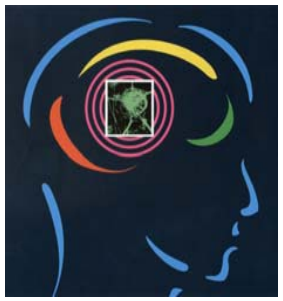
Stanford MEDICINE



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NIH StrokeNet COORDINATOR WEBINAR

May 24, 2017

Stephanie Kemp

Adam Henry

Janice Carrozzella

NIH StrokeNet

PREVENTION | TREATMENT | RECOVERY

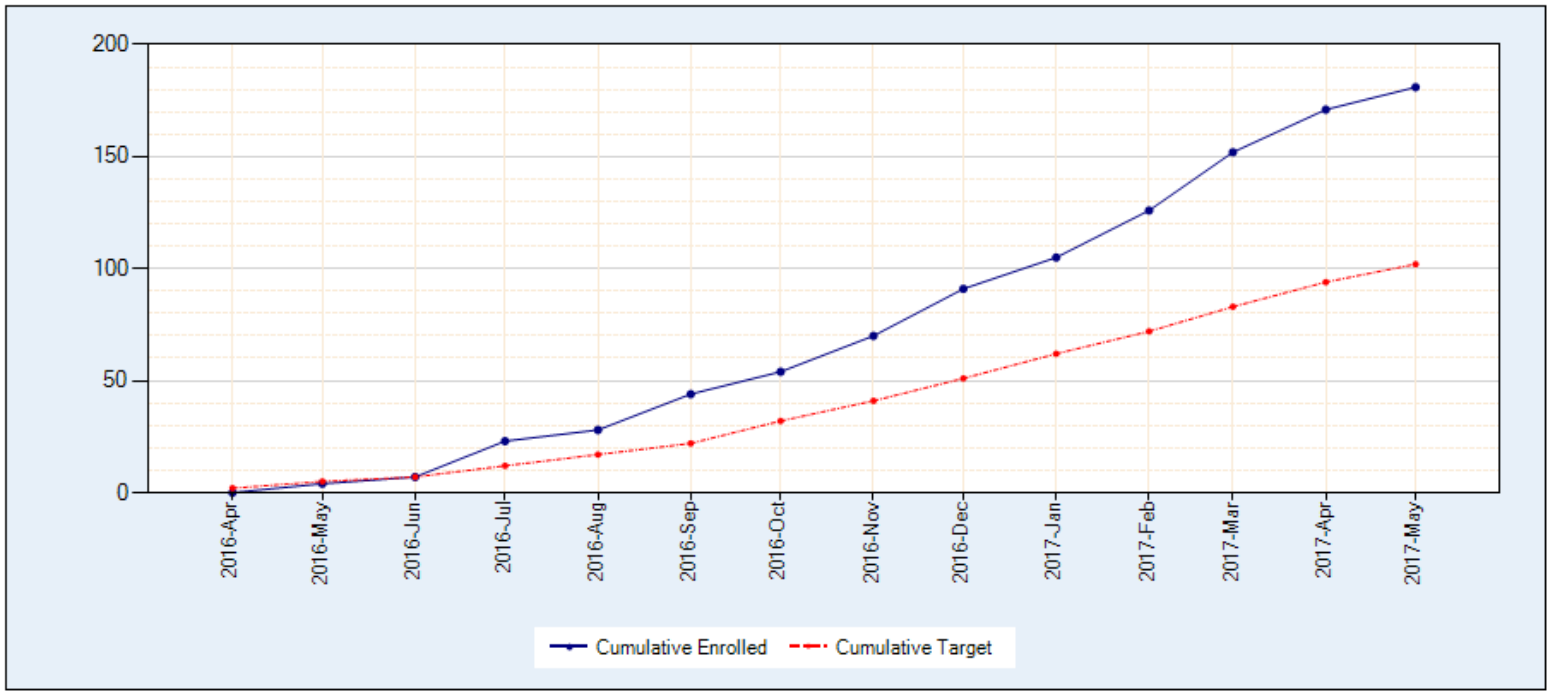
Funded by a Grant from the National Institutes of Health

Today's agenda

1) DEFUSE 3 brief study update
2) DAWN Study
3) Helpful tips and Reminders from FAQs
    - ICF CAP #2
    - Imaging documentation & transfer
    - Blinded outcome assessor
    - Screen failures
4) WebDCU updates
5) CIRB Continuing Review

Brief Study update

- 40 sites activated
- 182 patients randomized
- 112 Consented / Not randomized



DAWN STUDY

- Randomized study: Trevo stent retriever vs. medical therapy
- Industry funded, enrollment began in 2014, N=206
- 6-24 hour window, MCA / ICA occlusions
- Selected with RAPID software (clinical/core mismatch):

  < 20 ml if NIHSS ≥ 10 and ≥ 80 years

  < 30 ml if NIHSS ≥ 10 and age < 80 years

  < 50 ml if NIHSS ≥ 20 and age < 80 years
- About 60% of DEFUSE 3 patients are "DAWN eligible"
- DAWN results: mRS 0-2 at 90 days

endovascular arm	49%	
medical arm	13%	p<0.001

DAWN… now what???

