The Great Innovate

Overview: Human Subject Data Capture

Background

The Department of Radiology at UCSD is a leading institution in the field of medical imaging and radiological sciences. The department is actively engaged in a diverse range of *studies* aimed at advancing medical imaging technology, improving clinical outcomes, and enhancing patient care across various medical specialties. These *studies* may require human subjects, whereby coordinators at the department recruit and schedule volunteers (human subjects) to come in for an MRI, CT, ultrasound, X-ray, etc. When the human subject arrives for their appointment, operators will conduct the scan and complete a paper packet with the collected data. The data eventually goes to data analysts who use it for the studies.

What is a s*tudy*?

A study is a deep dive into a specific topic to learn more about it. It involves gathering information, doing experiments, or analyzing data to answer questions or solve problems. In the context of the Department of Radiology at UCSD, their studies might involve things like testing new imaging techniques, understanding how diseases show up in medical images, or figuring out ways to make treatments more effective and less invasive. These studies help doctors and scientists learn more about how to diagnose and treat illnesses, ultimately aiming to improve patient care and outcomes.

Problem Statement

Capturing and recording human subjects' data from novel magnetic resonance imaging (MRI) research visits should be accurate and completed in a timely manner to ensure the quality of study results and support a positive coordinator-operator working relationship. The current process results in defects, where paper packets arrive to coordinators with missing information. Packets with incomplete data can compromise study results, as well as create compliance risks in the event of an audit.

Key Pain Points:

- Coordinators print out physical copies after confirming most recent forms are used (as opposed to digitally)
- Limited onboarding/ training available for packet process
- Paper packets are 8-12 pages, text-heavy with a combination of fields and check boxes
- The amount of time it takes for human subjects and operators to review and sign paper packets varies and depends on how many questions the human subject may have, or the operators' understanding of the study as they explain it to the human subject
- Sometimes it takes a few minutes to locate the requested information or signature fields in the paper packets
- Operator must offer subject a physical copy of completed informed consent form; can notify Coordinator to scan and email later, sometimes copy machine is located far away
- If the operator is unfamiliar with the study, sometimes it takes longer to correctly position the human subject for adequate scanning
- 60-70% of packets are incomplete, e.g., missing a consent signature, payment signatures, missing human subject information, dates and times of scans, any scanner errors, etc.
- 5-10% of packets are missing critical information, i.e., consent signatures and signature dates
- Coordinators must track down operators for missing information in paper packets

Process: Human Subjects Data Capture

Process Steps

The process involves a coordinator qualifying and scheduling human subjects for MRI scans, preparing paper packets, and ensuring compliance with regulations. Operators review and sign packets with subjects, record imaging data, and return packets to the coordinator for quality checks and filing.

1. Coordinator qualifies human subject via phone / email (out of scope)

There are approximately 10-100 human subjects per study and around 10 studies conducted annually. Subjects are pre-screened and cold-called, with a 40% response rate. Phone scripts are available, but usage varies. Eligibility criteria determine qualification of a human subject, typically handled by a coordinator, though operators can also recruit and schedule participants independently.

2. Coordinator schedules human subject visit to MRI center (out of scope)

There are 3 locations at UCSD that facilitate scans.

3. Coordinator prepares paper packet for human subject & operator

To prepare a paper packet for human subjects and operators, PDF templates are used and occasionally updated. Coordinators print the most recent forms, verify the contact information, and include compensation details when applicable. The 8–12-page packets are text-heavy, featuring fields and checkboxes, and must comply with regulations. Limited onboarding is available for the process. Some documents are internally created, while others are provided or approved by external entities like the MRI center or IRB.

4. Human subject shows up to visit at MRI center

When visiting the MRI center, 25% of human subjects cancel or no-show, and another 25% are often late due to navigation or parking issues. Subjects call the operator upon arrival, or the operator waits at the door or in the waiting room.

5. Human subject AND Operator review and sign paper packet

Operators review the paper packet with human subjects, with the duration varying based on the subject's questions and the operator's understanding of the study. Locating requested information or signature fields can take a few minutes. The operator must offer the subject a physical copy of the completed informed consent form and can notify the coordinator to scan and email it later, especially if the copy machine is far away.

6. Operator records imaging data of human subject and fills out paper packet

Recording imaging data involves positioning the human subject for adequate scanning, which can take longer if the operator is unfamiliar with the study. If the patient requests copies of the scan, the operator can burn a CD on the spot or create it later and have the coordinator mail it.

7. Operator brings paper packet to coordinator

When bringing the packet to the coordinator, operators may drop off paper packets in bulk, hours or days later if they are busy.

8. Coordinator reviews packet data and performs a quality check

During the packet data review and quality check, 60-70% of packets are found to be incomplete, lacking items like consent signatures, payment signatures, subject information, scan dates and times, or scanner error details. Additionally, 5-10% of packets miss critical information, such as consent signatures and dates. Coordinators must then track down operators to obtain the missing information.

9. Coordinator files data

QA'd subject packets are filed in patient binders and later reviewed during data analysis. These packets may also be reviewed by additional parties, such as the IRB or RCI, if the laboratory is audited.

Process Stakeholders

There are three key process players (Coordinators, Operators, and Human Subjects), and four tangential process players (Data Analyst, Institutional Review Board – IRB, Research Compliance and Integrity Office – RCI, and Office of Compliance and Privacy).

A. Coordinators

Facilitates various administrative and operational aspects within the Radiology department.

B. Operators

Operates imaging equipment to produce magnetic resonance (MR) images of patients. The operator may be a PhD student, a postdoctoral researcher, and/or the lead researcher of a study (PI, or Principal Investigator).

C. Human Subjects

Eligible individuals who participate in a research study as a voluntary participant.

D. Data Analyst

Reviews and organizes collected human subjects data to perform analyses and determine correlations, associations, and other trends. Interprets and presents data to research community in abstracts, visual presentations, and published articles. Will sometimes be the same individuals who serve as operators, but not always.

E. Institutional Review Board (IRB)

Upholds the highest standards of ethical conduct and regulatory compliance in human subjects research, fostering a culture of integrity, respect, and responsible inquiry within the university community.

F. Research Compliance and Integrity Office (RCI)

A central resource that ensures compliance with regulatory requirements and promotes integrity in research activities. Promotes a culture of integrity and accountability.

G. Office of Compliance and Privacy

Responsible for ensuring that the university complies with various laws, regulations, and policies related to privacy, data protection, and other compliance matters.

Process Narrative

It's a typical busy day at the UCSD Department of Radiology, where a myriad of studies are continuously advancing medical imaging technology. As part of these studies, Amina Patel, a coordinator, is actively qualifying and scheduling human subjects for MRI scans across three locations at UCSD. Once a subject is scheduled, Amina prepares a comprehensive 8–12-page paper packet, ensuring it includes the most recent forms, verified contact information, and any applicable compensation details.

On the day of the MRI appointment, human subjects like Javier Rodriguez check in at reception and the operator, Mei Lin, finds him waiting in the reception area. Together, they review and sign the paper packet, a process that can vary in duration depending on Javier's questions and Mei's familiarity with the study.

Mei then proceeds to record the imaging data, positioning Javier for the scan. This task can be time-consuming, especially for Mei if she is less familiar with the study. If requested, Mei can create a CD of the scan for Javier, either immediately or later, with Amina handling the mailing.

After the scan, Mei delivers the paper packets to Amina, often in bulk if her schedule is particularly busy. Amina then performs a quality check, discovering that the packet is incomplete, missing crucial elements like consent signatures or scan details. Amina must track down Mei to fill in these gaps.

Once verified, the packets are filed in patient binders and later reviewed during data analysis. These packets are also subject to review by external entities, such as the IRB or RCI, especially during audits. A lab with noncompliant practices may be shut down for one year or longer. This comprehensive process ensures the accuracy and compliance of the data captured, supporting the department's commitment to advancing medical imaging and improving patient care.

Process Actors

Coordinator	Operator	Human Subject
		
Name: Amina Patel **Responsibilities:** • Scheduling and coordination • Patient communication • Documentation and consent • Monitoring study visit attendance and compliance • Data quality assurance, storage, and management • Workflow troubleshooting **Needs:** • Completed and accurate paper packets • Communication with Operator **Pain points:** • Receiving incomplete paper packets	**Name:** Mei Lin **Responsibilities:** • Operating imaging equipment • Conducting and supporting research studies • Preparing and positioning patients • Ensuring participant safety • Documentation and consent • Image/data quality control **Needs:** • Sufficient study context • Easy to follow required forms (paper packets) **Paint points:** • Familiarity with study	**Name:** Javier Rodriguez **Responsibilities:** • Voluntary participation • Informed consent • Undergo radiological procedures • Compliance with study protocols **Needs:** • Clear instructions • Payment (if applicable) **Paint points:** N/A

Additional Data:

#	Date of Scan	Operator Name	Time of Scan	Consent signature	Payment signature	Human subject information	MRI scan information (date/time/image review)	Scanner errors	Form Completer/Operator Name	Body Part Information
1	2/27/2024	Operator 1	PM	not missing	not missing	missing	missing	not missing	not missing	not missing
2	3/1/2024	Operator 1	PM	not missing	not missing	missing	missing	not missing	not missing	not missing
3	2/23/2024	Operator 1	PM	not missing	not missing	missing	missing	not missing	not missing	not missing
4	2/25/2024	Operator 1	AM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
5	9/25/2023	Operator 1	PM	not missing	not missing	not missing	not missing	not missing	missing	not missing
6	9/26/2023	Operator 1	PM	not missing	not missing	missing	missing	not missing	missing	not missing
7	10/7/2023	Operator 1	PM	not missing	not missing	missing	missing	not missing	missing	not missing
8	10/11/2023	Operator 1	PM	not missing	not missing	not missing	not missing	not missing	missing	not missing
9	10/21/2023	Operator 1	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
10	10/21/2023	Operator 1	PM	not missing	not missing	not missing	missing	not missing	not missing	not missing
11	8/26/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	not missing
12	8/25/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	not missing
13	8/24/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	not missing
14	8/24/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	not missing
15	8/23/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	missing
16	8/11/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	missing
17	8/11/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	missing
18	8/4/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	not missing
19	8/2/2023	Operator 2	PM	not missing	not missing	missing	missing	not missing	missing	not missing
20	8/3/2023	Operator 2	PM	not missing	not missing	missing	missing	not missing	missing	missing
21	1/9/2024	Operator 3	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
22	1/16/2024	Operator 3	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
23	1/16/2024	Operator 3	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
24	1/16/2024	Operator 3	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
25	9/11/2023	Operator 3	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
26	10/11/2023	Operator 3	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
27	10/5/2023	Operator 3	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
28	2/19/2024	Operator 4	PM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
29	2/17/2024	Operator 5	PM	not missing	missing	not missing	not missing	not missing	not missing	not missing
30	2/18/2024	Operator 5	PM	not missing	missing	not missing	not missing	not missing	not missing	not missing
31	11/17/2023	Operator 2	AM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
32	11/17/2023	Operator 2	AM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
33	11/17/2023	Operator 2	AM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
34	11/20/2023	Operator 2	PM	not missing	not missing	not missing	not missing	not missing	missing	not missing
35	11/15/2023	Operator 2	PM	not missing	not missing	not missing	not missing	not missing	missing	not missing
36	11/17/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	not missing
37	12/2/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	not missing
38	12/15/2023	Operator 2	PM	not missing	not missing	not missing	missing	not missing	missing	not missing
39	12/12/2023	Operator 3	AM	not missing	not missing	not missing	not missing	not missing	not missing	not missing
40	12/13/2023	Operator 3	AM	not missing	not missing	not missing	not missing	not missing	not missing	not missing

Additional Data: