

GPAC – February 12, 2014

Announcements:

- Proposal Status Reports are due – please send!
- NIH announced that titles can now be longer than 81 characters. The new limit is 200. Though be very aware that revised applications must use the same previous title – no switching midstream. The announcement is below:

Project Title Field Expanded

With this release, eRA systems and databases will be able to accept grant application titles up to 200 characters. The project titles will no longer be truncated to the previous limit of 81 characters. Not all eRA screens and reports will reflect the expanded project title with this initial implementation. Over time these will be updated.

NOTE: When submitting a Revision application, applicants must use the exact project title displayed in eRA Commons for the awarded application. If the project title of the awarded grant was previously truncated to 81 characters, then only those 81 characters can be used for the Revision application.

Acceptance of Awards >20% reduction:

- ORSP announced at RAN that award acceptance for projects with a greater than 20% change will be restricted to the PI(s), division, department, and school of the administrative home stream posting comments to accept – GONE are the days of all 16 units participating having to post and holding up the award. A couple of caveats (of course)
 - a. The initial notice of the award being on campus will be sent to EVERYONE on the project team. Even if you don't need to post a comment, you do get notified.
 - b. You might need to reach out to the project team if you need to register your concern or needs prior to the award being accepted.
 - c. If you are the project team, you should work with the PI about the scope of work. They can't just say "I accept" – they now have to say "I need to renegotiate the specific aims" – which has to be done prior to award issue... OR "I accept, but do not need to change the specific aims for the budget offered."

NIH Salary Cap:

- The federal government finally gave raises to employees and the new salary Cap II is \$181,500 as of 1/12/14. You may move folks to the new cap after 1/12/14 but remember if you move one person on the project, you need to move them all. We don't know why NIH announced 1/12/14 as the date and it seems strange, but barring any clarification that is what UM is using....
- The over-the-cap and VA MoU spreadsheets have been revised and can be found here: <http://medicine.umich.edu/medschool/research/office-research/grant-review-analysis/pre-award-information/proposal-preparation/budgeting-costs/budget-templates>
- The next iteration of the salary cap review will be coming soon from campus. It looks like this will be going out twice a year, rather than quarterly as originally stated.

Upcoming Professional meetings:

- NCURA Region IV Meeting will be in Indianapolis on April 27-30, 2014. See attached handout for more information. Or, visit the website: <http://www.ncuraregioniv.com/conferences.html>

- SRA Michigan Chapter Meeting will be in Dearborn on June 5-6, 2014. See website for more information: <http://srainternational.org/meeting/chapter/michigan-chapter-meeting>

Clinical Trial Routing Forms (CTRF):

- See attached powerpoint slides for more info, a few highlights:
 - CTRF is required for Clinical Trial Site Activity (31200) or investigator-initiated, industry-sponsored clinical trials when there is a draft agreement to review. This includes amendments!
 - The Office of Research has a goal to get the process down to 90 days to complete contract negotiation, financial negotiation, and regulatory approval

MICHR Clinical Trials Office (MCTO) and Clinical Research Management (CRM)

- Jill Malayang presented about the services available through MCTO, her full presentation is attached
- MCTO is available for to create budgets and billing calendars, route UFAs and CTRFs, negotiate budgets with the sponsor, complete initial IRB application, and draft consent/assent forms for Industry Initiated Clinical Research

Grant Review & Analysis presents:

The Clinical Trial Routing Form (CTRF)

February 12, 2014



You will learn:

- What a CTRF is
- When it should be used
- Why it is important
- How it benefits you
- How to use it
- What to do after 'routing'



What is a CTRF?

- Clinical Trial Routing Form (CTRF)
- A form in eRPM
- Mechanism to send a draft agreement to ORSP for review before routing a PAF
- Captures target dates for completion early in the process



When should a CTRF be used?

It is required, and is to be used when:

- The activity is:
 - Clinical Trial Site Activity (class 31200) **OR**
 - An Investigator-Initiated, Industry-sponsored clinical trial

AND

- There is a draft contract to review



Why is it important to use the CTRF?

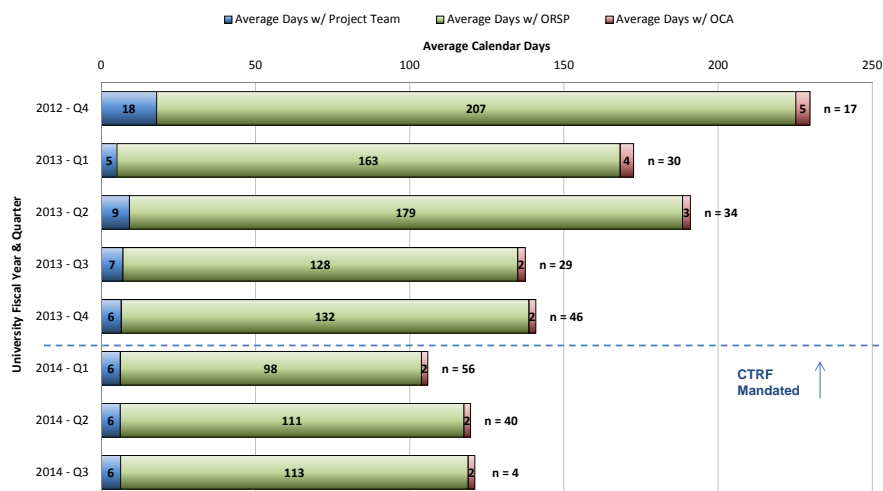
- Allows three processes to be worked on simultaneously
 - ORSP: Contract Negotiation
 - Project Team / CTO: Financial Negotiation
 - IRB: HUM application

- Tracking of metrics allows continuous improvements



All Active or Non-Executed CTRFs: Average Calendar Days from 'CTRF Created' to 'CTRF Active'

(If CTRF is not executed, the average # of days for all active CTRFS created in the last three quarters for each process owner is used)



Data Source: ITS 1/9/13

How does this benefit the project team?

- Faster overall time to project start
- Allows use of a “Priority Consideration Date”
- Standardized process leading to increased efficiency
- Transparency of activity / status of negotiation

How do I use a CTRF?

In eRPM, either:

- Choose the “Create Clinical Trial Routing Form” button from within an active Unfunded Agreement (UFA) Non-Disclosure Agreement (NDA)
 - System copies relevant information
- Choose the “Create New Clinical Trial Routing Form (CTRF)” button



How do I use a CTRF?

- Complete required fields and upload draft contract
- Choose activity "Notify ORSP CTRF is Complete"



Activities
Notify ORSP CTRF is Complete
Project Team Cancel PAF
Assign Ad Hoc Reviewer
ORSP Cancel PAF
Post a Comment for the Entire Project
Edit Staff Notes
Post a Project Note
Add PAF to Mollot

Introduction - CTRF
1. General Information
Introduction - CTRF
Sponsor Information - CTRF
2. People
UM Key Personnel
Administrative Personnel
Project Administration - CTRF
End of Worksheet
End Of CTRF Worksheet



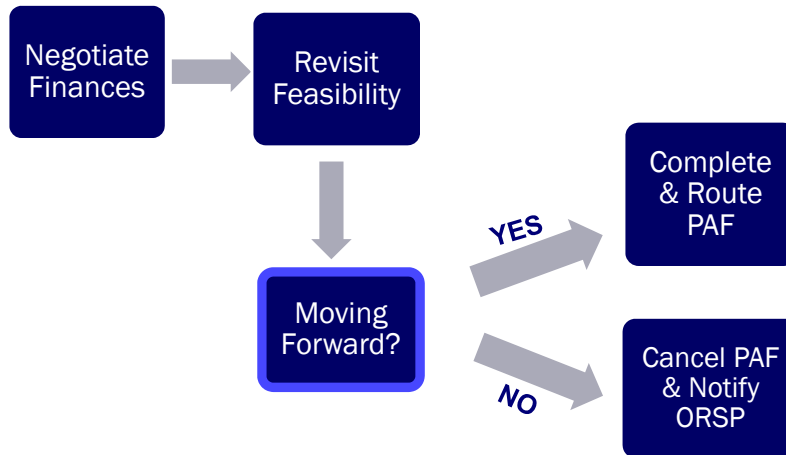
How do I use a CTRF?

- ORSP now has your contract queued for review/mark-up to send to the sponsor
- CTRF has auto-converted to a full PAF; opening the remaining fields

Introduction - CTRF
1. General Information
Introduction - CTRF
Sponsor Information - CTRF
Project Information
2. People
Project Personnel
UM Investigators
Administrative Personnel
Project Administration
Project Personnel Details
3. Budget
Budget Components
Budget And Time Period
4. Space
Space For UM Investigators
General Space
5. Supporting Information
Research Activity
Routing Instructions
6. Proposal Documents
Proposal Documents
End of Worksheet
End Of PAF Worksheet



What should I do after routing a CTRF?



What should I do after routing a CTRF?

- PAF: After the financial negotiations are complete, “Route for Approval” →
- If all has gone well, when your PAF arrives at ORSP, their negotiation will also be complete. If IRB is also approved, ORSP can execute your agreement!

Activities
Route for Approval
Project Team Cancel PAF
Assign Ad Hoc Reviewer
Negotiation in Progress
ORSP Cancel PAF
Post a Comment for the Entire Project
Edit Staff Notes

What should I do after routing a CTRF?

- Follow-up
 - First revision of contract should be sent to the sponsor by ORSP within 2 weeks
 - If it has not, inquire using the “Post a Comment” activity
 - Inquire again, as needed, on 1 week intervals using “Post a Comment”
 - Discuss with the Medical School Grants Office if you are unable to get a response



What if ORSP is done, but I'm not?

- If ORSP finishes contract negotiations, but the financial negotiations are not yet complete (or the completed PAF has not been routed) they will ping you.



Notes/Issues

- Once a CTRF is started it cannot be converted into a PAF without sending a draft agreement to ORSP.
- A PAF cannot be converted into a CTRF if you realize you need one.
 - ‘Placeholder’ PAFs/CTRFs cannot be utilized
 - If you need a change of type, cancel and start over



Notes/Issues

- Amendments/Extensions should also be processed on a CTRF
 - Each new trial covered by an original NDA can have a new CTRF created
 - Each amendment of costs on an existing award can have a new CTRF created
 - Cloning feature not yet available



Need help?

Contacts:

- Medical School Grant Review & Analysis:
msgrants@umich.edu or 763-4272
- ITS (eRPM):
4help@umich.edu or 764-HELP (764-4357)



Grant Review & Analysis

Questions?



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MICHR Clinical Trials Office (MCTO) and Clinical Research Management (CRM)

Jill Malayang and Sue Burhop
Michigan Institute for Clinical & Health Research (MICHR)

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MCTO Scope

- Industry Initiated Clinical Research
- Route Unfunded Agreements (UFA) and Clinical Trial Routing Form (CTRF)
- Create feasibility, sponsor and internal budgets
- Create billing calendar
- Negotiate budget with sponsor
- Complete Initial IRB application
- Draft consent/assent forms, negotiate language
- Monitor progress of Contract Approval

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What have we been up to since 2011?

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Current State

- 3 Active Studies
- 44 Completed Studies
- 19 Cancelled Studies

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Duration of Completed Studies

Grant year ending	Number of Studies	Approximate Duration (calendar days)
2011	1	180
2012	19	180
2013	21	180
2014	9	80

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Departments Served

Department	Number of Studies	Percentage
Cardiac Surgery	3	7%
Dentistry	5	11%
Emergency Medicine	2	5%
Internal Med - Infectious Disease	4	9%
Internal Med - Allergy	4	9%
Internal Med - Cardiology	5	11%
Internal Med - GI	13	30%
Internal Med - Hematology/Oncology	12	27%
Internal Med - Nephrology	4	9%
Internal Med - Pulmonary	1	2%
Internal Med - Rheumatology	5	11%
Neurology	2	5%
Ophthalmology	1	2%
Otorhinolaryngology	1	2%
Pediatrics - Hem Onc	1	2%
Psychiatry	3	7%

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Other Activities

- Manage portfolio and track progress using Microsoft Project Management System
- Establish Clinical Trial Huddle Meeting to surface potential issues with studies. Attendees are from Cancer Center CTO, IRB, ORSP, Internal Medicine Hematology Oncology Clinical Trial Pre-Award Office and MCTO
- Development of budget templates, best practices, and template language for justifications

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What's new?

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Billing Calendar a la carte

- MCTO will now complete billing calendars for any industry funded study.
- Will consider doing Investigator Initiated studies on a case by case basis.
- Includes creation of billing calendar, meet with study team to get designations (in person or by email), review informed consent to ensure consistency with billing calendar and make changes based on CRAO review.
- Charged at an hourly rate of \$55.

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Tracking of clinical trial studies

- Clinical Trial Huddle Group will review all studies that are waiting on only one process to be approved for study activation (IRB, budget or contract approval)
- Track and follow-up on all Quintiles studies

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Other Clinical Trial Services

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Study and Data Management Mentoring and Consultation Services

- Management of multicenter clinical projects from start-up through termination
- Preparation and negotiation of budgets and contracts
- Design, cleaning, and management of Case Report Forms (CRFs)
- Preparation of multi-site informed consent template(s)
- Management of regulatory document submission
- Maintenance of the operational study file
- Coordination of investigator/study coordinator meetings
- Editing and distribution of study newsletter

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Study Monitoring

- Investigator and clinical site qualifications
- Protocol-specific site training/certification
- Monitor site performance
- Quality improvement, Quality assurance
- Adverse Event (AE)/Serious Adverse Event (SAE) reporting
- On-site clinical monitoring (routine site visits)
- Data query resolution
- Study close-out visits
- Investigational material accountability
- Consult with investigators on development of clinical protocol, consents, protocol manual of operations and recruitment materials

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Project Database Design and Implementation

- Build Project database to store and manage clinical research data.
- Make recommendations on data collection and database organization to promote efficiency, improve data quality and streamline data reporting and analysis.
- Manage change requests, provide technical support and to create reports during implementation phase of study.
- Coordinate loading of research data from other sources if needed.
- Coordinate database 'lock' after all data has been received and checked for accuracy.
- Provide guidance on access to datasets, data sharing and data security practices to ensure research data is safely and effectively delivered for final analysis.
- Provide training for REDCap and OpenClinica (MI-OC) EDC systems for study teams that want to develop and manage their own databases.

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Your thoughts...

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What Else?

- What other services would you like MCTO to offer?
- How can we work better with the study teams?
- What other barriers do you see in your departments?

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