Embolization in Splenic Trauma – II (ELSA II)

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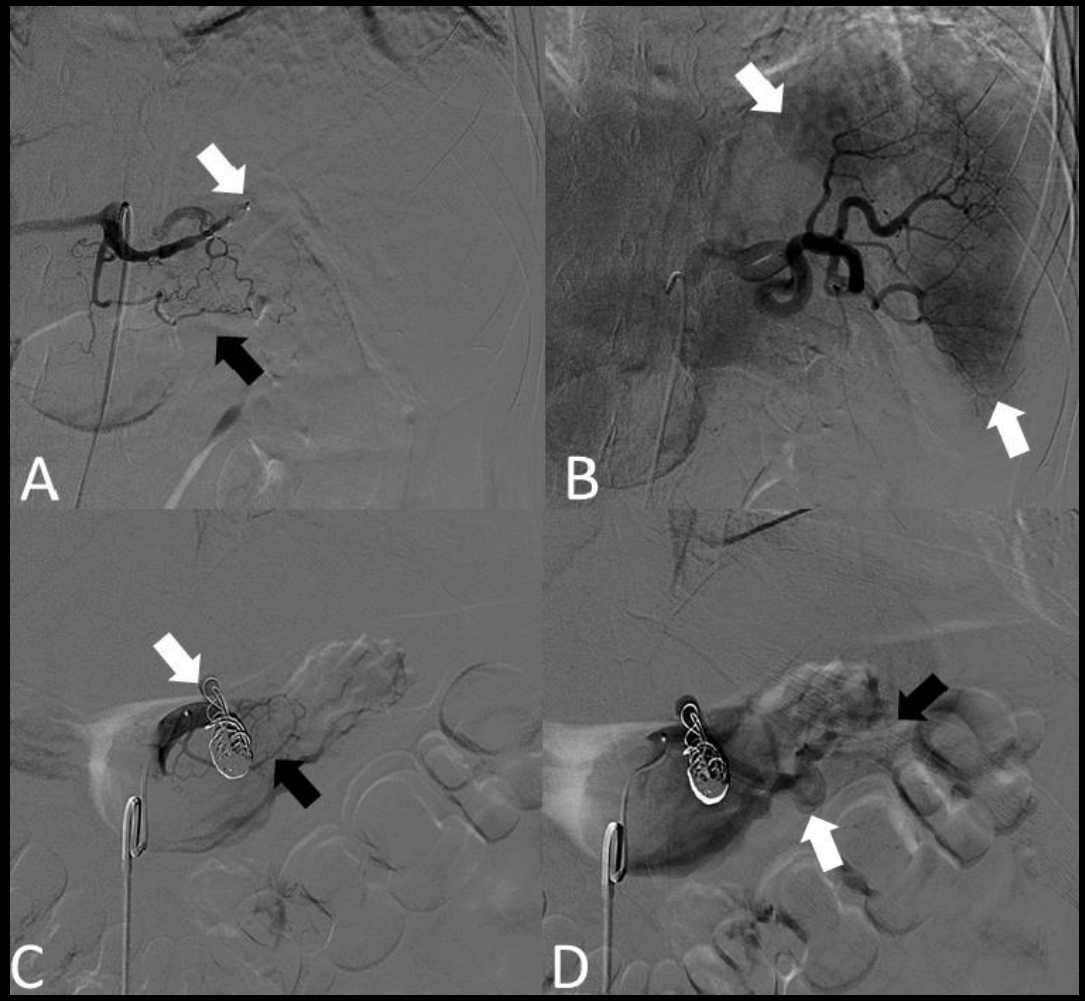
Principal Investigators

Splenic Trauma is Common

- Most commonly injured organ in blunt abdominal trauma
- Hemodynamically stable patients with high-grade splenic trauma are managed with splenic artery embolization (SAE)
- Proximal SAE (pSAE) decreases the perfusion pressure to the spleen, allowing it to heal, while collateral flow preserves splenic function
- Little data comparing the two most common embolic agents, plugs and coils, for pSAE



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ELSA - I

- Single center (UAB), prospective, randomized clinical trial
- Primary outcome: Feasibility (enrollment and follow up)
- Secondary outcome: Identify clinically-relevant endpoints for a follow on clinical trial

Table 1. Baseline characteristics of the study cohort.

