the national data set. Fees for custom reporting have not yet been established.

As such, there will be a definite and reasonable time period between the release of AJRR's fee structure and the release of new legal agreements stating those fees. Similarly, there will be a reasonable time period for termination of the contract if a hospital does not agree with the fees.

Q. Our hospital mandates use of our own BAA for any contracts. Will AJRR sign our agreements?
A. Unfortunately, we are not able to sign any individual hospital agreements.

Q. The choice of law and forum is the state of Illinois. Could you please explain why we cannot change the law to reflect our state?
A. As noted above, AJRR will be contracting with hundreds of sites in virtually every state. It would be economically and legally infeasible for it to voluntarily agree to subject itself to the laws and jurisdiction of states other than Illinois where AJRR is incorporated, has its principal place of business, and holds the registry data.

Q. Why does our hospital need to sign both the AJRR Business Associate Agreement and Participation Agreement? If we sign the BAA, isn’t that sufficient?
A. No, sites need to sign both agreements. The Participation Agreement outlines most of the terms and conditions of our relationship, for example: how and when data will be submitted, term and termination, fees, ownership and confidentiality of data, and other terms and conditions for participation in AJRR. The BA/DUA Agreement is necessary to comply with our joint responsibilities as covered entity (you) and Business Associate (AJRR) under the security and privacy rules issued pursuant to the Health Insurance Portability and Accountability Act of 1996.

Q. In Section 7 of the AJRR Participation Agreement, we would like to delete the phrase “absent the gross negligence or willful misconduct of Participant”. We also would like phrasing to be altered throughout that section.
A. Given its nonprofit status and limited resources, AJRR cannot be in the position of accepting unlimited liability risk for the activities of the registry. This shared venture between participating sites necessitates some shared risk. However, AJRR will accept responsibility for gross negligence or willful misconduct by its employees and agents.

Q. Do physicians know that their data will be shared with AJRR?
A. During the enrollment phase, we have engaged in discussions with your hospital “Surgeon Champion” who is aware of your hospitals' potential participation in the AJRR. We expect that the Surgeon Champion will inform his/her colleagues of AJRR procedures and what data will be transmitted to us.
Preliminary Hospital Information

Once your hospital has become a participant with the registry, the AJRR will collect certain background information on your hospital and its orthopaedic surgeons in order to create your site’s Remedy account.

Please email info@ajrr.net if you would like the templates for providing this preliminary information about your hospital.

This information includes:

**Hospital:** Hospital Name, NPI, Address, Type of Hospital (Research, University, Community, Community Rural, or Teaching), and Number of beds
Main Contact Name, Email, and Phone

**Surgeons:** Name, NPI, Practice Name, Practice Address

**List of Manufacturers used**
The American Joint Replacement Registry (“AJRR” or “Registry”) will collect and utilize data derived from information submitted by physicians, hospitals and manufacturers related to joint replacements. Some of this data will qualify as protected health information (“PHI”) under the Health Information Portability and Accountability Act of 1996 (“HIPAA”) Privacy and Security rules (“HIPAA Rules”). ¹ This memorandum briefly describes AJRR’s HIPAA compliance strategy.

HIPAA Background

PHI is individually identifiable health information that requires patient authorization for use and disclosure unless such disclosure falls within one of many exceptions. ² HIPAA applies to “covered entities,” defined to include health care providers, health plans, and health care clearinghouses that handle electronic claims, as well “business associates,” defined as entities that provide services for or perform functions on behalf of covered entities. The HIPAA Privacy Rule allows for the disclosure of PHI without patient authorization for the purposes of treatment, payment or health care operations. ³ Health care operations include quality assurance and improvement activities.

The extent to which HIPAA will apply to the activities of the AJRR will depend on the nature of the data being collected, the purpose of the collection, and whether AJRR is actually physically receiving the data. For example, the AJRR would not be subject to HIPAA

¹ 45 C.F.R. Pt. 164.
² 45 C.F.R. § 164.502.
³ 45 C.F.R. § 164.506; 45 C.F.R. § 164.508(a)(2)-(3).
limitations when handling de-identified information, which is information that contains no personal identifiers or unique identifying numbers, characteristics or codes. Similarly, if the AJRR collected “limited data sets,” it would not need to obtain patient authorization or a waiver of such authorization from an Institutional Review Board (“IRB”). A limited data set is information that is partially de-identified by removing specific identifiers but retains certain information, such as addresses, gender, and date of birth. The limited data set exception applies only to the use of data for research, health care operations and certain public health purposes. This exception requires the covered entity to enter into a data use agreement with the limited data set recipient to preserve the confidentiality of the data and restrict its use.

The HIPAA rules allow covered entities to disclose only the “minimum necessary” information. They also permit covered entities to share PHI with “business associates” if they enter into business associate agreements that meet regulatory requirements.

**AJRR HIPAA Compliance Strategy**

AJRR will be aggregating and analyzing data and providing participants with reports on their performance relative to other registry participants. Participants are covered entities under HIPAA. To the extent that the purpose of such reports relates to health care operations, such as quality improvement, the AJRR will be performing data aggregation services for the participants and would qualify as a business associate. As such, it will be entering into business associate agreements with each participant prior to receiving the participant’s PHI. While it will receive and analyze each participant’s data and report back aggregate results to all participants, it will not share the PHI of any one participant with other sites. As a business associate, AJRR has adopted HIPAA-compliant policies and procedures necessary to protect the privacy and security of PHI received from participants.

