EMORY eIRB

Date: Monday, November 30, 2020 1:18:59 PM

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IRB00091978

View: Emory SF: Basic Study Information

Basic Study Information

1. * **Title of study:**
   Interventional Radiology: A Retrospective and Prospective Analysis of Clinical Outcomes

2. * **Short title:**
   IR Retrospective and Prospective Analysis

3. * **Brief Description (Lay Summary). Please see our IRB guidelines for required content:** Biomedical Guidelines **or** Sociobehavioral Guidelines**.**
   We will be retrospectively and prospectively reviewing imaging studies and associated patient medical records spanning a period of fifteen years between 01/01/2010 through 01/01/2025 for patients who underwent image guided procedures at Emory University,

4. * **What kind of study is this?**
   Single-site study

5. * **Will an external IRB act as the IRB of record for this study?**
   ○ Yes ● **No**

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6. * Local principal investigator:

Janice Newsome

7. * Does the local principal investigator have a financial interest related to this research?

○ Yes ● **No**

8. * Attach the protocol:

	Document	Category	Date Modified	Document History
View	91978 HIPAA And Consent Waiver Worksheets FOR CHART REVIEWS ONLY 8.8.17.docx(0.01)	IRB Protocol	2/4/2020	History
View	91978 HIPAA And Consent Waiver Worksheets FOR CHART REVIEWS ONLY 8.30.17(0.01)	IRB Protocol	2/4/2020	History
View	IR retrospective analysis protocol 8.8.17 clean.docx(0.01)	IRB Protocol	2/4/2020	History
View	IR - Retrospective Analysis Protocol 8.8.17 tracked changes.docx(0.01)	IRB Protocol	2/4/2020	History
View	IR retrospective analysis protocol 10 15 19 Final.docx(0.01)	IRB Protocol	2/4/2020	History
View	IR retrospective analysis protocol 10 15 19 track changes.docx(0.01)	IRB Protocol	2/4/2020	History

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	Document	Category	Date Modified	Document History
View	IR retrospective IRB protocol(0.01)	IRB Protocol	2/4/2020	History

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View: Emory SF: Study Funding Sources (not integrated with Grants)

Study Funding Sources

1. **Identify each organization supplying funding for the study:**

Funding Source	Sponsor's Funding ID	Emory EPEX ID	Attachments

There are no items to display

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IRB00091978 View: Emory SF: Local Study Team Members

Local Study Team Members

1. **Identify each additional person involved in the design, conduct, or reporting of the research. In addition to Emory personnel, this may include non-Emory persons with sponsored eIRB accounts, for persons who need access to the eIRB study record. If a name does not appear for selection, the person may not have an eIRB account. For more information about obtaining an eIRB account, click here.**

	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
View	Jonah Adler	Other Collaborator	no	no	jadler8@emory.edu	
View	Imon Banerjee	Other Collaborator	no	no	ibaner2@emory.edu	
View	Keywan Behbahani	Co-Investigator	no	yes	kbehbah@emory.edu	
View	Mircea Cristescu	Co-Investigator	no	no	mcriste@emory.edu	
View	Judy Gichoya	Co-Investigator	no	no	jgichoy@emory.edu	
View	Tarek Hanna	Co-Investigator	no	yes	thanna@emory.edu	
View	C Hawkins	Co-Investigator	no	yes	chawki5@emory.edu	
View	Christopher Johnson	Other Collaborator	no	no	ctjohn4@emory.edu	