		Randomized to		Received	
	All	Coils	Plug	Coils	Plug
n	46	23	23	25	21
DEMOGRAPHICS					
Sex					
Male, n (%)	33 (72)	17 (74)	16 (70)	19 (76)	14 (67)
Female, n (%)	13 (28)	6 (26)	7 (30)	6 (24)	7 (33)
Age, years, median (IQR)	38 (26-55)	39 (26-61)	34 (26-50)	39 (26-61)	33 (26-48)
Source					
Scene, n (%)	26 (57)	13 (57)	13 (57)	14 (56)	12 (57)
Interfacility transfer, n (%)	20 (43)	10 (43)	10 (10)	11 (44)	9 (43)
INJURIES					
Mode					
Blunt, n (%)	46 (100)	23 (100)	23 (100)	25 (100)	21 (100)
Penetrating, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mechanism					
MVC, n (%)	37 (80)	18 (78)	19 (83)	18 (72)	19 (90)
Fall, n (%)	8 (17)	5 (22)	3 (13)	6 (24)	2 (10)
Assault, n (%)	1 (3)	0 (0)	1 (4)	1 (4)	0 (0)
Injury severity and pattern					
Injury Severity Score, median (IQR)	25 (17-27)	25 (20-27)	26 (17-31)	25 (21-27)	22 (17-27)
Injury Severity Score >15, n (%) >15	36 (78)	18 (78)	18 (78)	20 (80)	16 (76)
Abbreviated Injury Scale, thorax, median (IQR)	2 (0-3)	2 (0-3)	3 (2-3)	2 (0-3)	3 (1-3)
Abbreviated Injury Scale, abdomen, median (IQR)	3 (3-4)	3 (3-4)	3 (3-4)	3 (3-4)	3 (3-3)
PHYSIOLOGY					
Vital signs on arrival in ED					
Systolic blood pressure, mmHg, median (IQR)	135 (121-144)	134 (119-143)	137 (123-148)	134 (120-144)	137 (125-146)
Heart rate, per minute, median (IQR)	95 (85-104)	93 (85-103)	98 (87-113)	93 (85-103)	98 (86-112)
Temperature, C, median (IQR)	97.6 (96.9-98.1)	97.5 (96.9-98.3)	97.7 (96.9-98.0)	97.5 (96.9-98.2)	97.7 (97.0-97.9)
Vasopressors runnning, n (%)	1 (2)	1 (4)	0 (0)	1 (4)	0 (0)
Intubated, n (%)	3 (7)	2 (8)	1 (4)	2 (8)	1 (5)
Major Hemorrhage Protocol activation, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
BLOODWORK					
Admission Laboratory Parameters					
Hemoglobin, mg/dL, median (IQR)	12.8 (10.2-14.9)	12.8 (11.4-14.9)	12.8 (10.0-14.2)	12.8 (11.1-14.9)	12.9 (10.1-14.2)
Platelet count, median (IQR)	203 (173-258)	197 (175-255)	219 (177-254)	193 (170-248)	221 (192-261)
Prothrombin time, median (IQR)	14.2 (13.6-15.0)	14.1 (13.6-14.8)	14.5 (13.6-15.1)	25 (24-28)	14.2 (13.6-15.0)
INR, median (IQR)	1.1 (1.0-1.2)	1.1 (1.0-1.2)	1.1 (1.0-1.2)	1.1 (1.0-1.2)	1.1 (1.0-1.2)
Creatinine, median (IQR)	0.9 (0.8-1.2)	1.0 (0.9-1.3)	0.9 (0.8-1.0)	1.0 (0.9-1.2)	0.9 (0.8-1.0)
Lactate, median (IQR) (6 missing)	1.7 (1-2.5)	1.7 (1.3-2.3)	1.1 (0.9-3.3)	1.7 (1.1-2.2)	1.4 (1.0-3.4)

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ELSA - I

- 92% of eligible patients were enrolled with 100% follow up in enrolled patients
- Splenic salvage was 98%; only 3 total complications
- Primary technical success was observed in 22 coil patients (96%; 95% CI: 87-100%) and 20 plug patients (87%; 95% CI: 73-100%). *Bayesian analysis suggests a >80% probability that primary technical success is higher for coils*

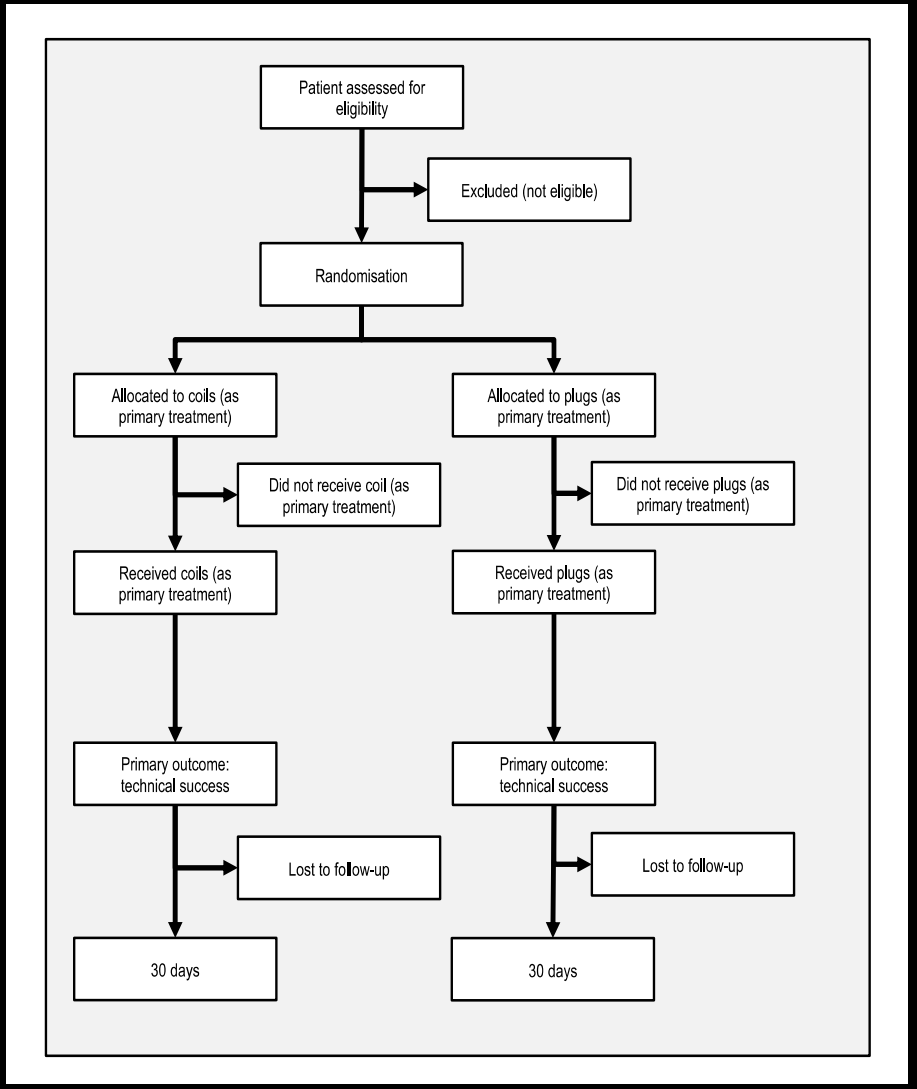
ELSA – II Objectives

- Primary outcome: Primary technical success of coils vs. plugs in pSAE for patients with high-grade splenic trauma

- Secondary outcomes will include clinically-relevant technical and clinical outcomes

ELSA – II Study Design

- Multi-center, randomized trial at 5 major Level 1 trauma centers
- Two arms powered for superiority, including 125 patients in each
- Study exit at 30 days



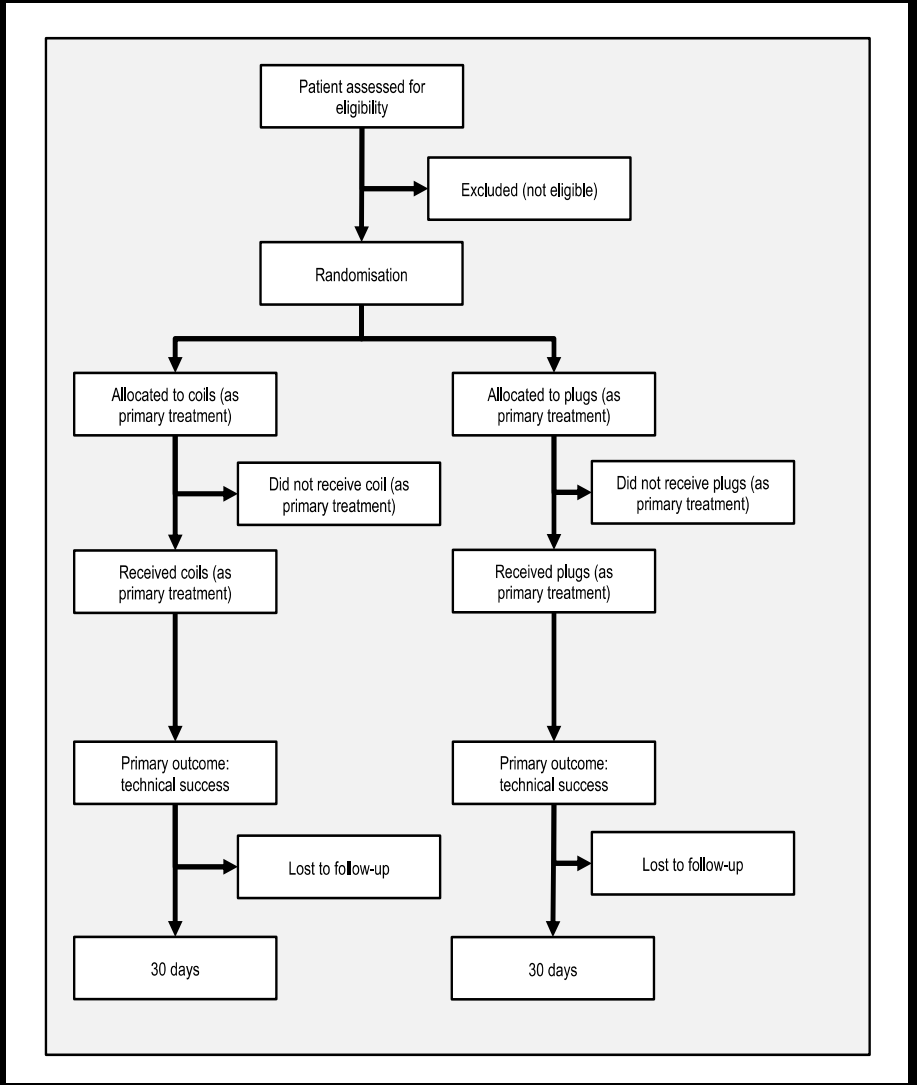
ELSA – II Sites

- Ohio State University/Wexner Medical Center
- Wake Forest Baptist Medical Center
- University of South Carolina – Greenville/Prisma Health
- University of Alabama at Birmingham
- University of Texas – Houston Medical Center

ELSA – II Institutional Work Flow

What would workflow look like at your institution?

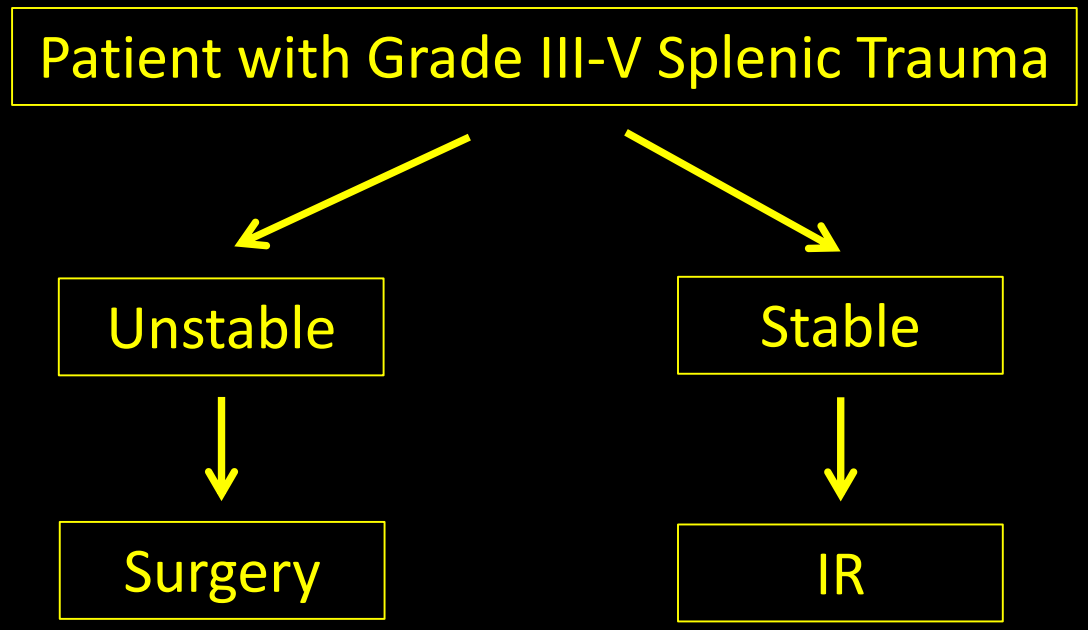
Who will be responsible for each of the steps in the workflow?



ELSA – II Screening and eligibility

Members of the study team are available 24/7 to screen patients for eligibility

Study protocol closely aligns with most clinical algorithms for the management of patients with splenic trauma



ELSA – II Screening and eligibility

Inclusion criteria:

a) ≥15 years of age
b) Trauma resulting in grade III or higher splenic injury on contrast-enhanced CT
c) Splenic injury to be treated by non-operative management as decided by attending trauma surgeon and interventional radiologist
d) The attending interventional radiologist determines that the patient will undergo proximal splenic artery embolization with the specific method to be decided by randomization.

Exclusion criteria:

a) Inability to obtain informed consent
b) ≤ 50kg
c) Uncorrectable coagulopathy
d) Patient is immunocompromised
e) Pregnant
f) Breast-feeding
g) Non-English speakers
h) Prisoners

ELSA – II Screening and eligibility

Informed consent: Written informed consent can be obtained from the patient or a legally-authorized representative (LAR). The LAR needs to physically sign the forms. Consent for the study ***cannot*** be obtained by telephone.

Non-English speakers: Participants ***do not*** need to be native English speakers to participate. As a general rule, if you need the assistance of a medical translator to obtain consent for the procedure, then the patient is ***ineligible*** for the study.

ELSA – II Informed consent

Written informed consent can be obtained from the patient or a legally-authorized representative (LAR).

The LAR needs to physically sign the forms. Consent for the study ***cannot*** be obtained by telephone.

If consent is signed by the LAR, the study team will continue to attempt to obtain consent from the subject once they become able to provide it

ELSA – II Informed consent

For each patient, there will be two consent forms:

Procedural Consent: usual consent obtained for the procedure following institutional guidelines

Study Consent: consent obtained for participation in the study that *needs to be signed by a study investigator (IR attending)*

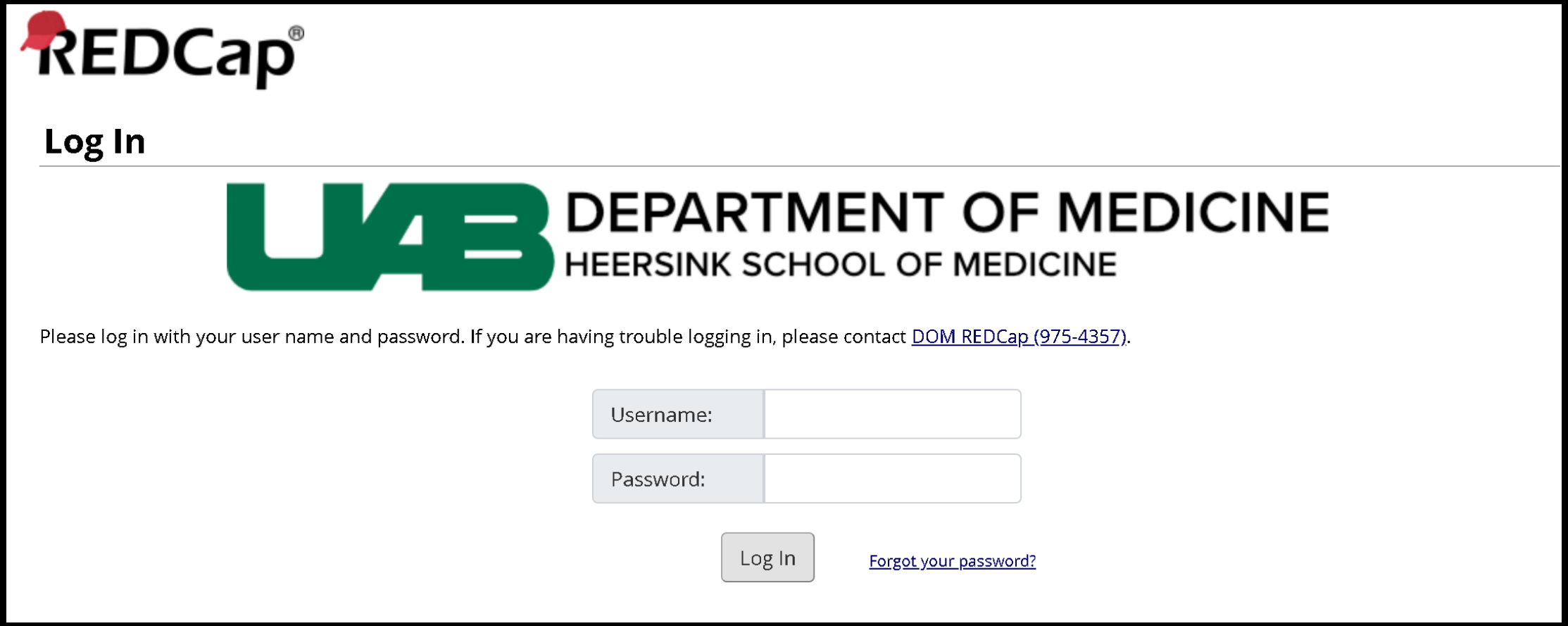
ELSA – II Randomization

Randomization to the plug arm or coil arm will occur via the REDCap site for the trial. This can be found here:

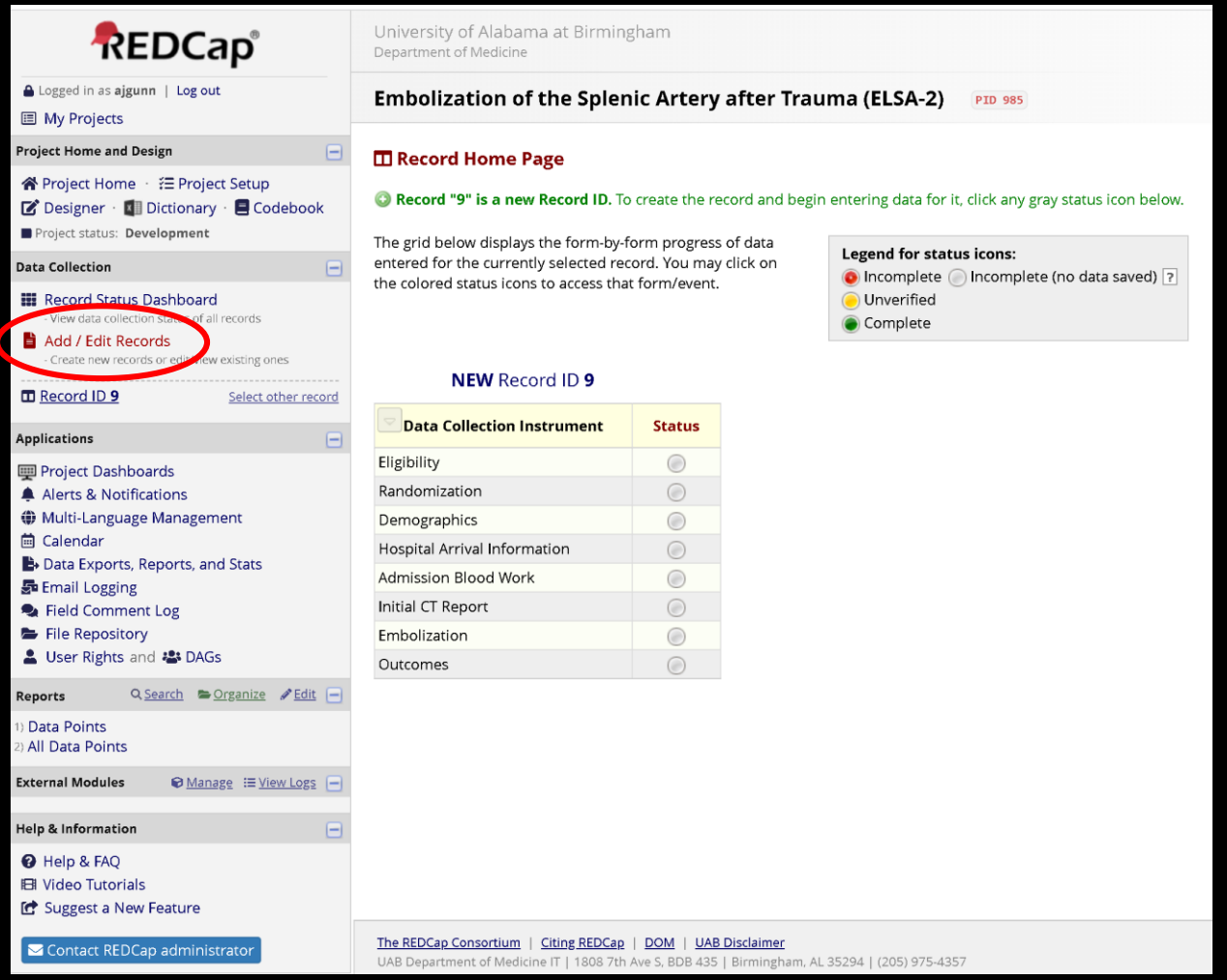
https://redcap.dom.uab.edu/redcap_v12.1.1/index.php?pid=985

All site investigators need a username and password

ELSA – II Randomization

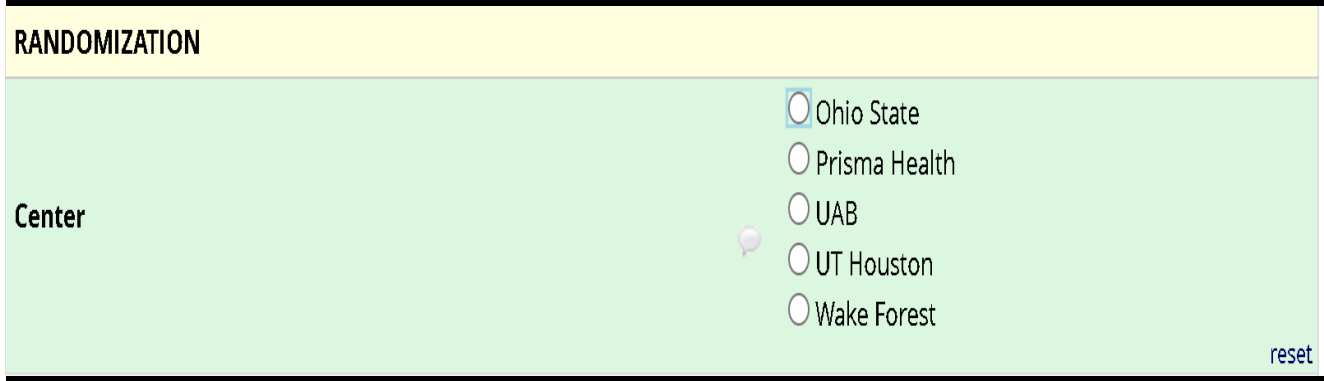


ELSA – II Randomization

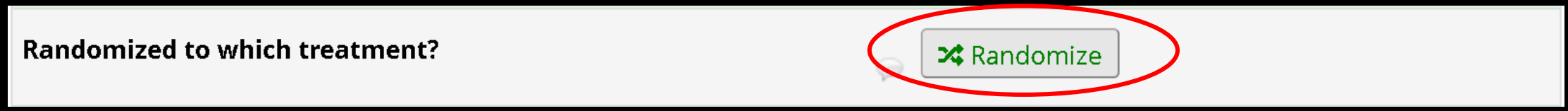


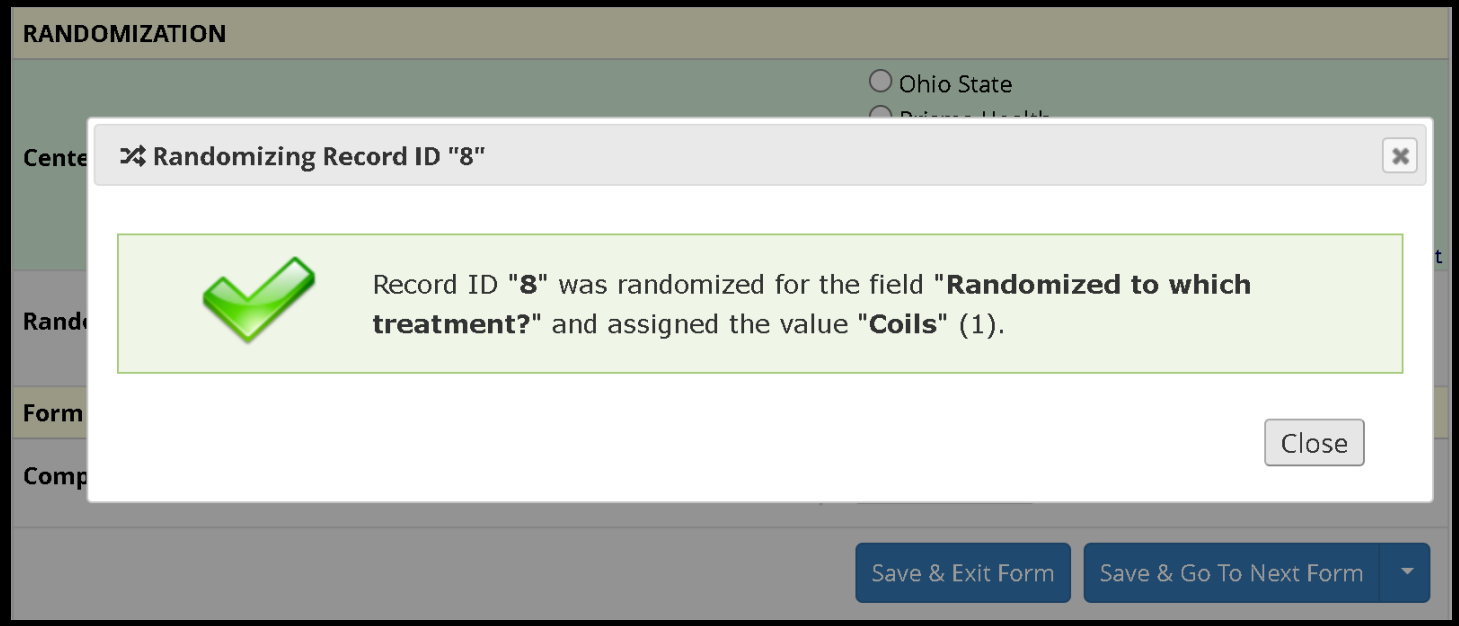
ELSA – II Randomization

Data Collection Instrument	Status
Eligibility	
Randomization	
Demographics	
Hospital Arrival Information	
Admission Blood Work	
Initial CT Report	
Embolization	
Outcomes	



ELSA – II Randomization





ELSA – II Randomization

Questions?

ELSA – II Data points

Note: Data does not need to be entered into REDCap at the time of the procedure. This can be done up to 14 days after the procedure. The information needs to be available in the procedural record, patient chart, or procedural dictation

1.3 Summary of Data Collected

ASSESSMENT	PRE-PROCEDURE	EMBOLIZATION	POST-PROCEDURE	30 DAYS
Eligibility	X			
Demographics	X			
Source	X			
Mechanism of Injury	X			
Vital signs	X			
Glasgow Coma Score	X			
Vasopressor use	X			
Intubated	X			
Massive transfusion protocol	X			
Injury Severity Score	X			
Anti-coagulation or anti-platelet use	X			
Laboratory work	X			
CT findings	X			
Procedure duration		X		
Radiation dose		X		
Contrast used		X		
Angiographic findings		X		
Type/size of embolics		X		
Primary technical success		X		
Secondary technical success		X		
Procedural complications		X		
Post-procedural complications			X	X
Transfusion requirements	X		X	X
Splenectomy			X	X
Mortality			X	X

ELSA – II Variable Elements of Procedure

Operators can perform pSAE using their typical techniques, including:

- Ability to use either femoral or radial artery access
- Ability to use any catheter, wire, or sheath combination to deploy the prescribed embolic
- Ability to sedate the patient using conscious sedation or general anesthesia
- Close the arteriotomy in the manner he/she sees fit

ELSA – II Required Elements of Procedure

Operators must do the following during the procedure:

- DSA of the celiac artery
