



MR Platform Guide to
Radiology Reads and Incidental Findings:
Workflow, Incidental Finding (IF) Levels, REDCap User
Guide, Processes

Radiology Read and Incidental Findings Workflow

Prior to an IRB protocol being submitted to the IRB, the PI or a designated lab member will send a form letter to CUIMC Radiology Director of Research Stephen Dashnaw smd2008@cumc.columbia.edu in Radiology requesting Incidental Findings (IF) reads. Stephen Dashnaw will countersign the letter and return it to the PI. The PI will submit the signed letter to the IRB with his/her protocol. (See Appendix A: "Form Letter to Initiate IF Checks".)

Prior to an IRB protocol being submitted to the IRB, the principal investigator (PI) of a study involving MR scans at ZMBBI, or a designated lab member, will contact the NI Senior Systems Administrator Zhi Qiang (Michael) Zhang (zqz1@cumc.columbia.edu) and ask him to create a new REDCap account for their incidental findings reads.

At the scan: the Level III scan operator must push the structural MR sequences directly from the scanners to the Radiology research PACS (RADIO) for reading by the assigned radiologists.

Immediately after the scan: a designated lab member will login to REDCap and create a record for the scan. (See "REDCap Safety Read Form User Manual".)

A radiologist will review each MR scan and complete the "Read" part of the form as soon as possible, but no later than 10 business days after receipt of the sequences.

Within 10 business days of the scan: the designated lab member retrieves the read from REDCap. They must log in to check; no alert is sent to them when the read is completed. If a read has not been completed in the required time, the designated lab member should email Stephen Dashnaw and cc the Director of MR Administration Kathleen Durkin (kd2649@columbia.edu).

If there is an incidental finding (rated Level 2-4; see "Incidental Finding Levels" guide) the participant must receive a call about this finding, and guidance on their next steps. The PI can either make a follow-up call themselves, or opt to have an MD make this call for them for \$250. If they prefer to work with the MD, the PI should email the radiology read (in the form of an anonymized PDF) to Neurology fellow Francesco Michaelassi MD, who has agreed to make these calls. He can be reached at fem2006@nyp.org. Cc Kathleen Durkin who will coordinate Dr. Michaelassi's \$250 payment. The PI also calls Dr. Michaelassi (773-848-2739) to provide the identity and contact information of the subject. Both the email and the phone call are required. Participant contact information cannot be emailed.

Dr. Michaelassi or the PI should take the following steps:

- research the finding and follow-up resources for the participant
- draft an email with relevant details
- call the participant to discuss the finding
- send the email if the participant wants a written record
- (if applicable) Dr. Michaelassi informs the PI this has been completed

If working with Dr. Michaelassi, the PI awaits confirmation that the phone call has happened, and the PI follows up after a week if no confirmation is received. \$250 will be charged to the PI's grant (or whichever fund the PI tells Kathleen to use) to pay Dr. Michaelassi after he confirms the call was completed with the PI and Kathleen.

The PI submits an IRB amendment with the finding.

Urgent Radiology Reads

Radiologists who spot urgent incidental findings in any ZMBBI MR scans will do the following:

1. Immediately email the PI of the study. (Their name is on the REDCap report, and their email is in the Columbia directory.) Tell the PI the following info:
 - the subject ID
 - the incidental finding
2. If there is no reply within a couple of hours, the radiologist cc's Steve Dashnaw who forwards the email to include all team members (the PI, the team member who created the REDCap account, and Kathleen Durkin). Steve follows up from there until confirmation of receipt.

Once the PI receives the email, they should get the participant's name and contact info, review the report, decide how to direct the participant (either "make an urgent appointment with a neurologist tomorrow" or "go to the emergency room now"), and then call the participant directly.

Alternatively, the PI may contact Neurology fellow Francesco Michaelassi MD, who has agreed to make these calls. He can be reached at fem2006@nyp.org or 773-848-2739. The PI should tell Dr. Michaelassi the incidental finding, the participant's name and phone number, and request an urgent follow up call.

Incidental Finding Levels

Level 1 - No medically significant findings (normal or normal variant findings). No medical follow up needed. This includes research subjects older than 60 years with atrophy and chronic microvascular ischemic changes (e.g. periventricular white matter, basal ganglia or pons).

Level 2 = Class B IF (minor findings) The subject should discuss the medical significance of these findings with their physician, but no specific time frame is recommended. No immediate medical attention is needed.

Level 3 = Class A-2 IF (abnormal findings) Expedited medical evaluation within two weeks is recommended for further evaluation of these findings.

Level 4 = Class A-1 IF (acute abnormal findings) Immediate medical evaluation needed today (e.g. emergency room)

EXAMPLES:

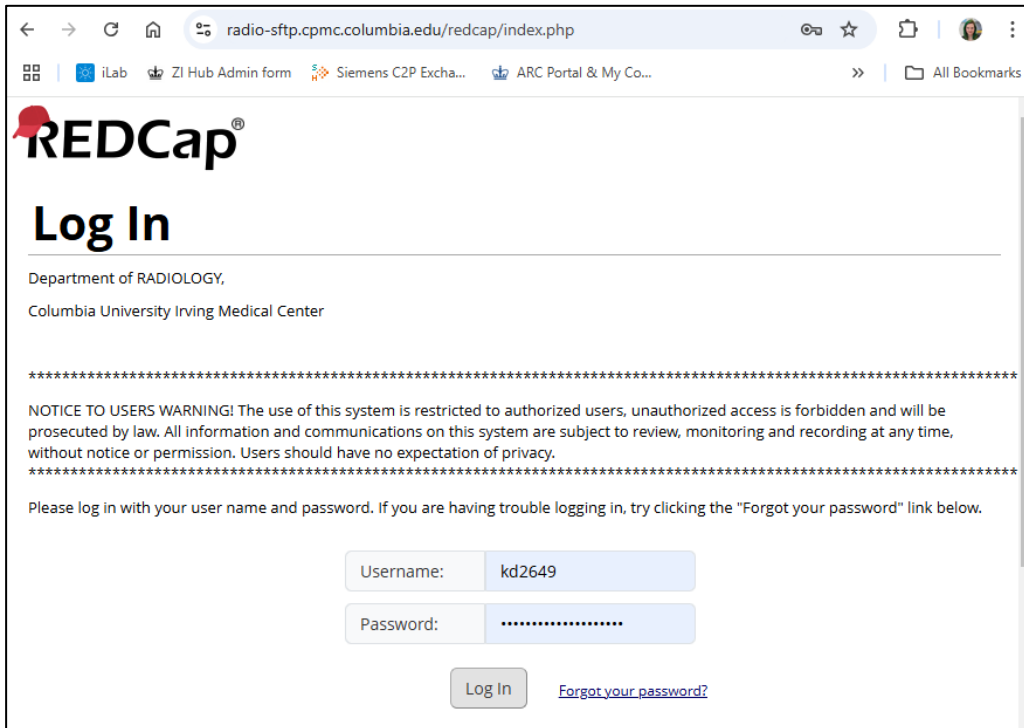
A Level 2 or Class B IF is not necessarily immediately life threatening or severe, but is likely to be deemed by a subject to be important to his/her health. Examples from brain imaging include acute sinusitis (with air/fluid levels) or mastoiditis, non-specific patchy white lesions in subjects less than 60 years of age, chronic infarct, chronic trauma, tonsillar ectopia, severe generalized-atrophy, focal atrophy (e.g., isolated brainstem and/or cerebellum), small meningioma (<3cm) without edema or cranial nerve or brain involvement, and possible demyelinating disease (non-enhancing). Examples from abdominal imaging include non-obstructing cholelithiasis or urolithiasis.

A Level 3 or Class A-2 IF is of more medical significance and requires expedited clinical evaluation (e.g, within 2 weeks). Examples from brain imaging include aneurysm, other vascular malformation (e.g., cavernous or AVM), mass or infiltrating lesion with minimal edema or mass effect (e.g., glioma, small possible metastases), and possible acute demyelinating or inflammatory (e.g., Lyme) disease with enhancement. Examples from abdominal imaging include renal, liver, pancreatic or pelvic mass lesions, aortic aneurysm, cholelithiasis or urolithiasis with biliary or ureteral obstruction, uterine or ectopic pregnancy, and spinal mass lesions. Examples from chest imaging include pneumonia, atelectasis, airway compression, cardiomegaly, aortic aneurysm, and spinal mass lesions. This class of IF's is of most concern because these serious conditions may not be clinically apparent or may be associated with vague or confusing symptoms.

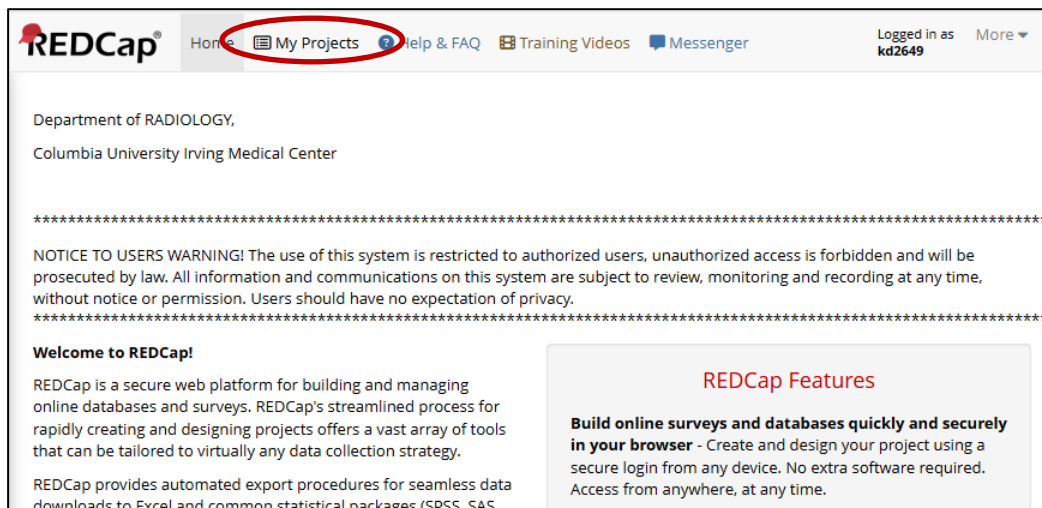
A Level 4 or Class A-1 IF is one that reveals a condition that is likely to be life-threatening or severe and that requires immediate (emergency room) or expedited clinical evaluation. Examples from brain imaging include acute infarct, acute hemorrhage (e.g., SAH, SDH, hematoma), mass with prominent edema or brain compression (intra or extra axial), and acute hydrocephalus. Examples from abdominal imaging include intraperitoneal free air, acute appendicitis, diverticulitis, cholecystitis, pancreatitis, bowel ischemia or perforation, and severe bowel obstruction. Examples from chest imaging include pneumothorax or hemothorax, aortic dissection, or pulmonary embolus.