To the extent that AJRR plans to collect PHI primarily for research purposes, where research is defined as “a systematic investigation, including research, development, testing and evaluation designed to develop or contribute to generalizable knowledge,” the business associate agreement will not protect the data. Instead, AJRR has obtained a waiver of the HIPAA patient authorization requirement for the submission of PHI for research purposes from Western Institutional Review Board (IRB) (http://www.wirb.com). The AJRR will also obtain separate IRB approval or waiver of authorization for any disclosure of PHI for specific research purposes.

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4 45 C.F.R. § 164.514.  
5 45 C.F.R. § 164.512(i).  
6 45 C.F.R. § 164.514.  
7 45 C.F.R. § 164.502(b).  
8 The term “participants” for the purposes of this memorandum, is defined as providers, hospitals, and any other entities submitting data to the AJRR.  
9 45 C.F.R. § 164.501.  
10 45 C.F.R. §164.501.  
11 45 C.F.R. 164.512(i).
The (U.S. Department of Health and Human Services (HHS) Office for Civil Rights (http://www.hhs.gov/ocr/) has clearly stated that the HIPAA rules do not require each site participating in a data registry to obtain a waiver from its local IRB:

The Privacy Rule permits covered entities reasonably to rely upon a researcher's documentation that a waiver was properly granted by a single IRB or Privacy Board, even if the IRB or Privacy Board is not affiliated with the covered entity. Under the Privacy Rule, one IRB or Privacy Board's documentation of waiver of Authorization suffices.\(^\text{12}\)

Therefore, sites submitting PHI to AJRR do not need to obtain local IRB waivers of the HIPAA patient authorization requirement.

**Common Rule**

The Common Rule does not apply to AJRR activities as that rule relates to research that is “conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.”\(^\text{13}\)

The Common Rule defines “research subject to regulation” as:

\[
\text{[R]esearch activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department’s or agency’s broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).} \text{\hspace{1cm}14}\]

Where the Common Rule applies, it covers research involving human subjects, which includes the collection of identifiable patient information.\(^\text{15}\) The Common Rule does not apply to privately-funded research activities such as the AJRR that are not otherwise subject to federal regulation.

The Common Rule also does not apply to participants that submit data to the AJRR. The HHS Office for Human Research Protections (http://www.hhs.gov/ohrp/) has clearly stated that data collected in the course of clinical care that is submitted to external researchers is not human subjects research and therefore is not subject to the Common Rule. Specifically, “Institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research” are not engaged in human subjects research.\(^\text{16}\) Thus, hospitals that submit PHI collected in the course of clinical care to national registries for research purposes are not engaged in human subjects research.


\(^\text{13}\) 45 C.F.R. §46.101(a).

\(^\text{14}\) 45 C.F.R. §46.102(e).

\(^\text{15}\) 45 C.F.R. §46.101(b).

THE AMERICAN JOINT REPLACEMENT REGISTRY
PARTICIPATION AGREEMENT

AMERICAN JOINT REPLACEMENT REGISTRY

THIS AGREEMENT is entered into and made effective the ___ day of ______, 2012, by
and between (a) THE AMERICAN JOINT REPLACEMENT REGISTRY, NFP, an Illinois not-for-profit corporation, with its principal place of business at 6300 North River Road, Rosemont, Illinois 60018 (“AJRR”); and b)    a _______________________________, solely on behalf of
the hospital known as ________________________ (“Hospital Participant” or “Participant”).

WHEREAS, AJRR has developed and owns certain computerized databases containing
information relating to patient treatment, the practice of medicine, and third parties submitting
data to these databases pursuant to AJRR rules (said databases collectively referred to herein as
the “Registry”); and

WHEREAS, Participant has expressed an interest in participating in the Registry in
accordance with AJRR requirements;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants
contained herein, and for other good and valuable consideration, the parties hereto agree as
follows:

1. Participation in American Joint Replacement Registry.

1.1 Participant agrees to participate in the Registry by transmitting data through a
web-based portal or other means designated by AJRR, either directly or via a third-party vendor
designated by Participant (“the Vendor”) for the collection and submission of data pertaining to
the practice of orthopedics.

1.2 Participant will participate in the data harvests conducted by the Registry by
submitting Participant’s data to the AJRR through the web-based portal, and otherwise
complying with the rules and harvest schedules reasonably established by AJRR in connection
therewith.

1.2.1 Participant hereby warrants, to the best of its knowledge, that all data
submitted for inclusion in the Registry will be accurate and complete, and acknowledges
that such data may be subject to independent audit in accordance with terms and
conditions mutually agreed upon by the parties. Participant will use its best efforts to
address any data or related deficiencies identified by AJRR, and agrees to cooperate with
and assist AJRR and its designees in connection with the performance of any independent audit.

1.2.2 Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the Registry.

1.2.3 Participant agrees to assist and cooperate with AJRR in its efforts to conduct the Registry.

1.2.4 Participant takes full responsibility for the acts and omissions of the Vendor in Participant’s participation in the Registry. For purposes of this Agreement, any submission of data by Participant through the Vendor shall be treated as if such data were submitted directly by Participant. Participant will immediately notify AJRR of any changes to the agreement with Participant and the Vendor. The Vendor must also complete an Authorized Vendor Agreement with AJRR in order to act on the Participant’s behalf and Participant acknowledges that Vendor will not be authorized to Participate in the Registry on Participant’s behalf until such agreement is completed.

