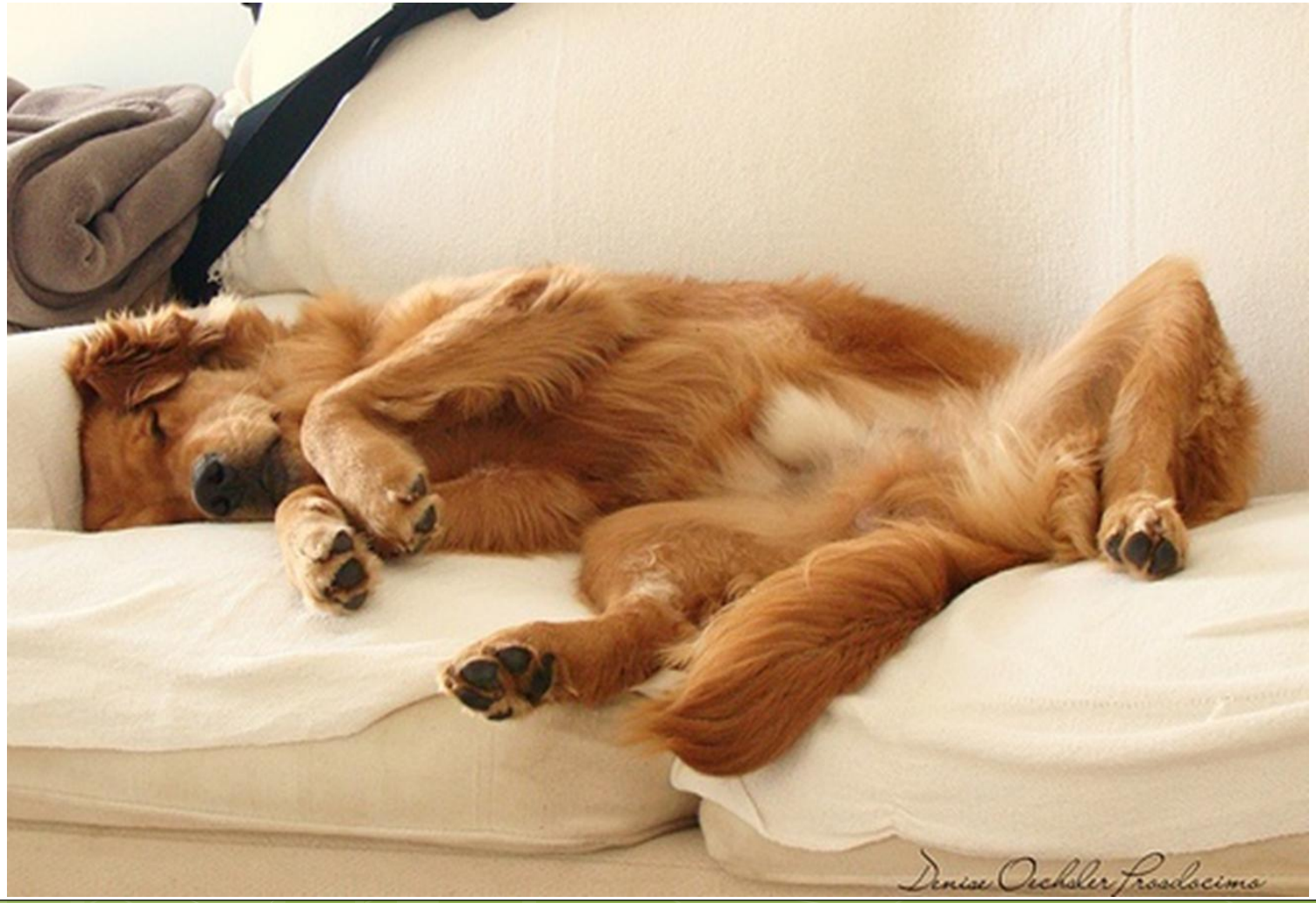
Auditing outside your comfort zone

NAICC 2013
Lee West

COMFORT



I'M MELTING!!!
OH KNOCK IT OFF, WE'RE ALL HOT!

HAS ANYONE SEEN
AL GORE LATELY?

TOO WET

TOO SCARY!!!

