

Official Title:

GRAVITY: **G**enicular **a**rtery embolization **v**ersus observation for the **t**reatment of symptomatic knee osteoarthritis: a randomized controlled trial.

NCT Number:

NCT04682652

Document Type:



Statistical Analysis Plan

Document Date:

version 1.0, 01Mar2026

## Statistical Analysis Plan

Document history and plan
This SAP document (V1 01Mar2026) is generated based on the clinical protocol 3.0 (02Sep2025).

Title	GRAVITY: Genicular artery embolization versus observation for the treatment of symptomatic knee osteoarthritis: a randomized controlled trial
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Document version	Version 1
Date	03Mar2026
Printed Name of Principal Investigator	Siddharth Padia
Principal Investigator Signature/Date	<div><div>Signed by: <i>Siddharth Padia</i></div><div> Signer Name: Siddharth Padia Signing Reason: I approve this document Signing Time: 05-Mar-2026   17:36 PST FA003B21EA044B91BC79ED2598FBE6B4</div><div>05-Mar-2026   17:36 PST</div></div>
Printed Name of Trial Statistician	Grace Hyun Kim
Trial Statistician Signature/Date	<div><div>Signed by: <i>Grace Hyun Kim</i></div><div> Signer Name: Grace Hyun Kim Signing Reason: I am the author of this document Signing Time: 06-Mar-2026   16:17 PST 43A8CA6A1D44443B94CF5F105105EC06</div><div>06-Mar-2026   16:17 PST</div></div>

**Protocol Title:** Genicular artery embolization versus observation for the treatment of symptomatic knee osteoarthritis: a randomized controlled trial.

**Protocol Number:** 3.0

**Compound Number:**

**Short Title:** GRAVITY

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**Funding Organization :** Varian Medical Systems

**Regulatory Agency Identifier Number(s):**

**Registry ID :** NCT04682652

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**Version History**

This statistical analysis plan (SAP) is for Study GRAVITY

<b>Master Protocol SAP Version</b>	<b>Date</b>	<b>Change</b>	<b>Rationale</b>
1	03Mar2026	Not applicable	Original version

## 1. Introduction

Osteoarthritis (OA) is the most common degenerative joint disease and a leading cause of chronic pain and physical disability in older individuals. The lifetime risks of developing symptomatic knee OA are estimated at 40% in men and 47% in women (Cross, 2014). Selective genicular artery embolization (GAE) is a minimally invasive procedure that involves catheterization of the genicular artery and partial occlusion of this vessel (embolization) with particles. Data from multiple single-arm prospective studies in humans have been completed and show an excellent safety profile and promising efficacy (Okuno, 2017; Okuno 2015; Bagla, 2020; Landers, 2020). The desired effect is to decrease vascularity, leading to a reduced inflammatory response and subsequent pain relief.

The knee receives its blood supply from the genicular arteries, branches from the superficial femoral and popliteal arteries. Deliberate partial blockage of the genicular arteries (embolization) leads to reduction of the inflammatory response, with potential improvement in pain.

The first prospective trial in the United States was recently published by Bagla and colleagues in 2020 (Bagla, 2020). The purpose of their study was to evaluate the safety and clinical outcomes of genicular artery embolization (GAE) using a permanent embolic agent (Embozene, Varian Medical Systems) in a U.S. population. Twenty patients with radiographic knee OA and moderate-to-severe pain refractory to conservative therapy were enrolled in this investigational device exemption trial. Patients were assessed with magnetic resonance imaging at baseline and at 1 month following GAE and with the Visual Analogue Scale (VAS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at baseline and at 1, 3, and 6 months. Adverse events were recorded at all time points.

<i>Generic name</i>	GRAVITY
<i>Protocol</i>	3.0
<i>Statistical Analysis Plan (SAP)</i>	Intervention-specific Appendix Statistical Analysis Plan (ISA-SAP)
<i>Subject</i>	100 Participants
<i>Population</i>	knee osteoarthritis
<i>Interim analysis</i>	Not Applicable

## 1.1. Objectives, Endpoints, and Estimands

### Primary estimand

The primary clinical question of interest is: What is the difference of genicular artery embolization (GAE) treatment in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) after 6 months of treatment in participants with radiographic knee Osteoarthritis (OA) regardless of intervention discontinuation for any reason and regardless of initiation of rescue intervention or change in background intervention?

The estimand is described by the following attributes:

Population: participants with radiographic knee OA. Further details can be found in Section 4 of the Clinical Protocol.