1.3 Participant agrees and acknowledges that its (or Vendor’s) failure to submit data to the Registry, or its (or Vendor’s) submission of data to the Registry that does not comply with AJRR requirements, may result in Participant’s failure to receive one or more reports generated by the Registry (see paragraph 2) and/or an assessment of additional Participant fees to reflect additional expenses incurred by AJRR in order to render Participant’s data appropriate for inclusion in the Registry (see paragraph 4.2).

1.4 Participant agrees and acknowledges that the data captured by the Registry will include certain hospital and physician-identifying information (which shall be encrypted during transfer and at rest in the AJRR software system). Participant agrees that it is Participant’s responsibility to obtain any permissions required in order to submit such data for inclusion in the Registry, and specifically agrees to indemnify, save and hold harmless AJRR and its independent data warehouse service provider, if applicable, from and against all claims and liabilities associated therewith to the extent permitted by applicable law.

2. AJRR Reports. Provided that Participant participates in the Registry in accordance with AJRR requirements (including but not limited to Participant’s payment of all applicable fees), Participant will be entitled to receive quarterly and annual Registry reports, each of which will include both aggregated data from the Registry and Participant-specific information, and such other reports as AJRR or its independent service providers may prepare for Participants. All such reports shall be structured to reflect data of the Participant, as directed by Participant in a written amendment. Additional reports may be created for Participant in consideration for the fees required by AJRR in order to provide them. The aggregated data included in any and all reports provided hereunder constitute “AJRR Intellectual Property” (as defined herein) and, as such, may not be reproduced, further disseminated or otherwise used except as provided in paragraph 6.4 of this Agreement or as otherwise permitted by AJRR policies and procedures (which shall be made available to Participant).
3. Participant Ad Hoc Queries. Participant may submit to AJRR for analysis such requests for ad hoc queries (requiring access to and analysis of aggregate data from the Registry) as Participant may desire. All such requests for ad hoc queries shall be subject to prior approval by AJRR, in accordance with such procedures and other requirements as it may reasonably establish, before efforts are undertaken to respond thereto. In its response to each of Participant’s ad hoc queries, AJRR shall give due consideration to scientific merit, the funds and other resources available to address ad hoc queries and other pertinent factors; provided, however, that if adequate funding is not otherwise available, AJRR may condition its approval of a request for an ad hoc query upon Participant’s agreement to pay the fees required by the AJRR and any other service providers required in order to appropriately address Participant’s ad hoc query. As a part of its efforts to promote the use of the Registry as a tool for the development of beneficial scientific information, AJRR will provide reasonable assistance to Participant in refining Participant’s requests for ad hoc queries so as to enhance their potential for approval in light of the pertinent factors noted above.

4. Participant Fees.

4.1 Fees payable by Participant to AJRR pursuant to this Agreement are as follows:

4.1.1 The initial participation fee shall be $0. This fee shall entitle Participant to receive only one set of reports, capturing the aggregate data submitted by Participant pursuant to paragraph 2.

4.1.3 Such participation fees as AJRR may establish for future calendar years, provided that said fees will be established by AJRR prior to December 1 in 2012 and in each succeeding year (payable by January 1, 2013, and each succeeding year).

4.2 Any additional fees payable to address data submitted to the Registry that fails to conform with AJRR requirements.

4.3 Any additional report-related fees required pursuant to paragraph 2.

4.4 Any additional ad hoc query fees required pursuant to paragraph 3.

5. Confidentiality. AJRR acknowledges that the data submitted to the Registry by Participant are deemed confidential. Accordingly, AJRR agrees and acknowledges that it will require any future data warehouse service providers to treat such information as confidential pursuant to an appropriate and material term within its written data warehouse service contract for the American Joint Replacement Registry. The parties hereby agree to comply with all applicable statutes and regulations, under federal and state laws, concerning patient privacy and data security, including but not limited to the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). To that end, it is agreed and acknowledged that they are executing the Business Associate Contract and Data Use Agreement attached hereto as Appendix I in conjunction with their execution of this Agreement,
which is incorporated herein by reference and made part of this Agreement. Further, Participant understands and agrees that AJRR, which for purposes of this Agreement is an “Organized Health Care Arrangement” as defined by HIPAA regulations, may share patient data submitted to the Registry (including PHI) with other covered entities that have treated the same patient to enable the other covered entity to follow the treatment of the patient; provided that AJRR will only share such data with those covered entities that agree in writing to comply with the same terms and conditions as provided in this Agreement and Appendix I.

6. **Intellectual Property.**

6.1 It is agreed and acknowledged that all data submitted for inclusion in the Registry by or on behalf of Participant are and shall remain Participant’s proprietary information, and may be used by AJRR and its designees only in accordance with the terms of this Agreement and any subsequent instruction from Participant with respect thereto (e.g., in connection with data collection efforts of geographically based groups of physicians).

6.2 Participant hereby agrees that all data submitted by or on behalf of Participant to AJRR or AJRR’s designee for purposes of inclusion in the Registry may be used by AJRR as a part of the Registry and any subset thereof that AJRR may choose to create and use as it sees fit for the purposes of promoting Participant’s health care operations and medical research (as defined by HIPAA regulations), and the other interests of the Registry (including, without limitation, publication of such data); provided, however, that no such data shall be used in such a way as to identify Participant or institution of Participant, unless and until Participant advises AJRR in writing that it has secured appropriate consent therefor. AJRR will not share PHI with third-parties except as otherwise authorized under this Agreement, the BA/DU Agreement in Appendix I, or HIPAA.

6.3 Participant acknowledges that AJRR is and shall be deemed the owner of all rights to the Registry (including the aggregate data contained therein and subsets thereof), any and all reports based thereon, all information derived therefrom (including, without limitation, all risk algorithms and associated Beta coefficients and Y intercepts) and all trademarks (including, without limitation, AJRR, AMERICAN JOINT REPLACEMENT REGISTRY and all variations thereon and graphic representations thereof), trade secrets and all other intellectual property arising from or reflected in the Registry (collectively, “AJRR Intellectual Property”) with the exception of Participant’s data.

6.4 Participant may not use AJRR Intellectual Property without first obtaining the express written consent of AJRR, provided that Participant may use aggregated data from the Registry that have been included in AJRR Reports to Participant or previously released to the public by AJRR (e.g., in published reports and slide sets) without first obtaining such written consent so long as Participant does not make any statements about such data that are false and misleading.

6.5 Neither party shall use the name, trademark, or logo of the other party or its employees for promotional purposes without prior written consent of the other party.
7. **Limitation of Liability; Indemnification.** AJRR agrees to indemnify, save and hold harmless Participant from and against any and all third party claims, costs and expenses (including attorneys’ fees and expenses), demands, actions and liabilities of every kind and character whatsoever arising or resulting in any way from AJRR’s breach of its obligations under this Agreement, absent the gross negligence or willful misconduct of Participant. All of the foregoing rights of indemnification shall apply to any expenses incurred by Participant in defending itself against claims of gross negligence or willful misconduct unless a court of competent jurisdiction concludes in a final judgment that such party seeking indemnification has committed gross negligence or willful misconduct.

Participant agrees to indemnify, save and hold harmless AJRR and its independent data warehouse service provider (if any) from and against any and all third-party claims, costs and expenses (including attorneys’ fees and expenses), demands, actions and liabilities of every kind and character whatsoever arising or resulting in any way from Participant’s submission of data to the Registry or use of data obtained through the Registry, absent the gross negligence or willful misconduct of AJRR or any independent data warehouse service provider, respectively. All of the foregoing rights of indemnification shall apply to any expenses incurred by AJRR and any independent data warehouse service provider in defending themselves, respectively, against claims of gross negligence or willful misconduct unless a court of competent jurisdiction concludes in a final judgment that such party seeking indemnification has committed gross negligence or willful misconduct.

Under no circumstances will either party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

[IF PARTICIPANT IS A GOVERNMENT INSTITUTION THAT IS NOT ABLE TO PROVIDE INDEMNIFICATION, THE FOLLOWING ALTERNATIVE PROVISION MAY BE SUBSTITUTED FOR THE ABOVE SECTION 7:

7. **Responsibilities of the Parties**

Each party to this Agreement agrees that it will be responsible for its own acts and omissions and the results thereof; and, shall not be responsible for the acts and omissions of the other party and the results thereof. Each party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees under this Agreement. Under no circumstances will either party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.]

8. **Insurance.** At all times during the term of this Agreement and the accompanying Business Associate Contract and Data Use Agreement, Participant and AJRR shall maintain
insurance with coverage and limits reasonably sufficient to cover their respective obligations hereunder.

9. **Term and Termination.**

   9.1 Subject to the terms of paragraph 9.2, this Agreement shall be effective through December 31, 2012, and shall be automatically renewed on an annual basis thereafter unless any party provides the other(s) with a written notice of termination on or before December 1, 2012, or December 1 of any subsequent renewal year.

   9.2 This Agreement may be terminated prior to December 31, 2012 (or December 31 of any subsequent renewal year) upon any party’s material breach of this Agreement and any other party’s provision of written notice thereof; provided, however, that if said breach is cured to the non-breaching party’s(ies’) satisfaction (as reflected in written notice thereof) within thirty (30) days after the provision of such notice, said termination notice shall of no further force or effect and this Agreement shall be fully reinstated.

10. **Equitable Relief.** The parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this Agreement, and that each party shall be entitled to emergency injunctive relief as a remedy for any such breach by any other party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this Agreement, but shall be in addition to all other remedies at law or in equity to the non-breaching party (ies).

11. **Independent Contractors.** The relationship of the parties to this Agreement is that of independent contractors, and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.

12. **Notices.** All notices and demands of any kind or nature which any party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States mail, by facsimile transmission or by overnight courier (e.g., Federal Express or DHL) to the following addressees:

   If to Hospital Participant:
   ______________________________
   ______________________________
   ______________________________
   ______________________________
   Tel: ____________________________
   (fax #) _________________________
   Attn: __________________________
If to AJRR: American Joint Replacement Registry
   6300 North River Road
   Rosemont, IL 60018
   Tel: __________________
   (fax #) ________________
   Attn: __________________

Service of such notice or demand so made shall be deemed complete on the day of actual
delivery. Without limiting the generality of the foregoing, if notice is given by facsimile
transmission, such notice shall be deemed to be provided upon confirmation of the receipt of the
transmission. Any party hereto may, from time to time, by notice in writing served upon the
other party(ies) as aforesaid, designate a different mailing address or a different person to which
all further notices or demands shall thereafter be addressed.

13. **Headings.** The headings of the various paragraphs hereof are intended solely for the
convenience of reference and are not intended for any purpose whatsoever to explain, modify or
place any construction upon any of the provisions of this Agreement.

14. **Assignment.** This Agreement may not be assigned by any party without the prior express
written approval of the other party(ies).

15. **Counterparts.** This Agreement may be executed in one or more counterparts, each of
which shall be deemed an original and all of which taken together shall constitute one and the
same instrument.

16. **Waiver.** A waiver by any party to this Agreement of any of its terms or conditions in any
one instance shall not be deemed or construed to be a general waiver of such term or condition or
a waiver of any subsequent breach.

17. **Choice of Law and Forum.** All disputes regarding the meaning, effect, force or validity
of this Agreement shall be determined according to federal law and the law of the State of
Illinois. The parties expressly agree that the federal and state courts located in the State of
Illinois are the most reasonable and convenient forums for resolutions of any such disputes, and
designate said courts as the exclusive forums in which all such disputes shall be litigated.
Accordingly, the parties consent to the jurisdiction and venue of, and service of process by, said
courts. Each party agrees that the provisions of this paragraph are specifically enforceable, and
that it shall pay all expenses, damages, and costs (including attorneys’ fees and expense) of any
other party if said other party commences, prosecutes, or permits to continue any actions in any
other forum.

18. **Severability.** All provisions of this Agreement are severable. If any provision or portion
hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of this
Agreement shall remain in full effect, provided that its general purposes remain reasonably
capable of being effected.
19. **Survival.** The provisions of paragraphs 1.4, 5-11, 17 and all other terms within this Agreement that are necessary or appropriate to give meaning thereto shall survive any termination of this Agreement.

20. **Entire Agreement.** This Agreement (a) constitutes the entire agreement between the parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the party against whom enforcement is sought.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement, as of the date and year first written above.

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APPENDIX I: STANDARD FORM
BUSINESS ASSOCIATE CONTRACT
AND DATA USE AGREEMENT
(2012 Version)

THIS AGREEMENT is entered into and made effective the ___ day of ____________, 2012
(the “Effective Date”), by and between (a) THE AMERICAN JOINT REPLACEMENT
REGISTRY, NFP a not-for-profit corporation, with its principal place of business at 6300 North
River Road, Rosemont, Illinois 60018 (“AJRR”); and (b) ______________________________,
with its principal place of business at ____________________________________________,
(“Hospital Participant” or “Participant”). AJRR and Participant are each a Party to this Agreement
and are referred to collectively as the “Parties.”

WHEREAS, AJRR and Participant are parties to that certain Participation Agreement,
dated as of ____________________, 2012, setting forth the terms of Participant’s participation in
the AJRR (such agreement to be referred to herein as the “Participation Agreement” and such
American Joint Replacement Registry as “The Registry”);

WHEREAS, the Participation Agreement permits and provides for the conduct of data
analyses that relate to the Participant’s Health Care Operations, including but not limited to Data
Aggregation, quality assessment, and peer review functions;

WHEREAS, the Participation Agreement may from time to time require the receipt, Use,
and/or Disclosure of Protected Health Information (“PHI”);

WHEREAS, the Participation Agreement may from time to time require the Disclosure of
PHI in the form of a Limited Data Set (“Limited Data Set Information”) for AJRR to provide
services to Participant related to its Health Care Operations and for Research purposes; and

WHEREAS, the Parties desire to allocate responsibility for the Use and Disclosure of PHI,
including Limited Data Set Information, and to comply with applicable requirements of the Health
Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”) and the
regulations promulgated thereunder by the United States Department of Health and Human
Services (“HHS”) codified at 45 CFR Parts 160 and 164, (commonly known as the Privacy and
Security Rules) as amended by the Privacy and Security provisions set forth in Section 13400 of the
Health Information Technology for Economic and Clinical Health Act, Public law 111-5
(“HITECH Act”), (collectively referred to herein as the “HIPAA Regulations”), as they pertain to
Business Associates and Limited Data Sets;

NOW THEREFORE, in consideration of the mutual promises and conditions contained
herein, and for other good and valuable consideration, the Parties agree to amend the Participation
Agreement as follows:

SECTION 1
DEFINITIONS

Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning
ascribed to them in the HIPAA Regulations or the Participation Agreement, as the case may be.
Except as otherwise specified herein, the term “Agreement” refers to this Business Associate
Contract and Data Use Agreement and not the Participation Agreement. PHI will have the meaning ascribed to it in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Participant to AJRR or an agent or subcontractor of AJRR, or created by AJRR or its agent or subcontractor on behalf of Participant. Limited Data Set Information will have the meaning ascribed to “Limited Data Sets” in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to Limited Data Set Information transmitted from or on behalf of Participant to AJRR or an agent or subcontractor of AJRR, or created by AJRR or its agent or subcontractor on behalf of Participant. Unless otherwise specified, the use of the term PHI will be interpreted to include Limited Data Set Information.

SECTION 2
EFFECT AND INTERPRETATION

The provisions of this Agreement shall apply with respect to the Use or Disclosure of any PHI by the Parties under the Participation Agreement. In the event of any conflict or inconsistency between the Participation Agreement and this Agreement concerning the Use or Disclosure of PHI, the terms of this Agreement will prevail unless the Parties mutually agree that the applicable terms of the Participation Agreement would be more protective of PHI. The provisions of this Agreement are intended in their totality to implement 45 CFR 164.504(e) and 45 CFR 164.314(a) as they concern Business Associate Contracts and 45 CFR 164.514(e) as it concerns Data Use Agreements. The provisions of the Participation Agreement will remain in full force and effect and are amended by this Agreement only to the extent necessary to effectuate the provisions set forth herein.

SECTION 3
GENERAL OBLIGATIONS OF AJRR

Section 3.1. Business Associate Contract Obligations.

The obligations set out in this Subsection 3.1 apply with respect to AJRR’s Use or Disclosure of PHI, other than Limited Data Set Information.

(a) AJRR agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law and agrees to maintain the security and privacy of all PHI in a manner consistent with all applicable laws; provided that Participant will inform AJRR of any specific state laws that it believes are applicable to PHI submitted by Participant and would require AJRR to take compliance steps beyond those required under the HIPAA regulations.

(b) AJRR agrees to use appropriate safeguards to prevent Use or Disclosure of PHI other than as provided for by this Agreement. Without limiting the generality of the foregoing, AJRR further agrees to:

(i) implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic PHI that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.314(a);
(ii) ensure that any agent, including any subcontractor, to whom it provides such PHI agrees to implement reasonable and appropriate safeguards to protect the PHI; and

(iii) report promptly, but in no case later than five (5) business days after Discovery, to the Participant any Security Incident or Breach of Unsecured PHI that is known to or reasonably should be known to AJRR and shall mitigate, to the extent practicable, any harmful effects of said Security Incident or Breach.

(c) AJRR agrees to report promptly, but in no case later than five (5) business days after Discovery, to Participant any Use or Disclosure of PHI which is not authorized by this Agreement of which AJRR becomes aware.

(d) AJRR agrees to ensure that any agent or subcontractor to whom, directly or indirectly, it provides PHI, will agree in writing to comply with the same restrictions and conditions with respect to such information that apply through this Agreement to AJRR. For the purposes of this Agreement, all PHI provided at AJRR’s direction to an agent or subcontractor of AJRR will be deemed to have been provided to AJRR.

(e) If PHI provided to AJRR, or to which AJRR otherwise has access, constitutes a Designated Record Set, AJRR agrees to provide Participant with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Participant’s request, to provide an Individual with access to his or her PHI in order to meet the requirements under 45 CFR 164.524 concerning access of Individuals to Protected Health Information. In the event an Individual contacts AJRR or its agent or subcontractor directly about gaining access to his or her PHI, AJRR will not provide such access but rather will forward such request to Participant within three (3) business days of such contact, unless otherwise required by law.

(f) If PHI provided to AJRR, or to which AJRR otherwise has access, constitutes a Designated Record Set, AJRR agrees to make timely amendment(s) to such PHI as Participant may direct or agree to pursuant to 45 CFR 164.526. In the event an Individual contacts AJRR or its agent or subcontractor directly about making amendments to his or her PHI, AJRR will not make such amendments, but rather will promptly forward such request to Participant, unless otherwise required by law.

(g) AJRR agrees to make internal practices, books and records relating to the Use and Disclosure of PHI available to the Secretary of the United States Department of Health and Human Services, during regular business hours, for purposes of the Secretary’s determining Participant’s compliance with HIPAA or the HIPAA Regulations.

(h) AJRR agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. In addition, AJRR agrees to provide promptly to Participant or an Individual, upon Participant’s reasonable request, information collected in accordance with this Subsection 3.1(h) in order to permit Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. Notwithstanding the foregoing, this Subsection 3.1(h) will not apply with respect to Disclosures made to carry out Participant’s Health Care Operations or the Disclosure of Limited Data Set Information, in accordance with the exceptions to 45 CFR
164.528 as set forth in the HIPAA Regulations, provided that this exception shall not apply to
Disclosures of PHI through an electronic health record.

   (i) AJRR shall mitigate, to the extent practicable, any adverse effects from any
improper Use and/or Disclosure of Protected Health Information by AJRR that are known to
AJRR.

Section 3.2. Data Use Agreement Obligations.

The obligations set out in this Subsection 3.2 apply only with respect to AJRR’s Use or
Disclosure of Limited Data Set Information.

(a) AJRR agrees to not Use or further Disclose Limited Data Set Information
other than as permitted by Section 4(c) of this Agreement, or as otherwise Required By Law.

(b) AJRR agrees to use appropriate safeguards to prevent Use or Disclosure of
the Limited Data Set Information other than as permitted by Section 4(c) of this Agreement.
Without limiting the generality of the foregoing, AJRR further agrees to:

   (i) implement Administrative, Physical, and Technical Safeguards that
reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the
limited electronic Limited Data Set Information that it creates, receives, maintains, or transmits on
behalf of Participant as required by 45 CFR 164.314(a);

   (ii) ensure that any agent, including any subcontractor, to whom it provides
such Limited Data Set Information agrees to implement reasonable and appropriate
safeguards to protect such information and that are substantially similar to the terms of this
Agreement;

   (iii) report promptly, but in no case later than five (5) business days after
Discovery, to the Participant any Security Incident or Breach of Unsecured PHI of which
AJRR becomes aware.

(c) AJRR will report promptly, but in no case later than five (5) business days
after Discovery, to Participant any Use or Disclosure of the Limited Data Set Information not
permitted by Section 4(c) of this Agreement of which AJRR becomes aware.

