

Begin forwarded message:

From: "Stanton, Bonita" <bstanton@med.wayne.edu>
Subject: Mandated use of ONCORE after January 7, 2016
Date: December 23, 2015 at 3:59:43 PM EST
To: All Basic Sciences Faculty <AllBasicSciencesFaculty@med.wayne.edu>, All Clinical Faculty <AllClinicalFaculty@med.wayne.edu>
Cc: "Chairs - (Clinical)" <Chairs-Clinical@med.wayne.edu>, "Chairs - (Basic Science)" <Chairs-BasicScience@med.wayne.edu>, "Sobel, Jack" <JSobel@med.wayne.edu>, "Lanier, Stephen (lanier@wayne.edu)" <lanier@wayne.edu>, "Levy, Phillip" <plevy@med.wayne.edu>, "Parker, Jackie" <jparker@med.wayne.edu>, "Stanton, Bonita" <bstanton@med.wayne.edu>

Dear faculty

Effective January 8, 2016, the use of ONCORE, a Clinical Trials Management software, will be mandatory for all clinical trials, funded or unfunded conducted by WSU faculty.

Many departments have already been using ONCORE, some for several years, and have found it to be very helpful. Most departments have had some experience with it. As many of you are aware, this discussion has been ongoing for several years. With the official opening of the Clinical Research Service Center in January, we have decided that it is time to fully implement the ONCORE program. In early December we advised the Department Chairs and Associate Chairs that we would be discussing this change at the Associate Chairs for Research meeting—and invited the chairs to join the discussion.

Please find attached a copy of the slides summarizing the ONCORE program (including the rationale for and implications of the decision to require its use and its implications for investigators) which Jackie Parker and Phil Levy presented to the Associate Chairs and Chairs at the meeting on December 16th. Both Dean Sobel and Vice-President Lanier were present at the meeting and, as they both stated at that time, believe in the importance of and fully support this mandate. Many of you may have questions about ONCORE, some or all of which hopefully are addressed in the slides.

This policy will **not** impact existing trials/grants ---but **will** apply to any future trials.

There are a wide range of options as to how the system can be used. Jackie and Phil would be very pleased to come to your departments to make presentations to the faculty and will be

holding training sessions for research and departmental staff who will need to know how to use the system. They would also be pleased to field by phone or email or one-on-one meetings any questions you have.

This is a good thing—long overdue—with minimal financial or clerical burden on investigators and substantial benefits for the SOM and the university—and for the investigators.

This is a good thing—long overdue—with minimal financial or clerical burden on investigators and substantial benefits for the SOM and the university—and for the investigators.

Thanks very much,

Bonnie

Bonita F. Stanton, M.D.
Vice Dean for Research
School of Medicine
Wayne State University
Professor of Pediatrics
313-577-9553 (office)
313-577-9399 (FAX)

Oncore Go Live

Phillip Levy
&
Jackie Parker

Objectives

- Who are we?
- What is Oncore?
- Why is it mandatory?
- How will it be implemented?
- When will implementation occur?

We are the Clinical Research Service Center (CRSC)

- The CRSC is a Wayne State University based research core
- Tasked by OVPR and SOM with, among other things, implementing Oncore Clinical Trial Management Software for all research involving human subject participants

Why is it Mandatory?

- Meets WSU need for research accountability as defined by the Baettle & Faegre consulting groups
- Provides WSU the ability to manage, track and report on all components of clinical research
- Allows for a central location to track patient recruitment and manage clinical trials leading to integration with other university software
- Provides WSU oversight for DMC compliance requirements for research conducted in their facilities

What is Oncore?

Clinical Trial Management software

- Tracks regulatory documents (IRB, sponsor documentation, FDA, CT.gov) (IRB electronic integration)
- Tracks accrual
- Tracks consents and notify for re-consents
- Tracks patient visits and completed procedures
- Tracks Adverse Events and Serious Adverse Events
- Manages study financials & contracts (SPA access to IRB approval)
- Utilizes centralized charge master to build study budgets
- Creates registries and link to WSU biobank
- Creates Biobanks

Access is web based and role restricted

Advantages

Institutional and Departmental Oversight, Awareness and Support of:

- Number of trials by PI, Department and location
- Participant accrual (and NIH demographics)
- Adverse and Serious Adverse Events reporting
- Data capture tools for statistical output (CRF)
- Budgets and finance
- Payments to entities for services performed

Implementation Steps?

All staff must be trained to gain access to Oncore. We will provide:

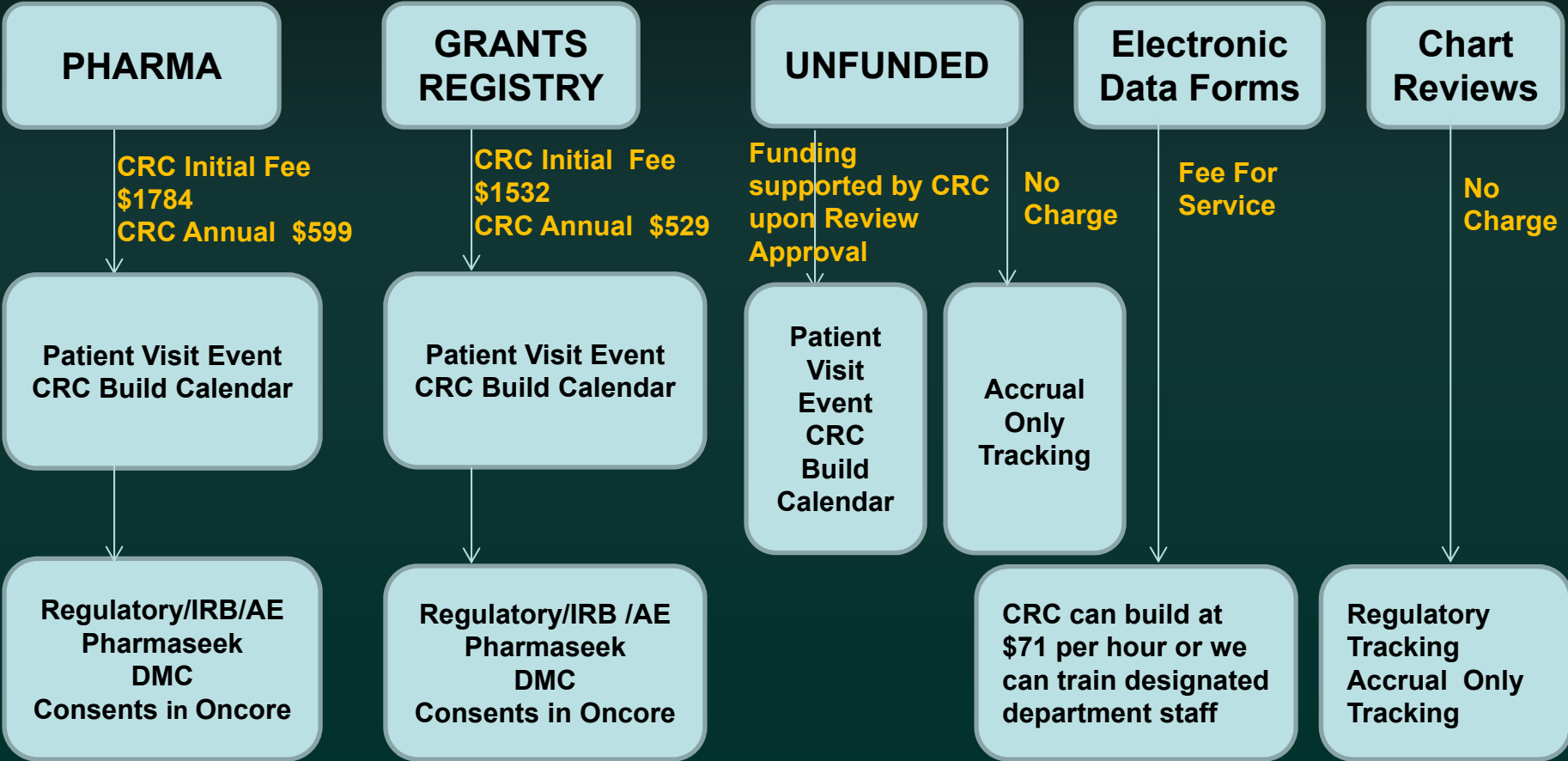
- Weekly staff training at rollout
 - Departments Identify Staff to train
 - (regulatory, participant entry, financial)
- One on one support to departments
- Centralized IT support 7 am to 7 pm
 - Phone
 - gotomeeting

Departments with Trained Staff

- Pediatrics
- Emergency Medicine
- Pharm Sciences
- DMC Research Office
- Dermatology
- Psychiatry
- Internal Med
- OB/Gyn

ONCORE Utilization for Clinical Research Studies

WSU Direct Access to Research conducted by Investigators



When Does This Start ?

- January 7, 2016
- Includes all grants, contracts and non funded studies starting after this date.
- CRSC staff will work with SPA and the IRB to track studies and contracts to ensure they are entered into Oncore

Contact Us

Additional Information on Oncore or any help

Jackie Parker

577-1001

jparker@med.wayne.edu

Phillip Levy

577-1214

plevy@med.wayne.edu

❖ Training

Lisa Palmer

577-1537

lpalmer@med.wayne.edu