Endpoint: Percentage of the clinical response (subjects achieving at least a 50% reduction from baseline) on Month 6 in WOMAC

Treatment condition: the randomized treatment with or without change in background medication (treatment policy strategy). Further details on study interventions and concomitants, including interventions can be found in Section 5 of the Clinical Protocol.

Population-level summary: Difference in Percentage of the clinical response between treatment conditions

Rationale for estimand: standardized validated scoring WOMAC has been used multiple trials. The first trial on GAE was reported by Okuno and colleagues in 2017 (Okuno, 2017), which was a prospective, open-label single arm trial from 72 patients. The intent-to-treat clinical success rate at 6 months of follow-up was 86.3% (95% CI, 78%–92%).

Given the lack of approved therapies, any changes to treatment are believed to be in the interest of the participants of knee OA.

### Secondary estimands

The clinical question of interest is for the secondary objective regarding [GAE]: What is the treatment difference in the percentage of participants achieving [WOMAC] after [6 months] of treatment in participants with [radiographic knee OA] regardless of treatment discontinuation for any reason and regardless of initiation of any interventions affecting [outcome], eg, [medication and/or surgery]?

The estimand is described by the following attributes:

Population: participants with [radiographic knee OA]. Further details can be found in Section 4 of the clinical Protocol.

- Endpoints:
  - clinical response of WOMAC at Month 1
  - clinical response of WOMAC at Month 3

- Longitudinal clinical response rate over 1 months, 3 months, 6 months, 12 months, and 24 months
- Longitudinal changes in mean of WOMAC (measured by percentage) over 1 months, 3 months, 6 months, 12 months, and 24 months.
- Longitudinal changes in pain measured in visual analog scale (VAS) over 1 months, 3 months, 6 months, 12 months, and 24 months.
- Longitudinal changes in health-related quality of life (measured by Knee injury and Osteoarthritis Outcome Score (KOOS)) over 1 months, 3 months, 6 months, 12 months, and 24 months.
- Compare clinical success rates based on varying reductions in WOMAC (16% - minimally clinically important difference, 75%, and 90%) over 1 months, 3 months, 6 months, 12 months, and 24 months.

Rationale for estimand: Mean WOMAC pain scores decreased significantly from 12.1 at baseline to 6.2 at 1 month, 4.4 at 4 months, 3.7 at 6 months, 3.0 at 12 months, and 2.6 at 24 months (all  $P < .001$ ). The mean total WOMAC score also decreased significantly from 43 at baseline to 24, 14.8, 11.2, 8.2, and 6.2 at 1, 4, 6, 12, and 24 months, respectively (all  $P < .001$ ). The mean VAS score significantly decreased from 72 (scale of 1 to 100) at baseline to 38, 29, 19, 13, and 14 at 1, 4, 6, 12, and 24 months, respectively (all  $P < .001$ ). Patients reported a decrease in the dose of medication used and frequency of other treatments after the procedure.

No serious adverse events were noted. Minor complications occurred, such as moderate subcutaneous hemorrhage at the puncture site and transient cutaneous color change on the treated knee, all of which resolved without treatment.

Treatment condition: the randomized treatment with or without any other GAE (treatment policy strategy). Further details on study interventions and concomitants can be found in Section 5 of the Clinical Protocol.

## 1.2. Study Design

- This is a pivotal phase study to investigate the efficacy and safety in cohorts of graphical evidence of knee OA.
- The Protocol describes the framework for the general study population and the common study elements of the study. The justification for the study intervention dose(s), the number of participants to be assigned to an intervention cohort, any additional inclusion and exclusion criteria, and any additional study elements for the study intervention(s) as applicable.
- The duration of individual participation will be approximately 24 months.
- Randomization across arms will be performed into 2:1 ratio of GAE to control.

- Throughout the study efficacy, safety, medical MRI imaging, inflammatory markers will be assessed at the Month 24 indicated in the applicable Schedule of Activities.
- A database lock is planned to occur after the completion of each intervention cohort.
- A Data Monitoring Committee will be commissioned to review safety data periodically.

## **2. Statistical Hypotheses**

### **2.1. Multiplicity Adjustment**

Statistical comparisons for the primary efficacy endpoint and an overall alpha level of 0.05 will be preserved for the primary endpoint. No adjustment for multiplicity is planned beyond primary and key secondary objective analyses.

### 3. Analysis Sets

- Definitions that apply to entire study should be described in the Protocol.