- Measure the diameter (in mm) of the mid-splenic artery where he/she intends to deploy the embolic
- DSA from the mid-splenic artery at the location of intended embolization to evaluate for extravasation, PSA >1cm, or AVFs
- Perform embolization (*see following slides*)
- Document time to hemostasis in the mid-splenic artery (*see following slides*)

ELSA – II Required Elements of Procedure

Performing embolization with coils:

7.3.5 Coil embolization. For patients randomized to coil embolization, a high-flow micro-catheter is navigated to the location of embolization with the assistance of a micro-wire. The micro-wire and micro-catheter combination will be left to the discretion of the attending interventional radiologist or surgeon. Once the micro-catheter is in place, a splenic angiogram will be performed to confirm location and assess for pseudoaneurysms, AVFs, or contrast extravasation. Coil embolization will then proceed per the manufacturer's instructions for use. In short, the first coil used is a sized anchoring coil to stabilize the coil pack in the mid-splenic artery. Subsequently, the anchoring coil is filled with packing coils. **The operator places any number of coils required to achieve an adequate radiographic coil pack, as is standard practice**.

ELSA – II Required Elements of Procedure

Performing embolization with plugs:

7.3.6 Plug embolization. For patients randomized to vascular plug embolization, the appropriately-sized catheter or sheath is advanced to the location of embolization. The tools used to access the mid-splenic artery will vary depending on the operator's experience and patient anatomy. Once the catheter or sheath is in place, a splenic angiogram will be performed to confirm location and assess for pseudoaneurysms, AVFs, or contrast extravasation. Vascular plug embolization will then proceed per the manufacturer's instructions for use. As is standard practice, only a single vascular plug is typically deployed.

ELSA – II Required Elements of Procedure

Hemostasis: defined as occlusion in the mid-splenic artery

Time to hemostasis: time from last coil deployment or plug deployment until hemostasis

Evaluated by unsubstracted hand angiograms performed every minute. When hemostasis is suspected, it is then confirmed by DSA

Recorded in two possible ways:

- Spot image is obtained at time of last coil deployment or plug deployment, which records the time. DSA time at hemostasis is recorded. The difference between the two times is the time to hemostasis
- Operator provides the time to hemostasis in the dictation

ELSA – II Procedural Elements

Questions?

ELSA – II Procedural Data Points

Primary technical success is the primary outcome of the study

Primary technical success is defined by:

- Was the prescribed embolic successfully deployed?
- Was hemostasis in the mid-splenic artery achieved within 15 minutes of deployment?

ELSA – II Primary Technical Success

- Patient is randomized to the vascular plug arm. After successful deployment of the vascular plug, hemostasis is achieved in the mid-splenic artery after 10 minutes. No other embolics are used. This would be recorded as ***primary technical success for the vascular plug***.
- Patient is randomized to the vascular plug arm. After successful deployment of the vascular plug, hemostasis is not achieved in the mid-splenic artery after 15 minutes. The operator decides to use an additional embolic. This would be recorded as ***primary technical failure for the vascular plug***.
- Patient is randomized to the vascular plug arm. Due to patient anatomy, the operator does not feel that he/she can safely deploy the plug. Instead, he/she decides to treat the patient with endovascular coils. This would be recorded as ***primary technical failure for the vascular plug***.
- Patient is randomized to the coil arm. After successful deployment of enough coils to achieve a radiographically-acceptable coil pack, hemostasis is achieved in the mid-splenic artery after 10 minutes. No other embolics are used. This would be recorded as ***primary technical success for the coils***.
- Patient is randomized to the coil arm. After successful deployment of enough coils to achieve a radiographically-acceptable coil pack, hemostasis is not achieved in the mid-splenic artery after 15 minutes. The operator decides to use an additional, non-coil embolic agent. This would be recorded as ***primary technical failure for the coils***.
- Patient is randomized to the coil arm. Due to patient anatomy, the operator does not feel that he/she can safely deploy the coils. Instead, he/she decides to treat the patient with a vascular plug. This would be recorded as ***primary technical failure for the coils***.

ELSA – II Secondary Embolic Agents

Examples of using a secondary embolic agent:

- Patient is randomized to the vascular plug arm. After successful deployment of the vascular plug, hemostasis has not been achieved after 15 minutes. The operator decides to add coils, gelatin sponge slurry, or particles in order to achieve hemostasis. This would be recorded as a ***primary technical failure for the plug with use of a secondary embolic agent***.
- Patient is randomized to the coil arm. After successful deployment of enough coils to achieve a radiographically-acceptable coil pack, hemostasis has not been achieved after 15 minutes. The operator decides to add plugs, gelatin sponge slurry, or particles in order to achieve hemostasis. This would be recorded as a ***primary technical failure for the coils with use of a secondary embolic agent***.

ELSA – II Secondary Technical Success

- Patient is randomized to the vascular plug arm. After successful deployment of the vascular plug, hemostasis has not been achieved after 15 minutes. The operator decides to add coils in order to achieve hemostasis. This would be recorded as a ***primary technical failure for the plug, with use of a secondary embolic agent to achieve secondary technical success.***
- Patient is randomized to the coil arm. After successful deployment of enough coils to achieve a radiographically-acceptable coil pack, hemostasis has not been achieved after 15 minutes. The operator decides to add a vascular plug to achieve hemostasis. This would be recorded as a ***primary technical failure for the coils with use of a secondary embolic agent to achieve secondary technical success.***
- Patient is randomized to the vascular plug arm. Due to patient anatomy, the operator does not feel that he/she can safely deploy the plug. Instead, he/she decides to treat the patient with endovascular coils and hemostasis is achieved at any time point. This would be recorded as ***primary technical failure for the vascular plug, but did achieve secondary technical success***.
- Patient is randomized to the coil arm. Due to patient anatomy, the operator does not feel that he/she can safely deploy the coils. Instead, he/she decides to treat the patient with a vascular plug. This would be recorded as ***primary technical failure for the coils, but did achieve secondary technical success.***

ELSA – II

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Glasgow Coma Score	X			
Vasopressor use	X			
Intubated	X			
Massive transfusion protocol	X			
Injury Severity Score	X			
Anti-coagulation or anti-platelet use	X			
Laboratory work	X			
CT findings	X			
Procedure duration		X		
Radiation dose		X		
Contrast used		X		
Angiographic findings		X		
Type/size of embolics		X		
Primary technical success		X		
Secondary technical success		X		
Procedural complications		X		
Post-procedural complications			X	X
Transfusion requirements	X		X	X
Splenectomy			X	X
Mortality			X	X

ELSA – II Safety monitoring

Third party, single IRB with Advarra

Independent medical monitor, Dr. Jeff Kerby, Director of Acute Care Surgery at UAB

Reporting procedures are outlined in the study protocol and manual of operations

Keys to Success

Stay motivated

Communicate with the site team

Solid training on consent and randomization procedures

Be available to help troubleshoot problems, especially early in the process

Questions and discussion

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