REDCap Safety Read Form User Manual

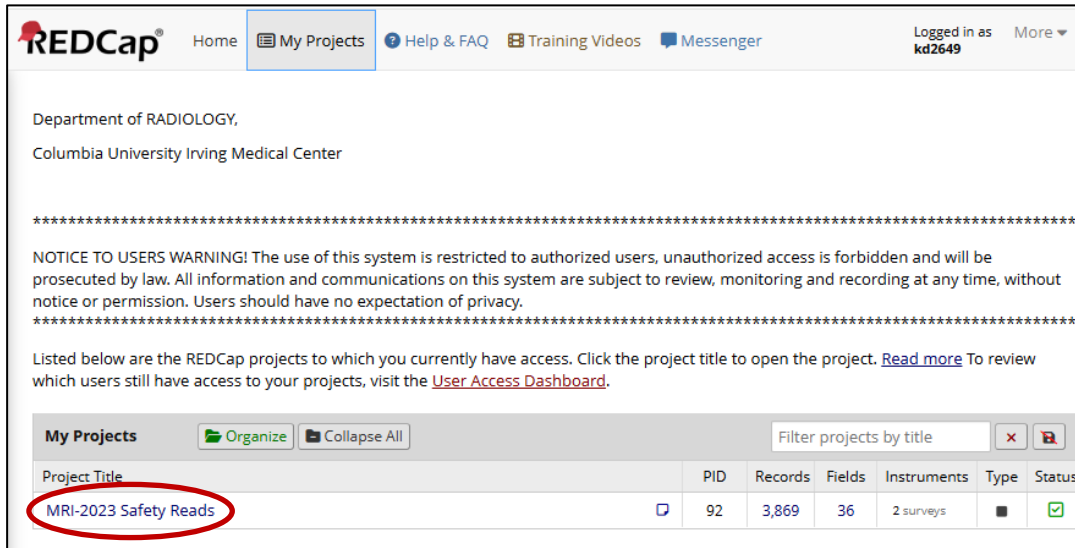
1. User open the link below:
<https://radio-sftp.cpmc.columbia.edu/redcap>
2. Login the website:



3. Click "My Projects".



4. Click “MRI-2023 Safety Reads”. Yes, 2023 is not the current year; that’s ok.



REDCap® Home My Projects Help & FAQ Training Videos Messenger Logged in as kd2649 More ▾

Department of RADIOLOGY,
 Columbia University Irving Medical Center

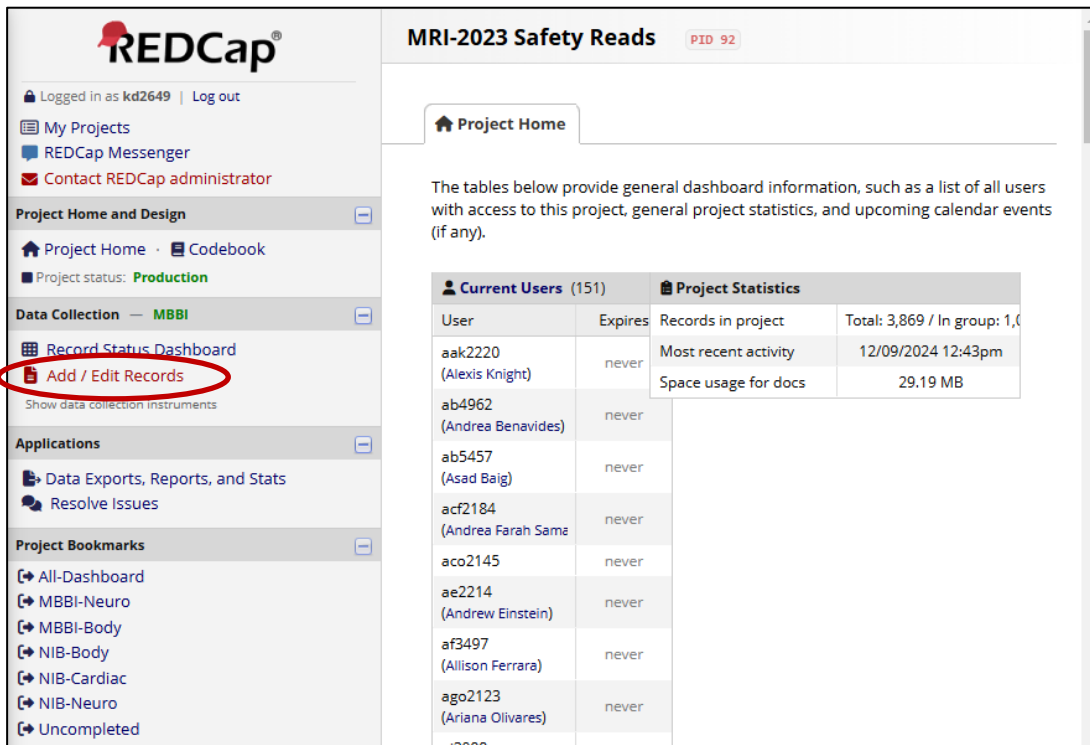
 NOTICE TO USERS WARNING! The use of this system is restricted to authorized users, unauthorized access is forbidden and will be prosecuted by law. All information and communications on this system are subject to review, monitoring and recording at any time, without notice or permission. Users should have no expectation of privacy.