For the purposes of analysis, the following analysis sets are defined:

Participant Analysis Set	Description
Full analysis set	<ul style="list-style-type: none"> <li>All randomized participants. Participants will be included in the analysis according to the planned intervention.</li> </ul>
Safety analysis set	<ul style="list-style-type: none"> <li>All participants are exposed to study intervention. Participants will be included in the analysis according to the intervention they actually received.</li> </ul>

The full analysis set is used to analyze endpoints related to the efficacy objectives, and the safety analysis set is used to analyze the endpoints and assessments related to safety.

PAS = participant Analysis set

The following data points sets are defined:

Data Points Sets	Description
DPS1: IIT	The intent-to-treat analysis will include all subjects who are enrolled in the study.
DPS2: PP	The per-protocol analysis will include all subjects without any major protocol deviations and were suitable for effectiveness assessments.

FAS and DPS1 are used to estimate the primary estimand and the secondary estimand for secondary objective 1. FAS and DPS1 are used to estimate the additional estimand for the primary objective.

Safety analysis set and DPS2 are used to present safety data.

For the purposes of this study, the Enrolled analysis set consists of patients who are registered to participate in this trial with informed consent signed and have undergone the inclusion/exclusion criteria assessment. At the time of enrollment, the patient's study identification code and dose cohort will be assigned. The demographic and baseline characteristics, medical history and pre-existing conditions of patients in the Enrolled analysis set will be summarized and listed.

The intent-to-treat analysis will include all subjects who are enrolled in the study. The per-protocol analysis will include all subjects without any major protocol deviations and were suitable for effectiveness assessments. In the secondary analysis, for those who in the observation arm have crossover to GAE at 6 months, the baseline will be set as the month 6 visit. The changes from months 1, 3, 6, 12, and 24 months will be adjusted from the average baseline. Crossover subjects will be included in the per-protocol analysis.

## **4. Statistical Analyses**

### **4.1. General Considerations**

- The statistical analysis will be performed in alignment with the following standards and regulations. The following paragraphs describe the statistical analysis for the evaluation of the primary and secondary endpoints and other analysis that will be performed at the end of the study..
- Patient demographics and baseline characteristics will be summarized on the FAS set, overall and by randomized treatment group, by means of summary descriptive statistics.
- For qualitative variables (e.g. sex), absolute (n=100 ) and relative frequencies will be calculated per treatment group. Data will be visualized by bar plots. For quantitative data (e.g. age), the number of valid observations (n=100 ), mean, standard deviation, standard error, median, interquartile range, minimum and maximum will be calculated for each randomized group.
- Data will be visualized by bar plot, histogram or boxplot and eventually described. whether reference/normative values will be plotted.

### **4.2. Primary Endpoints Analysis**

#### **4.2.1. Definition of Endpoint**

The primary endpoint is the clinical success rate at 6 months, where clinical success is defined by at least a 50% reduction in WOMAC pain score (version 3.1) [Bellamy 1988, Stratford 2006]

The WOMAC Score is comprised of the total score of the following 5 indexes (ranging 0-4), themselves comprised of 24 subtests, with total possible score of 96:

Measurement Domains: It consists of 24 items, categorized into three subscales: Pain (5 items), Stiffness (2 items), and Physical Function (17 items).

1. Pain – Walking, Stair Climbing, Nocturnal, Rest, and Weight bearing
2. Stiffness – Morning stiffness, and Stiffness occurring later in the day
3. Physical Function – Descending stairs, Ascending stairs, Rising from sitting, Standing, Bending to floor, Walking on flat surface, Getting in/out of car, Going shopping, Putting on socks, Lying in bed, Taking off socks, Rising from bed, Getting in/out of bath, Sitting, Getting on/off toilet, Heavy domestic duties, and Light domestic duties.

Scoring: Each item is typically rated on a 5-point Likert scale (0=None, 1=Slight, 2=Moderate, 3=Very, 4=Extremely), with subtotal scores ranging from 0–20 for pain, 0–8 for stiffness, and 0–68 for physical function.

**Total Score:** The total WOMAC score is calculated by summing all 24 items, ranging from 0 to 96, where higher scores indicate higher levels of pain, stiffness, and functional difficulty.

The Pain Score (0-20) and Total Score (0-96) will be calculated. Clinical success is defined by at least a 50% reduction in WOMAC pain score from baseline.

#### **4.2.2. Main Analytical Approach**

Continuous variables, including baseline characteristics, will be summarized by reporting the number of observations, mean, standard deviation, median, minimum and maximum. Categorical/discrete variables will be summarized using frequency tables showing the number and percentage of patients within a category. Unless indicated otherwise, summary statistics will be reported for observed data only. Missing data will not be imputed. If a baseline value is missing, no change from baseline will be calculated.

