November 22, 2019

Atrium Health

Bryan Saltzman, MD
OrthoCarolina
1915 Randolph Road
Charlotte, NC 28207

RESEARCH PROTOCOL APPROVAL, IRB File #11-19-20E

On November 22, 2019, the Institutional Review Board reviewed your research request:

Outcomes of Patients with Glenohumeral Osteoarthritis and Small to Large Rotator Cuff Repair

Your Protocol (dated 10/15/2019 version 1), Information Sheet, and Email Information Script were approved for use within the facilities of Atrium Health. Waiver of Consent Documentation was granted for the Information Sheet. Waiver of authorization was granted for the retrospective portion. The HIPAA Compliance Summary was approved. The Board determined your study poses minimal risk to subjects and meets criteria for Expedited review under 45 CFR 46.110, **Category #5: research involving materials that have been collected or will be collected solely for non-research purpose, and Category#7: Research on individual or group characteristics.**

The following materials were approved for use within this study:
-RCR in OA Email Script
-RCR in OA letter
-RCR in OA Phone Script
-ASES Patient Self Evaluation
-Sport 145 Patient Survey
-The Veterans RAND 12 Item Health Survey (VR-12)

If you plan to use the protocol in institutions outside of this facility, you must submit it to the IRB at that institution for approval. You are required to report any changes to the research study to the IRB for approval prior to implementation. The FDA requires that advertisements for recruiting subjects be reviewed and approved by the IRB before publication.

This approval expires on November 21, 2020. We will contact you in approximately 10 months to schedule an annual update and review of these projects. If you complete a study prior to receiving the form, please notify the IRB Office.

If we can be of any further assistance, do not hesitate to contact us. **Please use the IRB File # for reference.**

Sincerely,

Michael Runyon, MD
Chair, Atrium IRB

/jdt

Note: The IRB complies with the requirements found in Part 56 of the 21 Code of Federal Regulations and Part 46 of the 45 Code of Federal Regulations. Federal-Wide Assurance # 00000387. The Registration Number is IORG 0000740. The Carolinas HealthCare System Institutional Review Board follows the ICH GCP guidelines with regard to the rights of human subjects.

ATRIUM HEALTH
Institutional Review Board / Privacy Board

Request for Waiver of Consent Documentation

The CHS IRB/Privacy Board may waive the requirement for obtaining a *signed* informed consent form if it determines that certain conditions are met and justification is provided (45 CFR 46.117 and 21 CFR 56.109)

1. **The only record linking the subject and the research is the consent document, and the principal risk is potential harm resulting from breach of confidentiality. Each subject should be asked whether they want documentation linking them to the research and their wishes will govern.**

____X_____YES **_____NO**

2. **The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.**

____X____YES **_____NO**

3. **In order to grant the waiver, you will need to provide a justification for your request. Checking Yes/No above is not sufficient. (*Section will expand as you type*)**

Patients may no longer be in follow up and in order to answer the research question waiver of consent documentation is necessary

An Information Sheet containing basic elements of informed consent must be provided to the subject. Contact IRB office for details.

Investigator: **Bryan Saltzman, MD** **Department:** **OrthoCarolina Research Institute**
Phone: 704-323-3000

IRB File # 11-19-20E

Study Title: Outcomes of Patients with Glenohumeral Osteoarthritis and Small to Large Rotator Cuff Repair

Signature of Investigator **Date** 10/23/19

Your request has been reviewed and approved by the Chair or Vice Chair of the IRB on 25 NOV 19. It will be placed on file.

Michael Runyon, MD
Chair, AH IRB

Michael Brennan, DDS
Vice-Chair, IRB

Rachel Seymour, PhD
Vice Chair, IRB

CAROLINAS HEALTHCARE SYSTEM
Institutional Review Board / Privacy Board

Application for a Partial Waiver of Authorization For Screening/Recruitment Purposes

Submission Date:	**10/23/2019**	**IRB File #:**	11-19-20E
Investigator:	**Bryan Saltzman, MD**	**Dept: OrthoCarolina Research Institute**	
Coordinator:	**Caleb Michalek, CCRC**	**Phone: 704-323-3698**	

Study Title: Outcomes of Patients with Glenohumeral Osteoarthritis and Small to Large Rotator Cuff Repair

A. Describe your screening/recruitment method:
Include how and where subjects will be identified and recruited.
Indicate who will do the recruitment, and tell how subjects will be contacted.
Describe how you will protect the privacy of potential subjects during recruitment

A query of the OrthoCarolina administrative database will be performed from January 2010 to June 2017 to capture all patients who underwent rotator cuff repair, of a small to large tear with concomitant glenohumeral OA. The query will include a search of CPT code 29827. Clinic and hospital medical records will be reviewed to determine if inclusion/exclusion criteria are met. We will include the study specific existing data in the research database for those patients who have routine clinical and radiographic data available. Therefore, a partial waiver of authorization is requested for this group.

B. Explain how your method meets the following four criteria. Identifiers must be destroyed at the earliest opportunity unless there is a scientific or legal reason to keep.

1. The use of PHI for identifying eligibility and contacting potential subjects will not involve more than minimal risk to the individual's privacy:
Describe the protected health information (PHI) to be collected.
Describe the source(s).
When it will be de-identified or destroyed.

All information in OrthoCarolina medical record related to conducting surgical procedure or follow-up. PHI (name, DOB, medical record number, SSN, date of death, gender, race, ethnicity, email address, mailing address, and phone number) will be collected on those patients who meet study criteria. SSN will be used to check the social security death index to see if any patients are deceased.

PHI will not be shared. PHI will be used to access the medical records to identify eligible patients and to collect some data. Identifiers will be destroyed upon completion of data collection.
Data not disclosed unless stripped of identifiers.
Data coded prior to any disclosure.
The investigator retains a confidential master list.

2. The Waiver of Authorization will not adversely affect the rights and welfare of the participants:

The waiver of authorization will not adversely affect the rights and welfare of the participants. PHI will be used to access the medical records to identify eligible patients and to collect some data. Identifiers will be destroyed upon completion of data collection.

3. Recruitment can not be practicably carried out without the Partial Waiver of Authorization:

Patients may no longer be in follow-up.

4. Recruitment can not practicably be conducted without the participant's PHI:

Access to PHI is necessary in order to determine study eligibility and answer the research question. Patients are identified via a query and may no longer be in follow-up with the provider.

C. Submit Authorization for Release of Health Information for Purposes of Research.

The PI assures that participant's health information is protected against improper use or disclosure by agreeing to the following:
Only information essential to the purpose of screening/recruitment will be collected.
Access to the information will be limited to the greatest extent possible.
Protected health information will not be re-used or disclosed to any other person or entity.

Signature of Investigator **Date** 10/23/19

**Acceptable recruitment practices:
1. Health care professionals (HCPs) who are conducting a study may talk with their own patients about the option of study enrollment
2. HCPs may use their own knowledge of the patient's condition and their knowledge of colleague's studies to inform patients about a clinical trial
   - HCP may give researcher's contact information to the patient, and patient may initiate contact
   - The researcher may obtain a partial waiver of authorization from the IRB
   - Patient may give written authorization for participation
3. The researcher may post IRB-approved flyers or advertisements, and eligible patients directly contact researcher

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(For IRB Use Only)

Your documentation has been received, reviewed, and approved by the IRB on

25NOV19 (Date). It will be placed on file.

Michael Brennan, DDS
Vice Chair, IRB

Rachel Seymour, Ph.D.
Vice Chair, IRB

Michael Runyon, MD
Chair, IRB

Jon Schwaiger, CIP
Administrative Director/Research/IRB