(d) AJRR will not attempt to identify the Individuals to whom the Limited Data
Set Information pertains, or attempt to contact such Individuals, provided that this restriction
will not be interpreted to prevent AJRR from conducting such activities under the Business
Associate Contract provisions of this Agreement. Under no circumstances will AJRR attempt
to contact Individuals except with Participant’s prior written consent.

(e) AJRR agrees to require that any agent or subcontractor to whom it, directly
or indirectly, provides Limited Data Set Information will agree in writing to comply with the
same restrictions and conditions that apply through this Section 3.2 to AJRR.
(f) AJRR agrees to enter into a written agreement with each third party to which it Discloses Limited Data Set Information that includes the terms and provisions required by the HIPAA Regulations for such Disclosures.

SECTION 4
PERMITTED USES AND DISCLOSURES BY AJRR

(a) General Business Associate Contract Use and Disclosure Provisions.

Except as otherwise limited in this Agreement, AJRR may Use or Disclose PHI on behalf of, or in order to provide services to, Participant to the extent such Use or Disclosure is reasonably necessary to facilitate Participant’s participation in The Registry, consistent with the Participation Agreement, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant.

(b) Specific Business Associate Contract Use and Disclosure Provisions.

The permitted Uses and Disclosures set out in this Subsection 4(b) apply only with respect to AJRR’s Use or Disclosure of PHI other than Limited Data Set Information.

(i) Except as otherwise limited in this Agreement or the Participation Agreement, AJRR may Use PHI for the proper management and administration of AJRR or to carry out the legal responsibilities of AJRR.

(ii) Except as otherwise limited in this Agreement or the Participation Agreement, AJRR may Disclose PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or AJRR otherwise obtains reasonable assurances from the person to whom it Discloses the PHI that such person will a) protect the Confidentiality of the PHI; b) Use or further Disclose the PHI only as Required By Law or for the purpose for which it was Disclosed to the person; and c) promptly notify AJRR of any instances of which the person is aware that the Confidentiality of the PHI has been Breached.

(iii) Except as otherwise limited in this Agreement or the Participation Agreement, AJRR may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).

(iv) AJRR may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR 164.514(b), including without limitation any documentation requirements. AJRR may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this Agreement; provided that such Use or Disclosure is consistent with the Participation Agreement and applicable law.

(v) AJRR may partially de-identify any PHI to create a Limited Data Set, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2).
Uses and Disclosures Under Data Use Agreement Provisions.

Notwithstanding Subsection 4(b) above, AJRR may, consistent with this Agreement, Use or Disclose PHI that consists solely of Limited Data Set Information to a third party for Research, Public Health, or Health Care Operations in accordance with the provisions of the HIPAA Regulations concerning Limited Data Sets, provided that such Use or Disclosure is (i) limited to the minimum information necessary to facilitate Participant’s participation in The Registry or for AJRR’s Research purposes; (ii) is consistent with the Participation Agreement; and (iii) would not violate the HIPAA Regulations if done by Participant. The term Health Care Operations as used herein includes Data Aggregation.

SECTION 5
GENERAL OBLIGATIONS OF PARTICIPANT

(a) Participant’s Notice of Privacy Practices, Permissions, and Restrictions.

(i) Participant represents and warrants that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and any other applicable provisions of the HIPAA Regulations. Participant will provide AJRR with a copy of its Notice of Privacy Practices upon request.

(ii) Participant will provide AJRR with any changes in, or revocation of, the permission by an Individual to Use or Disclose PHI, if such changes affect AJRR’s permitted or required Uses and Disclosures.

(iii) Participant will ensure on a continuing basis that all Disclosures of PHI made to AJRR are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual’s PHI to AJRR impermissible. Participant will notify AJRR of any specific or general restrictions on the Use or Disclosure of PHI submitted to AJRR that Participant has agreed to in accordance with 45 CFR 164.522.

(b) Permissible Requests by Participant. Participant will not ask AJRR to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by Participant, provided that Participant may, as otherwise permitted under this Agreement, request that AJRR Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of AJRR, as provided for in 45 CFR 164.504(e)(4).

(c) Breach Notification. Participant and AJRR agree that if either fails to adhere to any of the provisions set forth in this Agreement or the Participation Agreement and, as a result, PHI or other confidential information is unlawfully accessed, used, or disclosed, the party or parties responsible for the Breach agree to pay all (or their proportionate share of) costs associated with any notification to affected individuals that is required by law, and the party or parties responsible will also pay any and all (or their proportionate share of) fines and/or administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting. Unless otherwise agreed upon by the parties, if AJRR notifies Participant of a Breach of Unsecured PHI, Participant shall be responsible for providing notification to comply with Breach Notification requirements set forth in the HIPAA regulations. Such notification shall be provided in a form mutually agreed upon by AJRR and Participant.
SECTION 6
TERM AND TERMINATION

(a) Term. This Agreement will commence as of the Effective Date and will remain in effect for a period that is coterminous with the Participation Agreement, unless (i) this Agreement is terminated sooner in accordance with either Subsection (b) or (c) of this Section; or (ii) the Participation Agreement is amended by written agreement of the Parties in a manner that the Parties mutually agree renders the provisions of this Agreement unnecessary.