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	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
View	Nima Kokabi	Co-Investigator	no	yes	nkokabi@emory.edu	
View	Venkatesh Krishnasamy	Co-Investigator	no	no	n966912@emory.edu	
View	Bill Majdalany	Co-Investigator	no	no	bill.majdalany@emoryhealthcare.org	
View	Janice Newsome	Co-Investigator	no	yes	jnewso4@emory.edu	
View	Adam Prater	Co-Investigator	no	yes	mmd7pa2@emory.edu	
View	John David Prologo	Co-Investigator	no	yes	john.david.prologo@emory.edu	404-778-2656
View	Maria Rivas	Co-Investigator	no	yes	mrivas2@emory.edu	
View	Hari Trivedi	Co-Investigator	no	no	hmtrive@emory.edu	
View	Brianna Vey	Other Collaborator	no	no	bvey@emory.edu	
View	Morgan Whitmore	Co-Investigator	no	no	mjwhitm@emory.edu	

2. External team member information (for non-Emory personnel, under Emory PI's direction, who will not be logging into eIRB).

Name	Description
There are no items to display	

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IRB00091978 View: SF: Study Scope

Study Scope

1. * **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
   ○ Yes ● **No**

2. * **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?** ***(Note: Knowing what the FDA considers to be a device can be tricky; click on page-level help text for guidance.)***
   ○ Yes ● **No**

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IRB00091978 View: SF: Local Research Locations

Local Research Locations

1. **Identify research locations where research activities will be conducted or overseen by the local investigator:**

	Location	Contact	Phone	Email
View	Emory Johns Creek Hospital	Rebecca Rouselle	404-712-0785	rebecca.rousselle@emory.edu
View	Emory St. Joseph's Hospital	Rebecca Rouselle	404-712-0785	rebecca.rousselle@emory.edu
View	Emory University Hospital (non-CRN)	Rebecca Rouselle	404-712-0785	rebecca.rousselle@emory.edu
View	Emory University Hospital Midtown	Rebecca Rouselle	404-712-0785	rebecca.rousselle@emory.edu
View	Grady Health System (non-CRN)	Rebecca Rouselle	404-712-0785	rebecca.rousselle@emory.edu

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IRB00091978 View: Emory SF: Local Site Documents

Local Site Documents

1. **Consent forms:** (attach local consent/assent documents)

Document	Category	Date Modified	Document History

There are no items to display

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

Document	Category	Date Modified	Document History

There are no items to display

3. **Other attachments:**

Document	Category	Date Modified	Document History

There are no items to display

Suggested attachments:

- Completed checklist of funding agency requirements, if applicable
- Other site-related documents not attached on previous forms
- Case Report Forms
- Data Use Agreements
- DSMB Charter
- Surveys, Questionnaires, Interview Guides

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View: Emory SF: Waiver Requests and Ancillary Considerations

Waiver Requests and Ancillary Considerations

1. * **Is this study designed/initiated by an Emory investigator?**
   ◯ Yes ◯ No
   (If yes, and clinical research: please see our Clinical Study Initiation and Tools webpage)

2. * **Will there be any international sites overseen by Emory investigators, and/or will data be obtained from international subjects by Emory investigators?**
   ◯ Yes ◯ No
   (If yes: see our International Research webpage)

3. * **Is any licensed Emory intellectual property used in this project?**
   ◯ Yes ◯ No

   (If yes, the study may need to be reviewed by an external IRB due to institutional conflict of interest, if it is not already; IRB analyst will consult with IRB leadership.)

HIPAA Applicability and Waivers Requested

Important: You must complete the HIPAA Applicability and Waiver Worksheet. Attach this document under question 4. (Required even if study is under external IRB review).

1. * **Based on the above-referenced Checklist, will your data be covered by HIPAA once it is in your research records?**

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◯ Yes ◯ No

If answering NO to the above question, please answer the following:

2. **Based on the above-referenced Checklist, will you be obtaining PHI from a covered entity, and thus require subject authorization or a waiver of authorization before that data may be disclosed to you for your research?**
   ◯ Yes ◯ No

3. **If the answer to either above question (1 or 2) is YES, please mark all waivers of HIPAA Authorization that you are requesting (if any). Please first review our guidance on waivers.**
   There are no items to display

4. * **Upload HIPAA Applicability and Waiver Worksheet here:**

Informed Consent Process and Waivers Requested

1. Methods of Consent and Assent:

a. * Please mark all methods that will be used to obtain **consent** and/or parental permission:
   There are no items to display

b. Please mark all methods that will be used to obtain **assent** (see Emory's assent age-based guidelines for types of assent)

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There are no items to display

2. **If applicable, mark all waivers of consent and/or assent that you are requesting. Please first review our guidance on waivers.**
   There are no items to display

3. **If different waivers are being requested for different cohorts or portions of the study, provide a brief explanation.**

Ancillary Review Information

1. * **Does this study relate to cancer *in any way*, even if sociobehavioral, chart review, or secondary analyses only?**
   ◯ Yes ◯ No

   If yes: requires submission to the CTRC (Clinical and Translational Review Committee); see "Ancillary Review" section on our website.

The remaining questions in this section are ONLY for biomedical research.

2. **Does this study include:**
   There are no items to display

If either of the first two options are checked, the study requires review by EHSO Biosafety office (or VA or other site equivalent, if applicable); see "Ancillary Review" section under Study Submission Guidance on our website.

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3. Exposure to any radiation? (Respond yes if protocol dictates timing or type of scans, even if they would be done as part of routine care outside of this study.)

◯ Yes ◯ No

If yes, requires review by EHSO Radiation Safety office (or VA or other site equivalent, if applicable); see "Ancillary Review" section under Study Submission Guidance on our website.

4. The administration of any investigational radioactive drugs?

◯ Yes ◯ No

If yes, requires review by EHSO Radiation Safety office (or VA or other site equivalent, if applicable); see "Ancillary Review" section under Study Submission Guidance on our website.

5. Human embryonic stem cells?

◯ Yes ◯ No

If yes, requires review by HESC Committee; see "Ancillary Review" section under Study Submission Guidance on our website.

6. The use of human fetal tissue?

◯ Yes ◯ No

If yes, the IRB may have additional considerations as part of their review.

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7. **Administration of any Schedule I controlled substances?**
   ◯ Yes ◯ No

   If yes, see the "Drugs, Devices, and Other FDA Regulated Products" section under Study Submission Guidance on our website.

8. **Administration of drug under the FDA REMS program?**
   ◯ Yes ◯ No

   If yes, see the "Drugs, Devices, and Other FDA Regulated Products" section under Study Submission Guidance on our website.

For Clinical Research/Expanded Access Only (click here for more guidance on clinical research)

1. **Is this an "applicable clinical trial" or a study that otherwise requires registration in ClinicalTrials.gov? See FAQ's here, and if unsure, contact Emory's Office for Clinical Research.**
   ◯ Yes ◯ No

   a. If yes, has the trial been registered with ClinicalTrials.gov?
      ◯ Yes ◯ No

2. **Will there be any clinical professional or technical charges (e.g., for drugs, medical devices, laboratory or radiology tests, physician services, or medical procedures) during the course of this study that**

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generate a CPT or CDM code at an Emory or Grady healthcare facility (regardless of funding source or if the charges might be considered "standard of care") that may be billed to study accounts or third party payors such as Medicare, Medicaid, or health insurance companies? (This determines if the study must be routed for billing analysis.)

◯ Yes ◯ No

3. Is this an expanded access submission for an unapproved drug or device?

◯ Yes ◯ No

(If yes, please review our guidance for expanded access submission. Single-use (one patient) uses can we done via an alternative method. See the guidance for more information. Please complete and attach the "Clinical Research Key Points Summary" referenced in Question 4 below.

4. Clinical Research Key Points Summary: If your study meets all of the criteria referenced on this page, please upload a completed "Clinical Research Key Points Summary" also found on the same page

5. Sensitive Study Status Requests: If this study meets the criteria for "sensitive study" status (per Emory's Sensitive Studies Policy), are you are requesting Sensitive Study Status? Emory IRB will review and inform you if the status is granted.

◯ Yes ◯ No

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