



# Indiana University Health

CTL TEAM MEETING  
08.28.2023

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## Housekeeping Items

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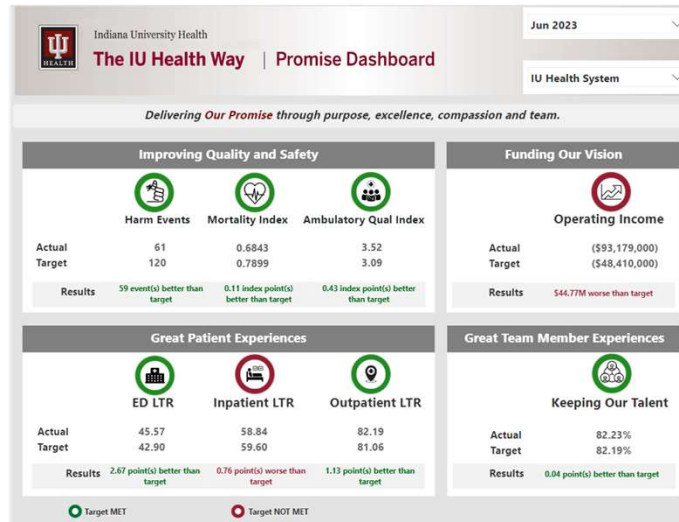
- Please include all supporting documents with occurrences, deviations, and non-conformities
  - Emails/diagnoses to the providers, temperature data, consents, release of ineligible products, etc
- Deviations must have Dr. Goebel and Dr. Reddy's signature.
  - Please always include Dr. Reddy in these communications.
- NMDP Training is now due annually. I will create a MediaLab Module.



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## Pillar Metrics Overview



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## IU Health Updates

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Get your smile ready—new badges coming for all team members

Heads up, leaders—new identification badges are coming to all team members by the end of the year.

New badges will have encrypted technology for a safer and more secure environment. Hard plastic sleeves will encase them to minimize damage.

Standard colors and badge orientations will allow patients and guests to more easily identify team members.

Update your own badge photo, check your name, help your team

To prepare for the new badges, all team members (including you) need to take and submit a cell phone photo that will be used on their ID. All team members includes contingent workers, non-workers and remote workers who come onsite. Follow this link on your phone to submit your photo by Saturday, Sept. 30. You may be prompted to authenticate your IU Health account.

Badges will include first and last names and simplified titles. To make sure your preferred professional name is used on the badge, update personal details in Oracle by Sept. 30.

1. Log into Oracle
2. Search for "Personal Details"
3. Click the edit pencil within the "Name" category
4. Enter your preferred professional name and submit

What happens next?

Leaders are getting this news first, so follow the steps above to update your photo and Oracle details.

After Labor Day, team members will receive instructions on making updates. You can help ensure they upload photos with huddle reminders or by assisting with the simple process.

Badges will be printed in October and distributed by facility in November and December.

Questions? Contact your leader and expect more process details in October.



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# Surveys from IU Health

Surveys will be sent out to employees (usually every quarter)

- There is only one question – rate your likelihood to recommend IU Health as a place to work
  - Rating 1-10
  - Please consider taking this survey when you get it.
  - It is used to calculate our Net Promotor Score.



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# CTL Metrics

IU Health Cellular Therapy 550 N University Bld Rm 3453 Indianapolis, IN 46202 v3.2022		2023 QUALITY INDICATORS DASHBOARD IU Health Cellular Therapy												CLIA # 1500902829 CAP # 7195447		
Policy Code#	Cellular Therapy Quality Indicator	Threshold	Frequency	Percent / Number per Indicated Frequency												
				Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
3.a	Occurrence Investigation: Assigned/Log/Short Term Action	100% Complete	M	100%	100%	100%	100%	100%	100%	100%						
3.b	Occurrence Investigation: Long Term Action Plan	100% Complete	M	100%	100%	100%	100%	100%	100%	100%						
3.c	Occurrence Investigation: CAPA Effectiveness	100% Complete	M	100%	100%	100%	100%	100%	100%	100%						
16	Equipment PM and Function Checks	100% Compliance	M	100%	100%	100%	100%	100%	100%	100%						
22.a	Data Integrity Audits - Electronic Record (June and December)	100% Data Retrieval	SA							100%						
22.b	Data Integrity Audits - Instrument Backup (June and December)	100% Data Retrieval	SA							100%						
7.b	BCP Scenario Drill (April and October)	100% Performed	SA				100%									
7.a	Business Continuity Plan Audit (January and July)	100% Performed	SA	100%												
2	Product Labeling	0 Products	M	0	0	0	0	0	0	0						
19	CTL Analyzer Quality Control Verification	100% Compliance	M	100%	100%	100%	100%	100%	100%	100%						
13	Specimen Submission, Handling, Referral	≤ 2%	M	0%	0%	0%	0%	0%	0%	0%						
14	Test Systems, Equip, Reagents, Supplies	100% Reviewed	M	100%	100%	100%	100%	100%	100%	100%						
17	Calibration and Calibration Verification	100% Reviewed	M	N/A	N/A	100%	100%	100%	100%	100%						
20	Comparison of Test Results	100% Complete	M	100%	100%	100%	100%	100%	100%	100%						
18.a	Sterility Reporting (January)	100% Compliance	M	100%	N/A	N/A	100%	100%	100%	N/A						
11	Environmental Monitoring	100% Complete	Q			100%				100%						
21	Test Formats (January)	100% Complete	A	100%												
4	Personnel Competency (December)	100% Complete	A													
6	Agreement Audit (July)	100% Complete	A													