(b) Termination for Material Breach. Either Party may terminate this Agreement based upon a material breach of this Agreement by the other Party, provided that the non-breaching Party gives the breaching Party thirty (30) days written notice and the opportunity to cure such breach, and the breach is not cured during the notice period. In the event such material breach is not cured, the non-breaching Party may terminate this Agreement immediately upon the expiration of the notice period. In the event it is not possible to cure such material breach, the non-breaching Party may terminate this Agreement immediately and without any notice.

(c) Termination Permitted Due to Change in Law. Either Party may terminate this Agreement as permitted in accordance with Section 8(b) of this Agreement upon a change in an applicable law that causes performance in compliance with this Agreement to violate the law.

(d) Effect of Termination.

(i) Except as provided in paragraph (ii) of this Subsection and except with respect to Limited Data Set Information, upon termination of this Agreement for any reason, AJRR will return or destroy all PHI received from Participant, or created or received by AJRR on behalf of Participant. AJRR will retain no copies of the PHI, except as provided in paragraph (ii) of this Subsection or to the extent that the PHI constitutes Limited Data Set Information.

(ii) In the event that AJRR reasonably determines that returning or destroying the PHI is infeasible due to inclusion of such PHI in a Database or for other reason, AJRR will not return or destroy the PHI, may retain copies of the PHI to the extent it has been entered into a Database, and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, AJRR will extend the protections of this Agreement to such PHI and limit any further Use or Disclosure of such PHI to those purposes that make the return or destruction infeasible, for so long as AJRR maintains such PHI.

(iii) The Parties acknowledge and agree that the provision of any PHI to AJRR in accordance with the Participation Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the Parties agree that Participant will refrain from submitting PHI to AJRR, and AJRR will refrain from accepting PHI from Participant. In the event of a termination under either Subsection (b) or (c) of this Section 6, either Party may also elect to terminate the Participation Agreement. In the event the Parties engage in negotiations undertaken in accordance with Subsection 8(b) of this Agreement, the Parties will suspend during such period of negotiation any provision of the Participation Agreement requiring or obligating either Party to Use or Disclose PHI in a manner that either Party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations.
(iv) The obligations of this Subsection 6(d) will survive any expiration or termination of this Agreement.

SECTION 7
INDEMNIFICATION

AJRR agrees to indemnify and hold harmless Participant from direct losses and damages relating to third-party claims suffered as a result of AJRR’s breach of its obligations under this Agreement. Participant agrees to indemnify and hold harmless AJRR from direct losses and damages relating to third-party claims suffered by AJRR as a result of Participant’s breach of its obligations under this Agreement. Under no circumstances, however, will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement. The Parties’ obligations under this Section 7 regarding indemnification will survive any expiration or termination of this Agreement.

[IF PARTICIPANT IS A GOVERNMENT INSTITUTION THAT IS NOT ABLE TO PROVIDE INDEMNIFICATION, THE FOLLOWING ALTERNATIVE PROVISION MAY BE SUBSTITUTED FOR THE ABOVE SECTION 7:

7. Responsibilities of the Parties

Each party to this Agreement agrees that it will be responsible for its own acts and omissions and the results thereof; and, shall not be responsible for the acts and omissions of the other party and the results thereof. Each party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees under this Agreement. Under no circumstances will either party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.]

SECTION 8
MISCELLANEOUS

(a) Regulatory References. A reference in this Agreement to a section in the HIPAA Regulations means the section as in effect or as amended from time to time and for which compliance is required.

(b) Amendment. This Agreement may not be amended except by the mutual written agreement of the Parties. Notwithstanding the foregoing, the Parties agree to work together in good faith to take such action as is necessary to make technical amendments to this Agreement from time to time if necessary for Participant and/or AJRR to comply with the requirements of HIPAA, the HIPAA Regulations, or any applicable provisions of any other federal or state law, as such laws or regulations may be amended from time to time. However, should any state or federal law or regulation now existing or enacted after the Effective Date of this Agreement, including without limitation HIPAA or the HIPAA Regulations, be amended or interpreted by judicial decision or a regulatory body in such a manner that either Party reasonably determines renders any provision of
this Agreement in violation of such law or regulation or adversely affects the Parties’ abilities to perform their obligations under this Agreement, the Parties agree to negotiate in good faith to amend this Agreement so as to comply with such law or regulation and to preserve the viability of this Agreement. If, after negotiating in good faith, the Parties are unable to reach agreement as to any necessary amendments, either Party may terminate this Agreement without penalty.

(c) **Interpretation.** Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participant and AJRR to comply with the HIPAA Regulations. Where provisions of this Agreement are different from those mandated in the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this Agreement will control.

(d) **Third Party Beneficiaries.** AJRR and Participant agree that Individuals whose PHI is Used or Disclosed to AJRR or its agents or subcontractors under this Agreement are not third-party beneficiaries of this Agreement or the Participation Agreement.

(e) **Waiver.** No provision of this Agreement may be waived except by an agreement in writing signed by the waiving Party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

(f) **Correspondence.** The Parties will send any reports or notices required under this Agreement to the addresses set forth in the notice provision of the Participation Agreement.

**IN WITNESS WHEREOF,** the Parties hereto have entered into this Agreement on the dates set forth below, so that it may take effect as of the Effective Date.

AMERICAN JOINT REPLACEMENT Registry, NFP

By: ________________________________
Print Name: __________________________
Title: ________________________________
Date: ________________________________

HOSPITAL PARTICIPANT (if any)

By: ________________________________
Print Name: __________________________
Title: ________________________________
Date: ________________________________