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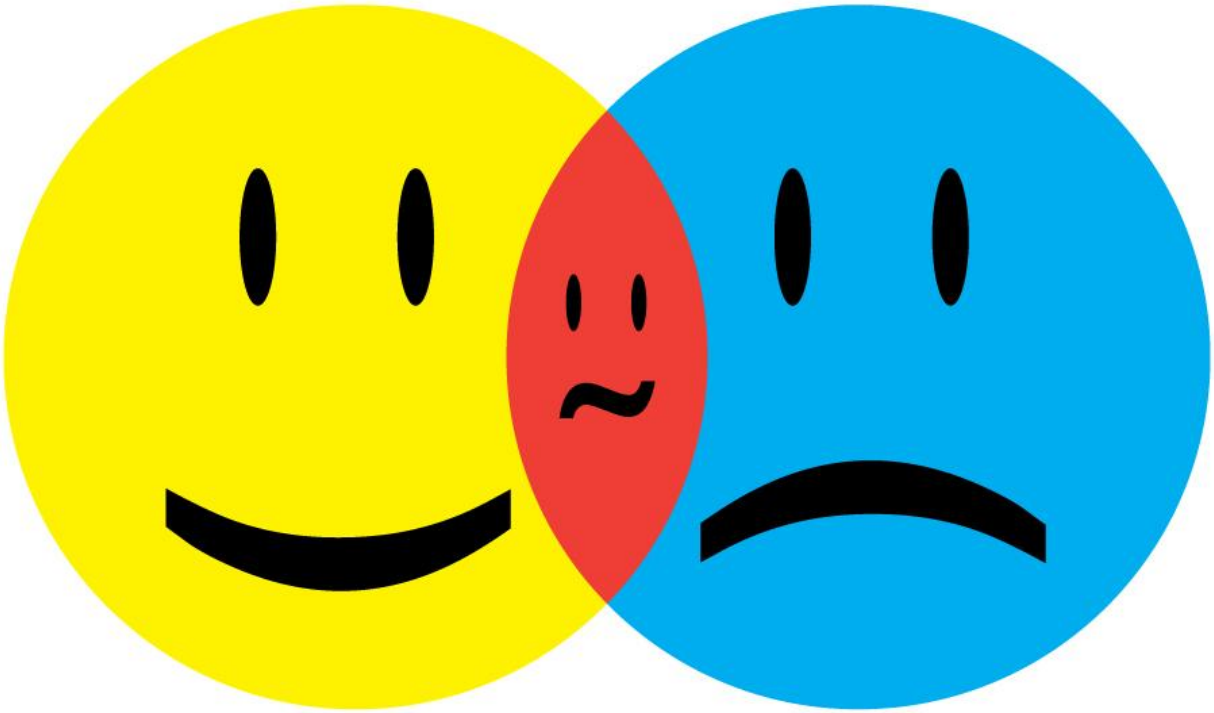
PACE YOURSELF

Luxury Accomodations

An Ode to Tapachula

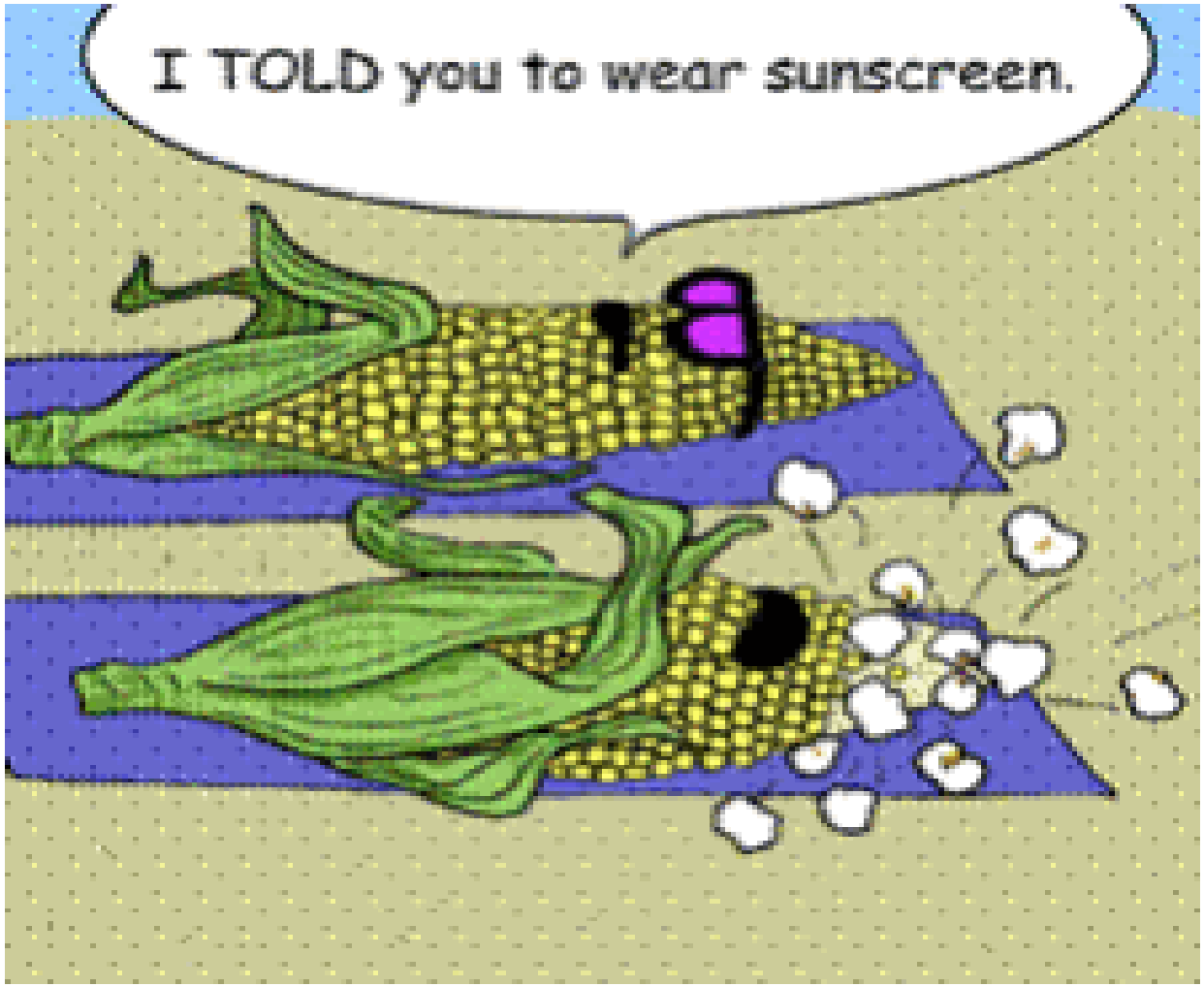
- There were snakes and biting bugs,
- The sun was hot, the field was mud
- The protocol was vague as hell
- And somehow still, things came out well.
- The data showed all that it should
- I did the best job that I could.
- Although the PI wrote in pink,
- I didn't have to make a stink,
- Because it was still permanent ink.
- I checked his facts, I saw the log,
- ……I even saw a speckled frog.

ATTITUDE



WARNING
CHALLENGES
AHEAD

Be Prepared



Do Your HOMEWORK

- Read the protocol
- Ask for and read the field site SOP's
- Use Google! Do your research.
- Anticipate what might happen.
- Ask questions.
- Read CV's and training logs to understand what is valued in the field.

"Nurse, get on the internet, go to SURGERY.COM, scroll down and click on the 'Are you totally lost?' icon."

5. 11. 2000

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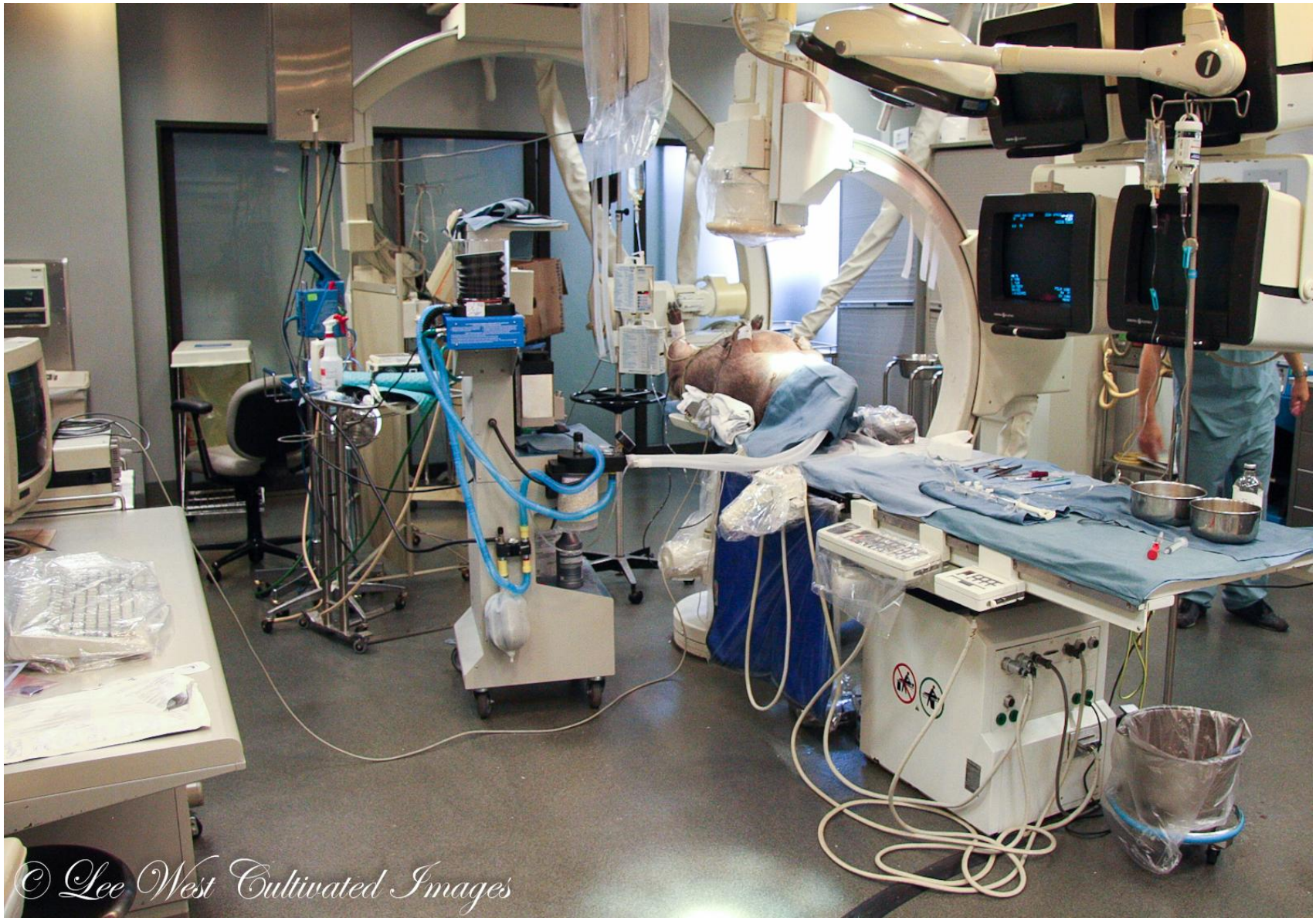
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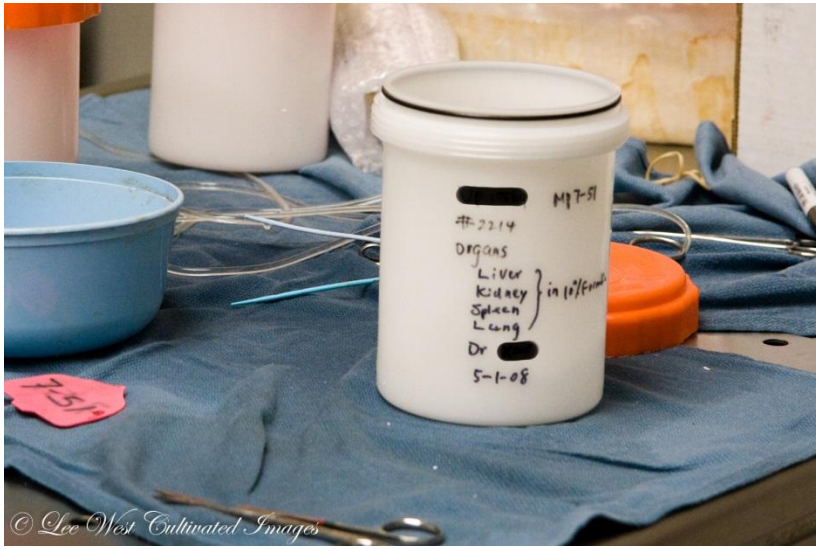
M7-51
#2214
Organs
Liver
Kidney
Spleen
Lung
Dr
5-1-08
7-51
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It's all about the people

- Are the people trained?
- Do they calibrate and maintain the equipment?
- Do they pay close attention to the protocol and SOP's?
- Do they document thoroughly?
- Are they conscientious?
- Do they understand and respect GLP?

Go with your GUT

- Do these people seem qualified and seem to care about what they do?
- Is there a sense that they understand the regulations?
- Does it look like this probably not their first rodeo?
- AUDIT WHAT'S FAMILIAR. It's probably transferrable.

You are not responsible for the conduct of the study

But you <u>are</u> supposed to confirm that SOMEBODY is!!

Keep in Mind

- Do your homework
- Pace yourself
- Be nice, be professional
- Do no harm
- Listen to your gut

This too shall pass

- You're a knowledgeable professional
- You know more than you think you do.
- Audit what you know, and the rest is probably going to follow suit.
- It's outside our comfort zone where our true personal development happens.
- No matter how bad it feels right now, you will be a better person when it's over!

Thank You!!!

RD4AG