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## Change in Practice

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- **Effective immediately** a second employee will witness all canisters being placed into the appropriate frames at the end of **all** cryopreservation cycles.
  - We will no longer have just one person waiting on the freezer to finish.
    - Having only one tech in the lab is also a safety issue.
    - I am glad to be that second person as needed.
  - We are updating the F-013, but, for now please initial behind the primary tech as a witness.
- The other change will be how we store the cryovials.
  - We will change from primary storage in the cryovial box to primary storage in the product canister.
    - We are still working on details so this is not in effect right now.
    - This will eliminate a step when putting canisters away, thus, eliminating a potential danger point.
- The SOP's will be updated ASAP to implement these corrections.



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## Staffing updates

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- We are going to try to put in for another MLS.
- Study protocols continue to grow
  - This is an important area for Dr. Feldman (especially CAR-T)
- Dr. Farag is taking a position at a different hospital.

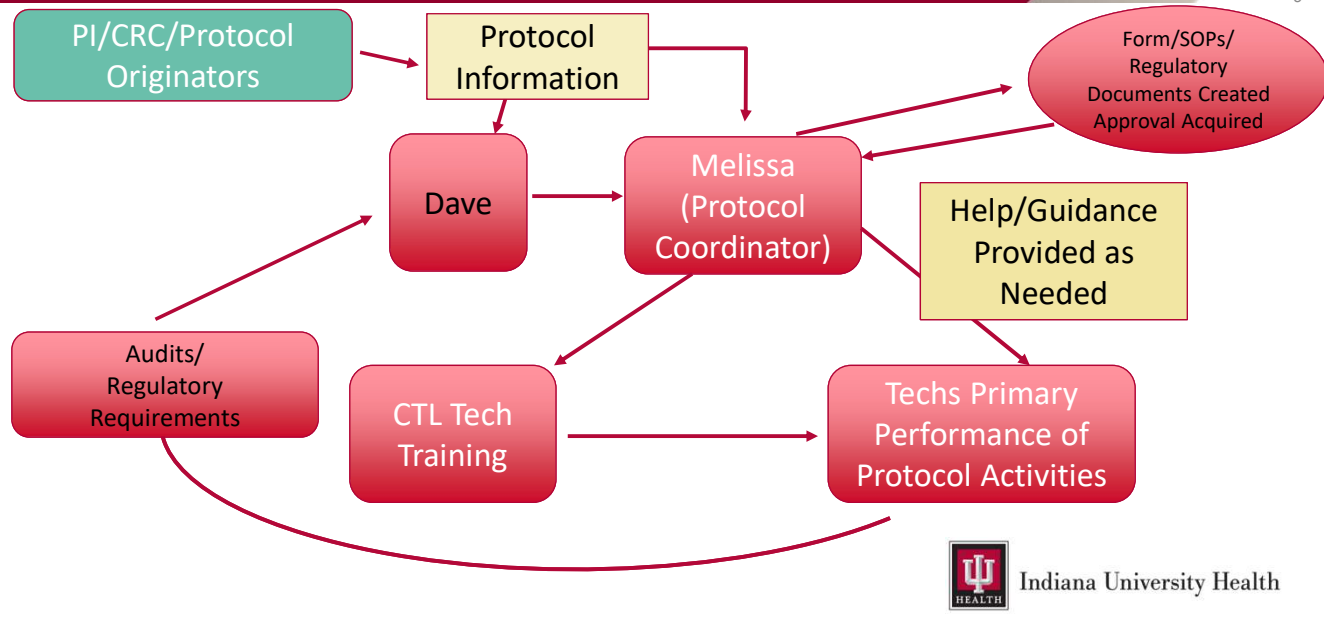


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## Protocol Workflow

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## Team Member Engagement

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### Engagement Update

#### – Q02. I Have the Materials and Equipment I Need to Do My Work Right

- Team members need specific resources to achieve their workplace goals. Without the means to do their work well, frustration quickly follows.
- Let me know as soon as you see a potential problem.
  - I am glad to escalate things early to save us from actually running out.
  - If an unexpected replacement item was sent instead of what was ordered
    - » We need to determine if the replacement is acceptable
    - » I can escalate to determine why we didn't get our usual item.

#### ▪ 2023 Team Member Engagement will be in October.

- We will have a separate meeting to go over all of the questions and what they mean.

#### ▪ Kudos for Colleagues

- Thanks to everyone who has participated, keep them coming!
  - It is always nice to hear that your co-workers appreciate you



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## QA Update

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### ■ Inspection Updates

#### –FACT preparedness

- FACT Inspection January 2024

#### –CAP, AABB, and NMDP Inspections

- All went very well – Well done team!!
  - 2 minor deficiencies from NMDP
  - No deficiencies from AABB or CAP

#### -BlueBird Bio and BMS Audits

- \* Both went well with no deficiencies



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## Values Acknowledgments: Purpose, Excellence, Compassion, Team

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### Teamwork and Purpose

- **Steven, Jennifer, and Brody ended up working 2 different weekends due to scheduling problems with incoming products.**
- **Emma and Hillary validated the Miltenyi freeze bags**



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