- **Keep screening and enrolling**
- **DSMB meeting scheduled for Friday and we will have more information after that meeting**
- **We will immediately inform the sites if anything changes**


Helpful
Tips
Reminders!

ICF CAP #2

FROM ALL SITES - Due by June 12

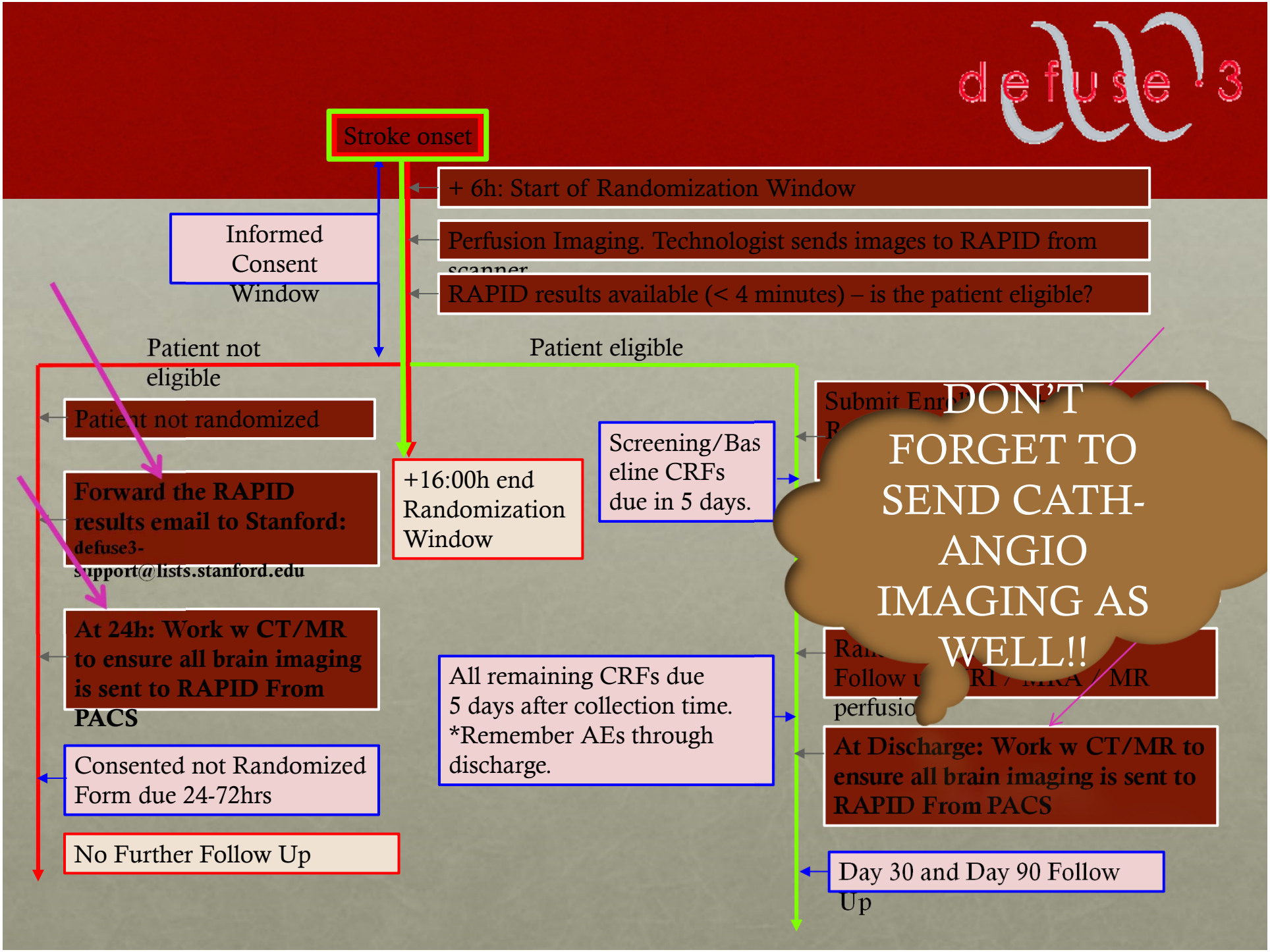
Written ICF Management plan –

- How the site will ensure that all old versions of the consent form are removed/destroyed as soon as a new version becomes available.
- The procedure(s) the research team will follow to access the current version of the ICF at the time of screening and how they will confirm it is the correct version.

PI meeting – documented on log-in sheet

- Review site violations (if any)
- Importance of proper consenting
- Local procedures & policies for obtaining ICF

Imaging Documentation & Transfer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Stroke onset
+ 6h: Start of Randomization Window
Informed Consent Window
Perfusion Imaging. Technologist sends images to RAPID from scanner
RAPID results available (< 4 minutes) – is the patient eligible?
Patient not eligible
Patient eligible
Patient not randomized
Forward the RAPID results email to Stanford: defuse3-support@lists.stanford.edu
+16:00h end Randomization Window
Screening/Baseline CRFs due in 5 days.
DON'T FORGET TO SEND CATH-ANGIO IMAGING AS WELL!!
At 24h: Work w CT/MR to ensure all brain imaging is sent to RAPID From PACS
All remaining CRFs due 5 days after collection time. *Remember AEs through discharge.
perfusio
At Discharge: Work w CT/MR to ensure all brain imaging is sent to RAPID From PACS
Consented not Randomized Form due 24-72hrs
No Further Follow Up
Day 30 and Day 90 Follow Up

Imaging form

- Make sure the data you enter on your imaging form matches with the imaging data that gets transferred to the core lab.
- DO NOT report the study-specif
the imaging form

Only enter data here if the subject went to the cath lab outside of treatment assignment

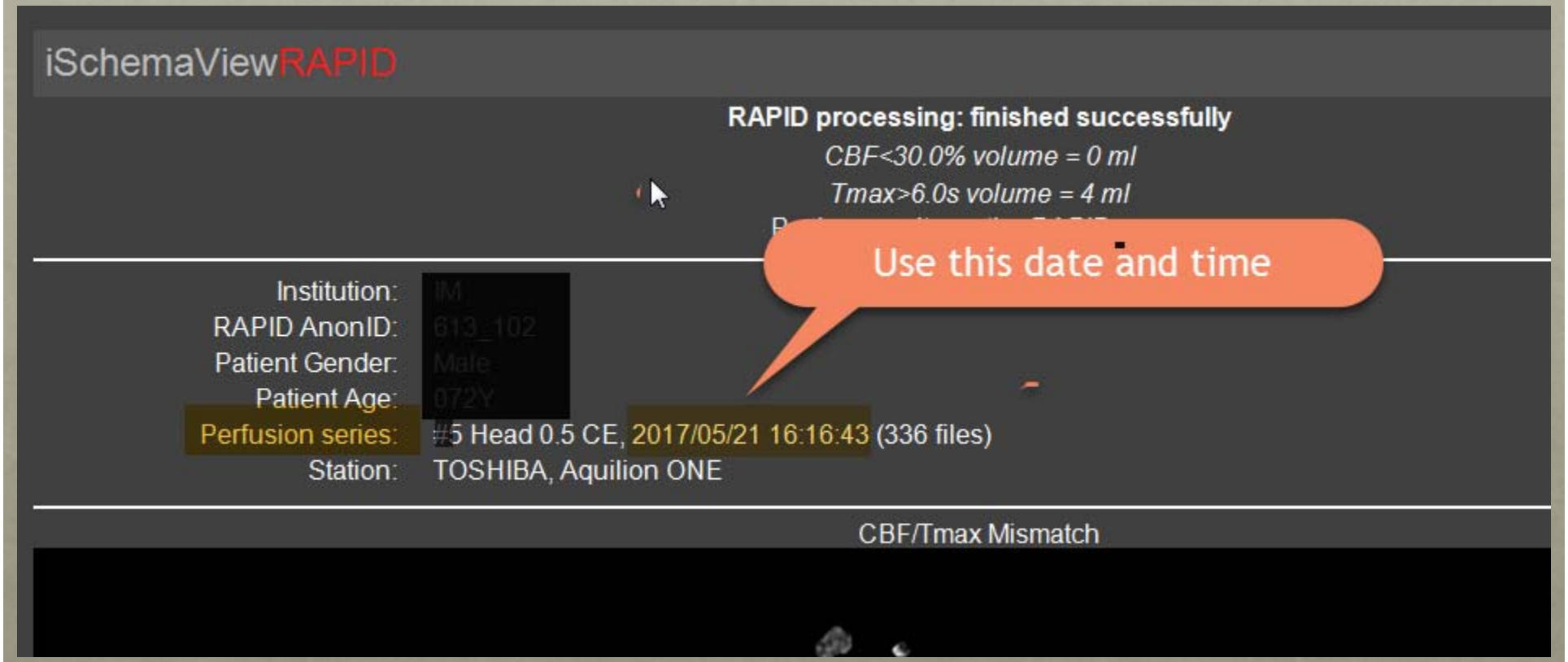
Form 110: Imaging (version 2) Page 1 of 1

List all brain scans done at the enrolling site since stroke onset through hospital discharge, excluding study treatment ang y.

	I. Scan ID	A. Date of scan (dd-mmm-yyyy)	B. Time of scan (24 hour clock, hh:mm)	C. Non-contrast CT	D. CTA	E. CTP	F. DWI	G. MR angiogram	H. MR perfusion	J. Cath Lab Angio?
Q01-1			__ __ : __ __	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes

Imaging form

- Use time from RAPID email for baseline scan. This is how we monitor the time parameter "imaging to groin puncture" - must be </= 90 minutes



The Blinded Rater

BLINDED RATER

Vitally important at Day 30 & 90 mRS & NIHSS to avoid biased outcome assessments

4 violations reported to date

Suggestions for successful blinding:

- **Identify a blinded team member early on!**
- **Blinded team member should not look in patient's WebDCU or medical chart**
- **Avoid discussing individual randomization assignments at group meetings**

What are Screen failures in DEFUSE 3?

Underwent acute embolectomy beyond 6 hours

+

Did not sign DEFUSE 3 consent form

=

Enter into WebDCU screen failure log by the 10th day of the following month

Screen failure examples

- Basilar artery occlusion
- Multiple vascular occlusions
- Patient > 90 years old
- NIHSS < 6
- Report if your site treats outside of DEFUSE 3 based on DAWN results

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DEFUSE 3

Adam Henry

WebDCU™ Update

Informed Consent Upload

- Web based portals are endorsed by FDA
- Secure file upload on separate server for security
- Access limited to only those who have uploaded or will be reviewing forms
- Automatically and permanently removed after acceptance

Informed Consent Upload

- Two new CRFs
  - F238 – Informed Consent Version 3
  - F239 – Informed Consent Version 4

  - The appropriate Version has been prepopulated to the CRF binders in WebDCU

Informed Consent Upload

- Re-consent
  - Subjects that were still participating in the trial at the time of the protocol amendment and needed to be re-consented need both F238 and F239

- Subjects who had their ICF process reviewed during an on-site monitoring visit prior to the enabling of this feature do not need to have forms uploaded

Project Documents

- Located on the DEFUSE 3 homepage under the 'Toolbox' tab
  - DEFUSE 3 and WebDCU™ resources
    - Newest versions of study book, protocol, regulatory document parameters, imaging manual, MOP etc.
    - First stop for question related to WebDCU and DEFUSE 3 WebDCU (but Data Managers are happy to assist as well!)

Team Members

- User Management
  - Study Team Member Request
    - Enables team members to be added to eDOA and upload regulatory documents
    - eDOA
      - Roles and Responsibilities added for team members
- User Permission Request
  - Add the appropriate user groups to allow team members to accomplish their specified roles/responsibilities
    - DMs then review and send login information (if necessary)

Team Members

- eDOA
  - When amending a study team member's roles and responsibilities, add end date for previous set and add a new line with their new set of roles/responsibilities
  - All appropriate regulatory documents must be uploaded to WebDCU before any changes/approvals can be made
  - End Dates effectively remove the team member from the eDOA
    - Final step to remove team member from WebDCU is to update their User Permission Request record
      - Make all items blank for DM approval

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CIRB Continuing Review

MAY 24, 2017

DEFUSE 3

Coordinator Webinar

Janice Carrozzella, MSN, CNP, RT(R), CCRA

NCC Project Manager

CIRB CR: Dates to Remember

- Current protocol approval expires **9/13/17**
- CR on CIRB agenda for review on **8/23/17**
- Completed site reports back to me by **6/23/17**
- Sites approved by **5/15/17** WILL NEED to submit new StrokeNet FCOIs…no exceptions
- No amendment requests after **6/15/17**

CR Documents - Reminders

- Return documents to me by 6/23/17
- CIRB CR form
- De-identified copy of last signed ICF
- StrokeNet FCOIs

CIRB CR Questons???

Questions about CR…contact

- CIRB liaison Sue Roll at rollsn@ucmail.uc.edu or 513-558-6061
- Janice Carrozzella at carrozj@uc.edu or 513-558-3942

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