Clinical Research Offices Newsletter

UWCCC Disease Oriented Working Groups (DOWGs) & Leaders

Melanoma DOWG of the Month:

**UWCCC DOWG of the Month: Melanoma**
The Melanoma DOWG is comprised of:

- **DOWG Leader** - Mark Albertini M.D.
- **Program Manager** - Jordan Kostlevy
- **Study Coordinator** - Jen Haldeman
- **Student Support** - Tierra Terrell
- **Researchers in Dr. Albertini’s lab** - Cindy Zuleger and Mike Macklin

Jordan has been with the melanoma group since 2005. She recently made the transition back to full time after spending the summer with her baby boy, Easton, who was born June 23rd, and daughter Marah who began 4K this fall.

Jen has been with the melanoma group since May 2009. Jen is relieved that she made it through the summer and is looking forward to spending time with her new puppy, Murphy, a Boxer born June 10th. Jen is also planning a wedding for June 2012.

Tierra has been instrumental in keeping things running smoothly in the melanoma office every day, but especially this summer during Jordan’s maternity leave. Tierra started with the melanoma group in March of 2008 and will be graduating in December. Don’t tell her…but Jen and Jordan are trying to determine how they can delay her graduation so she doesn’t leave!

It’s been a big year for melanoma with the recent FDA approvals of two new drugs: Ipilimumab (Yervoy) and Vemurafenib (Zelboraf). Everyone in the melanoma group is looking forward to the advances being made in this disease.
**Clinical Research Services Office Corner**

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**Research Budget and Billing Compliance News**

OnCore Financials is Coming! Sarah, V and the OST staff are working closely with staff from UW ICTR and Forte, Inc., in preparation for the implementation of OnCore Financials for budgeting and fiscal management of clinical trials. The SMPH Budget Database will soon be retired and OnCore will serve as the new budgeting database for SMPH researchers. Training sessions will begin for UWCCC staff later this fall, with full implementation targeted for early 2012. We’ll keep everyone informed of the progress for this initiative.

**Core Grant Competitive Renewal**

Progress is well underway throughout the UWCCC to prepare for the competitive renewal of the Cancer Center Support Grant, commonly referred to as the “Core” Grant. Since 2000 the UWCCC has successfully competed for and been awarded this competitive NIH grant, which supports a broad range of Programs and Shared Services of the UWCCC. The Clinical Research Offices and OnCore Support Team are supported in part by Core Grant funds, and the key clinical research oversight activities of the Protocol Review and Monitoring System and Data and Safety Monitoring System are requirements of the grant. The size and scope of the grant require months of preparation by UWCCC faculty, staff, and administration so that both internal and external outreach research activities in all basic, translational, and clinical areas of the UWCCC are accurately and thoroughly outlined.

In the areas of clinical and translational research, the OnCore Database is essential for collecting extensive data that are, in turn, submitted as reports with the grant. These reports, called Summary 3 and Summary 4 reports, are detailed summaries of the types of clinical and translational studies conducted at UWCCC and at Affiliate sites. The reports outline accrual to each study and identify the program areas involved in the research. Much of the continuous Quality Assurance performed by the OnCore Support Team is specifically to ensure we have accurate reports included in the Core Grant submission. Over the next several months you may hear more about the data or information we need as we prepare for the Core Grant submission, which is due in May 2012. Your efforts to provide this information is essential, and the success of clinical research in the UWCCC depends on it!

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**Fall WON Conference**

The Fall Wisconsin Oncology Network (WON) meeting will be held Saturday, October 22nd, 2011 at the recently opened Wisconsin Institutes for Discovery (WID) on the UW-Madison campus. [http://discovery.wisc.edu/discovery/](http://discovery.wisc.edu/discovery/)

We are very excited to hold the WON meeting at this new venue!

To make the meeting more engaging and interactive, we have restructured the format to include research breakout sessions for CRAs and an Industry Meet and Greet to facilitate connections and collaborations between industry and investigators.

**CRA breakout sessions:** Opportunities include SAE training, exploring OnCore v.11 functionality, and previewing the WON Manual.

**Industry Meet and Greet:** An opportunity for networking between MSLs and physicians from the UW and WON institutions. This time will be set aside to discuss new concepts, agents, and clinical trial initiatives.

**Directions:** WID is located at 330 N. Orchard Street between Campus Drive and University Avenue on the UW-Madison campus. Free parking is available in Lots 17 and 20. To see these parking options, go to [http://map.wisc.edu/](http://map.wisc.edu/)

Please let us know if you planning to attend and if you would like to join us for lunch. We are pleased to announce the luncheon keynote speaker will be Dr. Jeffrey Kanne, Associate Professor of Thoracic Radiology at the UW Hospital and Clinics.

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**Revised SOPs Posted to UWCCC Internet**

This month, 3 new SOPs were approved at the CRC meeting and have been posted to the UWCCC intranet site: [www.uwccc.wisc.edu](http://www.uwccc.wisc.edu)

- Human Subjects Protection Training & Certification SOP
- HIPAA Training & Certification SOP
- Physician Orders Tracking Logs SOP

Be sure to review each SOP and contact the CRO with any questions.
**Data and Safety Monitoring Tips of the Month**

**SAE reporting Tips**

#1 OnCore Details Report - Please remember to remove subject identifiers, other than the subject sequence number on the SAE Details report that you generate as an RTF before you save it and upload it in an email to saenotify@uwcarbone.wisc.edu. This means you must manually delete the Subject Name and MRN from the report. If the report is more than one page, you will need to remove it from each page.

#2 SAE Routing Form - Please remember to remove subject identifiers, other than the sequence number, on the SAE Routing Form.

**Protocol Review and Monitoring Tips of the Month**

**Collaborator Sign Off Tips**

#1: If the protocol is conducted through WON, you must list Anne Traynor with the role of Collaborator in the Protocol Staff section in the ePRMS Submission Console.

#2: If the protocol involves Radiotherapy, you must list Diana Trask with the role of Collaborator in the Protocol Staff section in the ePRMS Submission Console.

#3: The groups must allow the collaborators at least 5 working days to sign off on a protocol in ePRMS. You absolutely cannot send a collaborator signoff request the day before a PRMC submission deadline and expect them to have signed off, nor can you contact them to do so. If it has been over 5 working days, you may then email the collaborator and remind them that their signoff is needed.

Please join us in welcoming our newest additions to the Clinical Research Compliance Office:

**Belinda Buehl-Soppe** - Many of you may know her as the Protocol Development Specialist in the CRSO, but we are happy to report that Bel will now be moving over to the Compliance side of the Clinical Research Office. She will head up the NCI CTRP initiative and work to expand CRO educational and training activities.

**Kelsey Shay** will be joining us from the UW Preventive Cardiology department to assume the role of Compliance and Monitoring Coordinator. Along with Emily Jenner, our lead auditor, Kelsey will work with the research groups on a variety of monitoring activities, including QARs, Internal Audits and Response Reviews.
OnCore Support

OnCore Support Corner

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OnCore Tip of the Month

Do you get too many emails? Of course you do!
Get fewer QA’s in your inbox by utilizing the Data Field Definitions (DFDs) when entering information into OnCore.

Tip for CRA’s

Subject Console > On Study Tab > Diagnosis Date is a new field implemented in OnCore 11.0. We are NOT going to use this field at UWCCC. Do not complete this field.

Tip for Regulatory Staff

HIPAA records in OnCore do not expire like other IRB records; therefore it is important to remember to enter the HIPAA record separately without an expiration date in the PC Console > Reviews Tab > IRB.

In the Reviews tab > IRB, enter the HIPAA in a separate record with all the same fields as a regular record except for Review Reason select “Unspecified” and leave Expiration date blank. This HIPAA record populates the Subject Console > Consent Tab where the CRAs choose the HIPAA version used. If this record has an expiration date, it looks like the CRAs are using an expired HIPAA to consent subjects.

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