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

My Projects Organize Collapse All

Project Title	PID	Records	Fields	Instruments	Type	Status
MRI-2023 Safety Reads	92	3,869	36	2 surveys		✓

5. Create a new record.
 - a) Click “Add/ Edit Records”.



REDCap® MRI-2023 Safety Reads PID 92

Logged in as kd2649 | Log out

My Projects REDCap Messenger Contact REDCap administrator

Project Home and Design

- Project Home · Codebook
- Project status: **Production**

Data Collection — MBBi

- Add / Edit Records** (Circled in red)
- Show data collection instruments

Applications

- Data Exports, Reports, and Stats
- Resolve Issues

Project Bookmarks

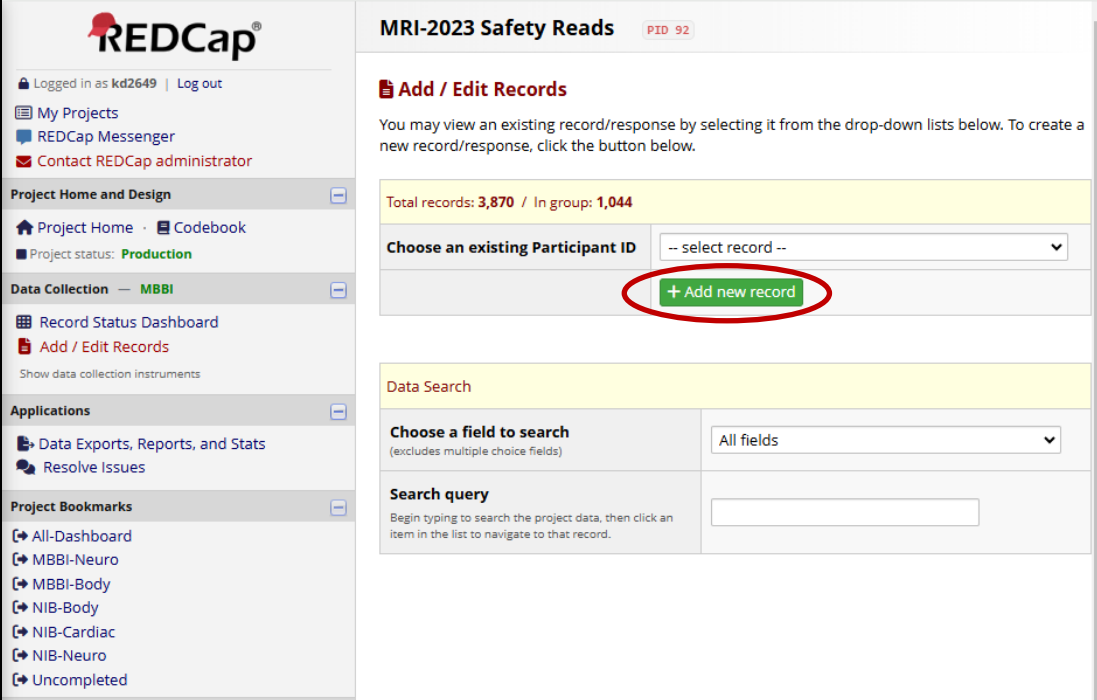
- All-Dashboard
- MBBi-Neuro
- MBBi-Body
- NIB-Body
- NIB-Cardiac
- NIB-Neuro
- Uncompleted

Project Home

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Current Users (151)		Project Statistics	
User	Expires	Records in project	Total: 3,869 / In group: 1,000
aak2220 (Alexis Knight)	never	Most recent activity	12/09/2024 12:43pm
ab4962 (Andrea Benavides)	never	Space usage for docs	29.19 MB
ab5457 (Asad Baig)	never		
acf2184 (Andrea Farah Same)	never		
aco2145	never		
ae2214 (Andrew Einstein)	never		
af3497 (Allison Ferrara)	never		
ago2123 (Ariana Olivares)	never		
ai3008			

b) Click the green “Add New Record” button.



REDCap
 Logged in as kd2649 | Log out
 My Projects
 REDCap Messenger
 Contact REDCap administrator

MRI-2023 Safety Reads PID 92

Add / Edit Records
 You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

Total records: 3,870 / In group: 1,044

Choose an existing Participant ID: -- select record --

+ Add new record

Data Search
 Choose a field to search: All fields
 Search query: []

c) Click the gray “Status” dot next to “Mri Research Info”. (The other option, “MRI Safety Read”, is for the radiologist.)



REDCap
 Logged in as kd2649 | Log out
 My Projects
 REDCap Messenger
 Contact REDCap administrator

MRI-2023 Safety Reads PID 92

Record Home Page
 Record "22-977" is a new Participant ID. To create the record and begin entering data for it, click any gray status icon.

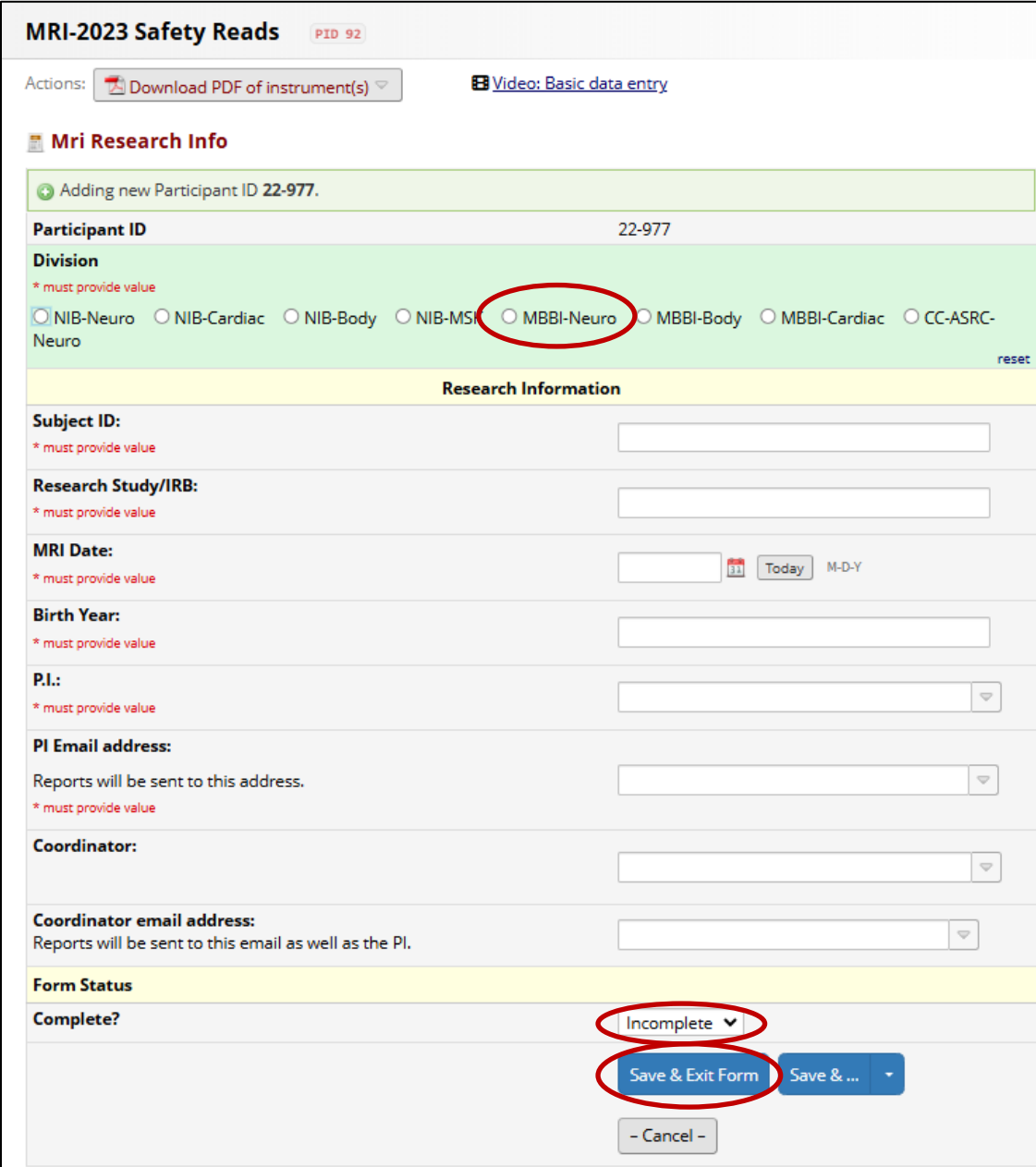
The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Legend for status icons:
 Incomplete (red dot) Incomplete (no data saved) (gray dot) ?
 Unverified (yellow dot) Partial Survey Response (orange dot)
 Complete (green dot) Completed Survey Response (green checkmark)

NEW Participant ID 22-977

Data Collection Instrument	Status
Mri Research Info (survey)	
Mri Safety Read (survey)	

d) Fill in the form:



MRI-2023 Safety Reads PID 92

Actions: [Download PDF of instrument\(s\)](#) [Video: Basic data entry](#)

Mri Research Info

Adding new Participant ID 22-977.

Participant ID 22-977

Division
* must provide value

NIB-Neuro NIB-Cardiac NIB-Body NIB-MSI **MBBI-Neuro** MBBI-Body MBBI-Cardiac CC-ASRC-Neuro reset

Research Information

Subject ID:
* must provide value

Research Study/IRB:
* must provide value

MRI Date:
* must provide value Today M-D-Y

Birth Year:
* must provide value

P.I.:
* must provide value

PI Email address:
Reports will be sent to this address.
* must provide value

Coordinator:

Coordinator email address:
Reports will be sent to this email as well as the PI.

Form Status

Complete? Incomplete

Save & Exit Form Save & ...

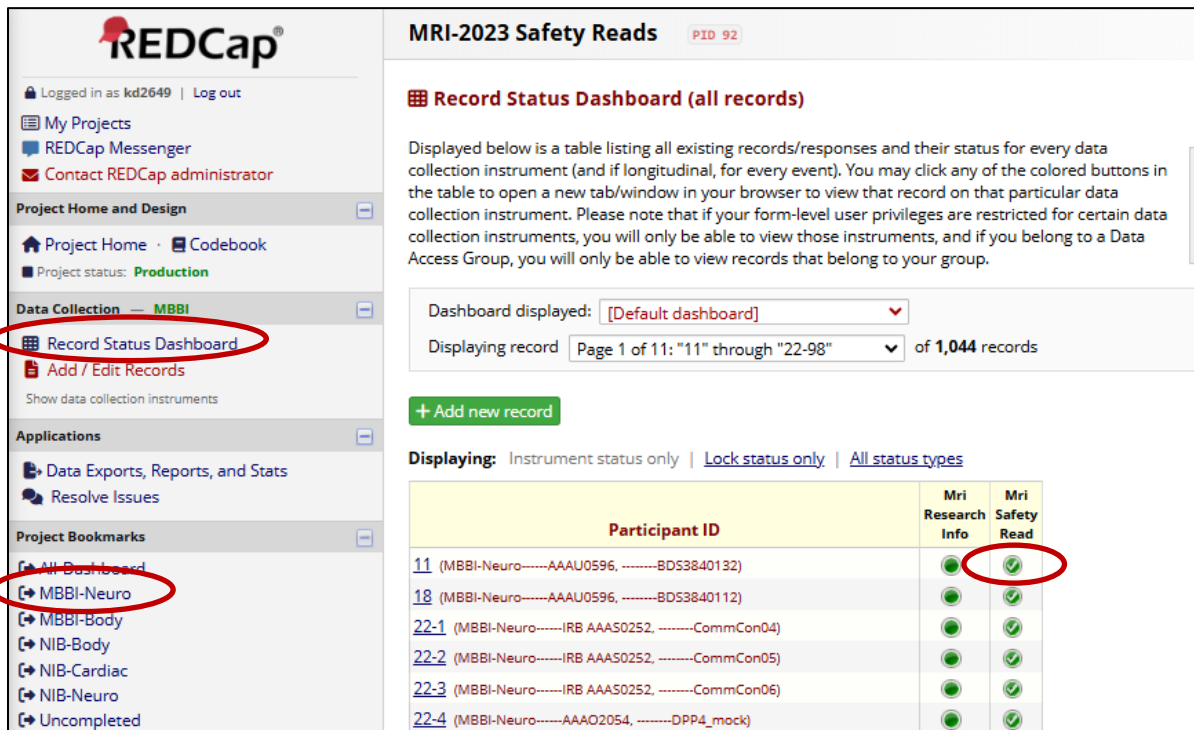
- Cancel -

- i) Choose division "MBBI_Neuro".
- ii) "Subject ID" – Use the complete "Patient Name" EXACTLY as it is entered on the scanner. (The radiologist uses this field to search for the study to review.)
- iii) IRB number, Scan Date, Birth Year, PI, PI email, Coordinator, Coordinator email.

e) Choose "Complete".

f) Click "Save & Exit Form".

- You can check the records by click "Record Status Dashboard", the webpage will list all records. Click the green button under "Mri Safety Read" to open the record. You can also click the Project Bookmarks to list records by division.



REDCap
 Logged in as kd2649 | Log out
 My Projects
 REDCap Messenger
 Contact REDCap administrator

Project Home and Design
 Project Home · Codebook
 Project status: **Production**

Data Collection — MBBI
 Record Status Dashboard
 Add / Edit Records
 Show data collection instruments

Applications
 Data Exports, Reports, and Stats
 Resolve Issues

Project Bookmarks
 All Dashboard
 MBBI-Neuro
 MBBI-Body
 NIB-Body
 NIB-Cardiac
 NIB-Neuro
 Uncompleted

MRI-2023 Safety Reads PID 92

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard]
 Displaying record Page 1 of 11: "11" through "22-98" of 1,044 records

[+ Add new record](#)

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

Participant ID	Mri Research Info	Mri Safety Read
11 (MBBI-Neuro-----AAAU0596, -----BDS3840132)	●	✓
18 (MBBI-Neuro-----AAAU0596, -----BDS3840112)	●	✓
22-1 (MBBI-Neuro-----IRB AAAS0252, -----CommCon04)	●	✓
22-2 (MBBI-Neuro-----IRB AAAS0252, -----CommCon05)	●	✓
22-3 (MBBI-Neuro-----IRB AAAS0252, -----CommCon06)	●	✓
22-4 (MBBI-Neuro-----AAAO2054, -----DPP4_mock)	●	✓

- Logout.

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Mortimer B. Zuckerman Mind Brain Behavior Institute

Columbia University Institutional Review Board Policy

Incidental findings from imaging procedures conducted for research studies

<https://research.columbia.edu/sites/default/files/content/378%20Incidental%20Findings%20Policy%20Final%2010.1.18.pdf>



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Mortimer B. Zuckerman Mind Brain Behavior Institute

Appendix A: Form Letter to Initiate IF Checks

Date:

To: Department of Radiology From: _____, Principal Investigator

Study Number and Title: AAA _____ ;

Participants in the above study will be scanned at the MR Platform in the Zuckerman Mind Brain Behavior Institute. Pursuant to the IRB Policy "Incidental Findings from Imaging Procedures Conducted for Research Studies" (the IF Policy), the scans will require Incidental Finding (IF) reads by a Credentialed Radiologist.

Please confirm by signing this memorandum that IF reads for this study will be completed in accordance with the IF Policy.

Principal Investigator:

Name:

Title: Date:

Department of Radiology:

Name:

Title: Date: