

Brief OCR Updates



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Office of Clinical Research

December 6 & 7, 2012

Learning Objectives

- Review results of survey “percent effort dedicated to clinical research”
- Discover an alternate venue to advertise clinical research studies
- Receive update of current OCR staff
- Review CTMS progress
- Have Fun!

Survey: Staff % Effort on Clinical Research

- For PI/Governance Group meeting
11/13/2012
- Survey sent 11/08/2012 at 17:19 hours
to my CRC distribution list
- Three options
 - I devote 100% effort to clinical research
 - I have other duties in addition to clinical
research
 - I do not work for USF

Staff % Effort Survey Results 11/13/2012

- Response rate: 19% (30/157)
- I devote 100% effort to clinical research: 17 (56%)
- I have other duties in addition to clinical research: 11 (36%)

Staff % Effort Survey Results

12/04/2012

- Response rate: 22% (35/157)
- I devote 100% effort to clinical research: 23 (66%) -
- I have other duties in addition to clinical research: 12 (34%)
- **THANK YOU FOR PARTICIPATING!**

Did You Know?



- Slides advertising research on the USF Health closed circuit TV monitors require prospective IRB review and approval
- Use the designated PowerPoint template
- Contact Gina Rathbun, Director, Physician & Community Relations USFPG to post your IRB approved slides

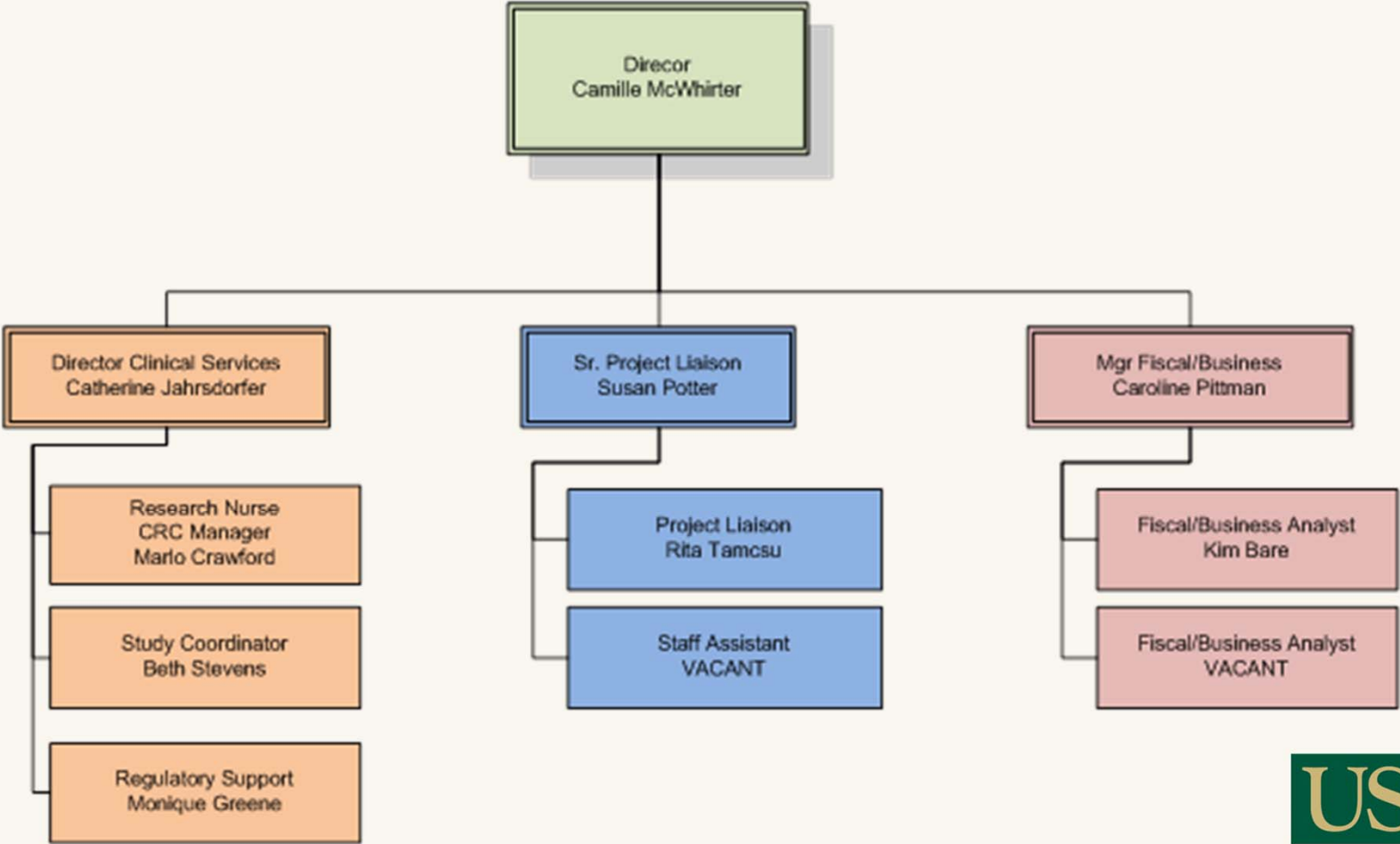
Do you have Psoriasis?

Use this template to
advertise your clinical
research studies on the
USF Health closed circuit
TV monitors!

For more information call:
Jenny at 867-5309

Current OCR Org Chart

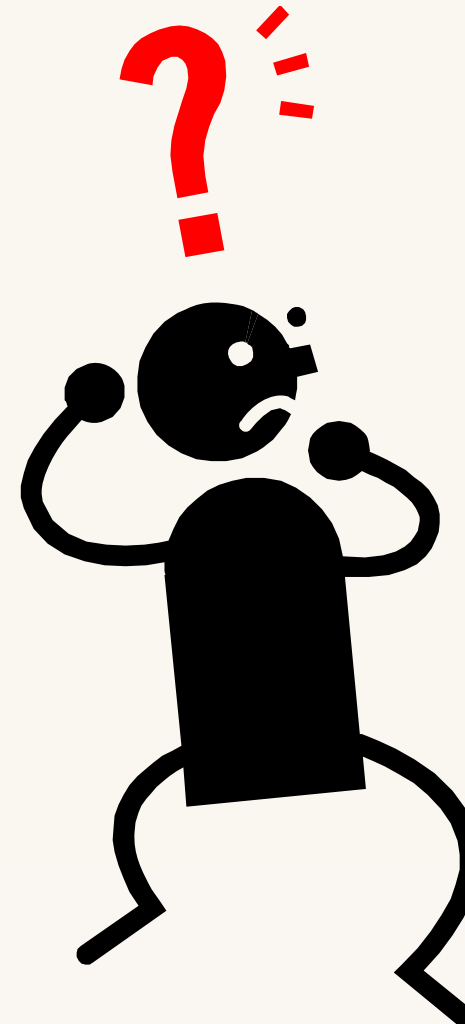
Office of Clinical Research
Organization Chart
December 2012



CTMS Update

- Study Manager Reveal now re-branded as Merge CTMS Investigator
- Health IS has hired our database administrator
- Test environment now being set up on-site
- Production database still hosted by Merge with plan to transition to on-premises
- First study being built in production database now

Questions,
Concerns,
Comments?



December 24th, Christmas Eve

Dr. K. Kringle, Adjunct Professor of Child Psychology
Far North University

Dear Dr. Kringle:

At the regularly scheduled December 24 meeting, the IRB reviewed your protocol, "A Global Observational Study of Behavior in Children." While we believe it has many good features, it could not be approved as submitted. If you choose to revise your study, please address the following concerns:

1. You propose to study "children of all ages." Please provide an exact lower and upper age limit, as well as the precise number of subjects. Provide a statistically valid power calculation to justify this large of a study.
2. Your only inclusion criterion is "belief in Santa Claus." Please provide a copy of the screening questionnaire that determines such a belief. Provide a Waiver of Authorization under HIPAA in order to record these beliefs prior to enrollment in your study. The Board recommends that you obtain a Certificate of Confidentiality as beliefs are sensitive and personal information.
3. You propose to "know when they are sleeping and know when they are awake". How will this be done? Will children undergo video monitoring in their beds? Will they have sleep EEGs? You list 100 elves as research assistants. Are any of them sleep physiologists?
4. Your primary outcome measure is to "know when they've been bad or good" .What standard is being used to determine "goodness"? Do children have to be good all year or just most of the time? What if they have been really, really good except for one time when they hit their little brother?
5. You propose to conduct your research by entering the subjects' homes through the chimney. Have you considered the damage to the roof, carpeting, etc. that this will cause? Moreover, children are likely to be startled by your appearance late at night. Please revise your protocol to conduct your home visits between 9am and 5pm Monday through Friday with a least one parent being present.
6. You state that compensation for participation will be "sugarplums, candy and toys" for the good little girls and boys. This may not be appropriate for children with obesity, dental caries and hyperactivity. Also, your proposal to leave a lump of coal in the stockings of the bad children will be unfairly stigmatizing to them individually and as a group. In general, the Board suggests a small token of appreciation for all participants. Perhaps a \$5 Toys-R-Us gift card would be better.
7. The database of good and bad children will be kept "on a scroll at the North Pole." Please describe the security provisions you have in place to protect the research data. Is the scroll kept in a locked cabinet in a locked room? Who has access to the scroll? Are there back up copies of the scroll and how often are they compared to the original?
8. You mention the participation of "eight tiny reindeer" in your protocol. Please provide the Board with documentation of Institutional Animal Care and Use Committee approval.
9. Please provide the Human Subjects Protection training date for Mrs. Clause and the elves.
10. As this study involves prospective data collection and is more than minimal risk without prospect of direct benefit to the subjects, informed consent signed by both parents will be required. Please have the consent translated into every language spoken by children.

Please submit 25 copies of your revised protocol to the IRB. The IRB will be on Holiday Season Schedule for the next two weeks. If approved, you will be able to conduct your study sometime in January.

Sincerely,

E. Scrooge, MD – Chair, Institutional Review Board
UNIVERSITY OF SOUTH FLORIDA

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