##### *Primary Efficacy Analyses*

The primary analysis of efficacy will be performed using the percentage of patients with clinical success at 6 months, with an intent-to-treat analysis. At least a 50% reduction in WOMAC must be reached to be considered a clinical success. Results will be compared between the experimental arm and observational arm using the exact Fisher's test, designed for a superiority study in favor of GAE. All statistical tests and confidence intervals (CIs) using binomial distribution of clinical response rate will be reported in two-sided with a nominal significance level of  $p < 0.05$  (95% confidence) at Month 6.

#### **4.2.3. Sensitivity Analyses**

No sensitivity analyses are planned.

#### **4.2.4. Supplementary Analyses**

We plan to run supplementary analyses by varying clinical response rates of 16% (MCID), 75%, and 90% changes in WOMAC total scores. These analyses can estimate the maximum difference of response rates in WOMAC total scores between two arms.

### 4.3. Secondary Endpoints Analysis

#### 4.3.1. Secondary Endpoints

##### 4.3.1.1. Definition of Endpoint(s)

Part one of Secondary analyses will also include analyzing clinical response rates from baseline to other time points and between post-treatment time points.

- Clinical response rate at Month 1
- Clinical response rate at Month 3

Part two of Secondary analyses will also include analyzing longitudinal changes from baseline to other time points and between post-treatment time points.

- The baseline and follow-up observations (Month 1, 3, 6, 12, 24) will be included in the model. For the GAE and observational arm, all the changes from baseline will be used.
  - Longitudinal clinical response rate over Month 1, Month 3, Month 6, Month 12, and Month 24.
  - Longitudinal changes in mean of WOMAC Pain score over Month 1, Month 3, Month 6, Month 12, and Month 24.
  - Longitudinal changes in mean of WOMAC Total score over Month 1, Month 3, Month 6, Month 12, and Month 24.

For the longitudinal changes, WOMAC score can be transformed into square-root and logarithm per Box-Cox transformation, before analysis if the secondary endpoint does not follow Normal distribution.

##### 4.3.1.2. Main Analytical Approach

###### Secondary Analyses of clinical response

At least a 50% reduction in WOMAC must be reached to be considered a clinical success. Results will be compared between the experimental arm and observational arm using the exact Fisher's test, designed for a superiority study in favor of GAE. All statistical tests and confidence intervals (CIs) using binomial distribution of clinical response rate will be reported in two-sided with a nominal significance level of  $p < 0.05$  (95% confidence) at Month 6.

###### Secondary Analyses of continuous scale

A linear mixed model (LMM) will be used to test for the mean change in WOMAC pain scores. For WOMAC, both landmark analysis (percentage of subjects achieving at least a defined reduction (e.g. 16%, 50%, 75%, 90%) reduction from baseline) and the longitudinal mean change will be used.

For those in the observation arm who cross over to GAE at 6 months, the baseline will be set as the month 6 visit. The changes from Month 1, 3, 6, 12, and 24 months will be adjusted from the average baseline. Crossover subjects will be included in the per-protocol analysis.

#### **4.3.1.3. Sensitivity Analyses**

In the case of transformation was made based on in WOMAC score, assumptions and the main analytical approaches will be examined. The exact transformation of efficient will be used for testing the treatment arm group. If there are more than 15% of missing outcomes, the missing data mechanism will be explored.

#### **4.3.1.4. Supplementary Analyses**

If there are any updated during study conduct and new intercurrent events, the new intercurrent events result in a change of secondary estimand a protocol amendment will be explored.

### **4.3.2. Supportive Secondary Endpoints**

- Longitudinal changes in other outcomes of pain (measured by VAS),
- health-related outcome (KOOS) will be analyzed.

For VAS pain scale, both landmark analysis (percentage of subjects achieving at least 50% reduction from baseline) and mean change over time will be used. Compare mean decrease in pain (measured by VAS: visual analog scale) between GAE and observation at various timepoints: 1 month, 3 months, 6 months, 12 months, 24 months. This will be a per-protocol analysis.

Similarly, For KOOS, change over time will be used to estimate the mean changes.

### **4.4. Exploratory Endpoints Analysis**

At the conclusion of the 24-month follow up, all subjects will be stratified into observation group, GAE with clinical responders (based on a threshold of 50% improvement in WOMAC score), and GAE with clinical non-responders for the purposes of MRI and biochemical analyses.

The 6- and 24-month change in imaging (MRI) and change in biochemical markers between the three groups will be compared to identify markers that correlate with symptom improvement. Also changes in inflammatory markers will be compared for GAE and observation arms at 6 and 24 months. Changes in chronic pain medication will also be summarized by each arm.

#### **4.5. Safety Analyses**

All safety analyses across all interventions in the study will be based on the Safety analysis dataset including all randomized participants who are exposed to study intervention(s). Participants will be analyzed according to the intervention(s) they actually receive.

##### **4.5.1. Extent of Exposure**

For each intervention, GAE or repeated treatments will be calculated over treatment duration in months/years.

##### **4.5.2. Adverse Events**

All safety analyses will be performed on the FAS. Treatment will be evaluated as treated. Safety analysis will be planned for both over 6 months as well as over the whole trial beyond 24 months. Cumulative rates of AEs will be estimated and 95% CIs will be reported. AEs will be analyzed as a composite of all AEs, composites based on major AE types or severity and as individual AE types. The rates will be compared qualitatively to values reported in the literature of other studies of GAE and knee arthroplasty.

#### **4.6. Other Analyses**

##### **4.6.1. Other Variables and/or Parameters**

Not applicable

##### **4.6.2. Subgroup Analyses**

Subgroup analyses of the primary endpoint and confirmatory secondary endpoints will be made to assess consistency of the intervention effect across the following subgroups:

- Age group: < 65 vs ≥ 65 years
- Sex: female vs male
- Race: white vs black vs other

If the number of participants is too small (less than [10%]) within a subgroup, then the subgroup categories may be redefined prior to unblinding the study.

The treatment effect and its associated 95% confidence interval will be estimated for each subgroup. A forest plot summarizing the results will be provided.

#### **4.7. Interim Analysis**

No interim analysis of the primary endpoint is planned to conduct. Real-time analysis of safety events (a secondary endpoint) is conducted.

#### **4.8. Changes to Protocol-planned Analyses**

No changes to Protocol-planned analyses are expected.

## **5. Sample Size Determination**

The study will involve a screening period in which patient eligibility is determined. Once eligibility is confirmed, subjects will then be randomized to GAE or observation in a 2:1 ratio. Group sample sizes of 67 and 33 achieve approximately 85% power to reject the null hypothesis of no difference in the clinical response defined by 50% or greater reduction in WOMAC between the treatment and observation arms with a significance level (alpha) of 0.050 using a two-sided two-proportions using Fisher's exact test. With 100 symptomatic knee osteoarthritis subjects, the power of study is approximately 85% where we assume a target response rate of 67.5% for the experimental arm and 31% for the observational arm with up to 20% drop-out rate prior to 6 months. All study subjects will undergo the initial procedures, consisting of a history and physical exam, dynamic contrast-enhanced knee MRI, blood serum and joint aspiration with biochemical analysis.

## 6. Supporting Documentation

### 6.1. Appendix 1: List of Abbreviations

Abbreviation	Definition
AE	adverse event
CI	confidence interval
KOOS	Knee Injury and Osteoarthritis Outcome
MedDRA	medical dictionary for regulatory activities
SAP	Statistical Analysis Plan
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

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If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

### **All notices and disclosures will be sent to you electronically**

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

### **How to contact UCLA Health System - Part 11:**

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: [DocuSignSupport@mednet.ucla.edu](mailto:DocuSignSupport@mednet.ucla.edu)

### **To advise UCLA Health System - Part 11 of your new email address**

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at [DocuSignSupport@mednet.ucla.edu](mailto:DocuSignSupport@mednet.ucla.edu) and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

### **To request paper copies from UCLA Health System - Part 11**

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to [DocuSignSupport@mednet.ucla.edu](mailto:DocuSignSupport@mednet.ucla.edu) and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

### **To withdraw your consent with UCLA Health System - Part 11**

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to DocuSignSupport@mednet.ucla.edu and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

### **Required hardware and software**

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <https://support.docusign.com/guides/signer-guide-signing-system-requirements>.

### **Acknowledging your access and consent to receive and sign documents electronically**

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to ‘I agree to use electronic records and signatures’ before clicking ‘CONTINUE’ within the DocuSign system.

By selecting the check-box next to ‘I agree to use electronic records and signatures’, you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify UCLA Health System - Part 11 as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by UCLA Health System - Part 11 during the course of your relationship with UCLA Health System - Part 11.