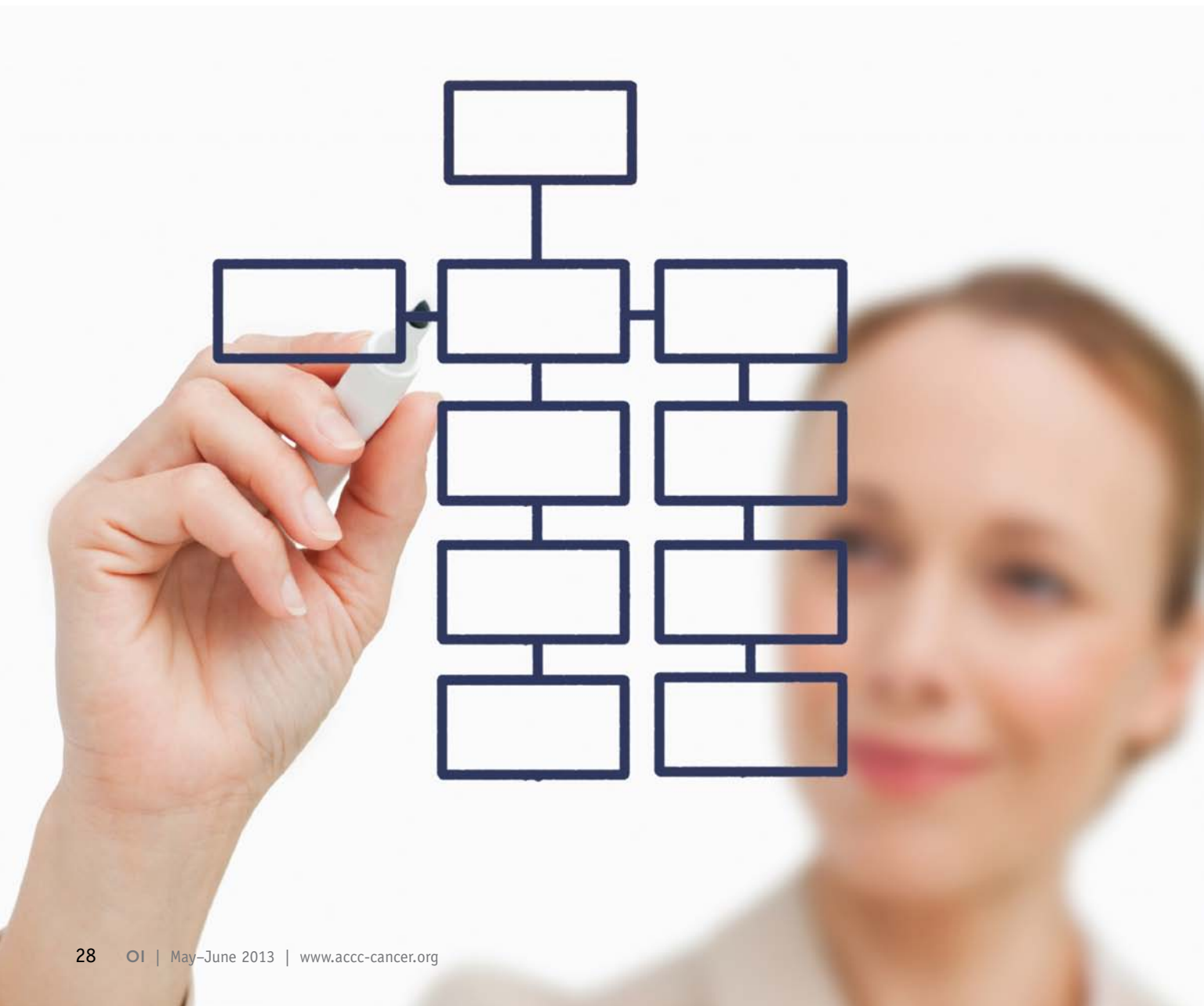
Improving Your Study

BY DEBORAH JONES, RN, BSN, OCN, CCRC



Review Process

In 2011 a small group of St. Luke's Mountain States Tumor Institute (MSTI) Adult Clinical Research staff evaluated existing processes for bringing new studies forward for IRB Review to identify all possible barriers to achieving efficient review. In hindsight, the situation in which the MSTI Research Department found itself had all the required elements for a "perfect storm" to occur. In this context, the phrase "perfect storm" refers to several developments that evolved throughout a one-year period that collectively hampered clinical research within our department, including:

- Not meeting clinical trial accrual goals. In 2011 MSTI had the lowest level of adult patient enrollment into oncology clinical trials in several years.
- Multiple studies closing to enrollment.
- Very few new clinical trials being opened and available to our patient population.

As a department, we also felt stymied in our ability to fulfill our mission of working with healthcare providers to offer opportunities for education and participation in clinical trials for the advancement of cancer care to the community. These "perfect storm" developments were the result of changes that occurred both within the larger St. Luke's Health System Office of Research Administration and within our own department. System changes included infrastructure, research software program implementation, administrative review process, and IRB submission process changes. Internally, departmental changes were tied to changes in the operational system research process and to the goal of meeting the clinical trials pillar deliverables of the NCI National Community Cancer Centers Program federal contract that was awarded to MSTI in April 2010.

The Importance of an Internal Review Process

In May-June 2011, informal but frequent small-group discussions focused on staff frustration and struggles with opening new clinical research studies. These group discussions led to a dissection of our current process. We developed a poster-sized flowchart of our existing new study review process and hung it in the office where it served as a reference tool during the focus group's internal evaluation (see Figure 1, page 30).

Our internal evaluation of the existing process revealed a lack of organization and consistent coordination. Additionally, the existing flowchart lacked well-defined directives for staff. In other words, the flowchart did not allow individual staff to clearly understand their role and responsibility in the process. The flowchart did not identify timelines at any point during the process—it was simply too general.

It was clear to our focus group that we needed to develop a more formalized, accountable, and organized process for tracking and reviewing potential new clinical research studies. A more clearly defined and articulated process would ensure that staff understood the underlying goals and the individual job responsibilities that were tied to the success of these goals. Our hopes were that research staff would hold each other accountable to this new process, improving both quality of and efficiency with new study review and resulting in greater numbers of new studies for IRB review in a timely manner.

New Process Flows & Tools

The outpouring of thoughts and ideas from the focus group clearly demonstrated they were fully engaged in this process improvement. Using the existing (but flawed) flowchart, the next step was to revise the new study review process and develop a flowchart of the revised process. In the end, because of differences between cooperative group studies and pharmaceutical studies, the focus group developed two flowcharts: a cooperative study flowchart (Figure 2, page 31) and a pharmaceutical study flowchart (Figure 3, page 32).

Next, the focus group modified its existing study tracker document (Figure 4, page 32). This tool was originally created by our newly-hired research assistant (RA), a new position within MSTI adult research and supported through the federal NCCCP contract. Recognizing the need to organize existing sponsor correspondence and track new study information, the

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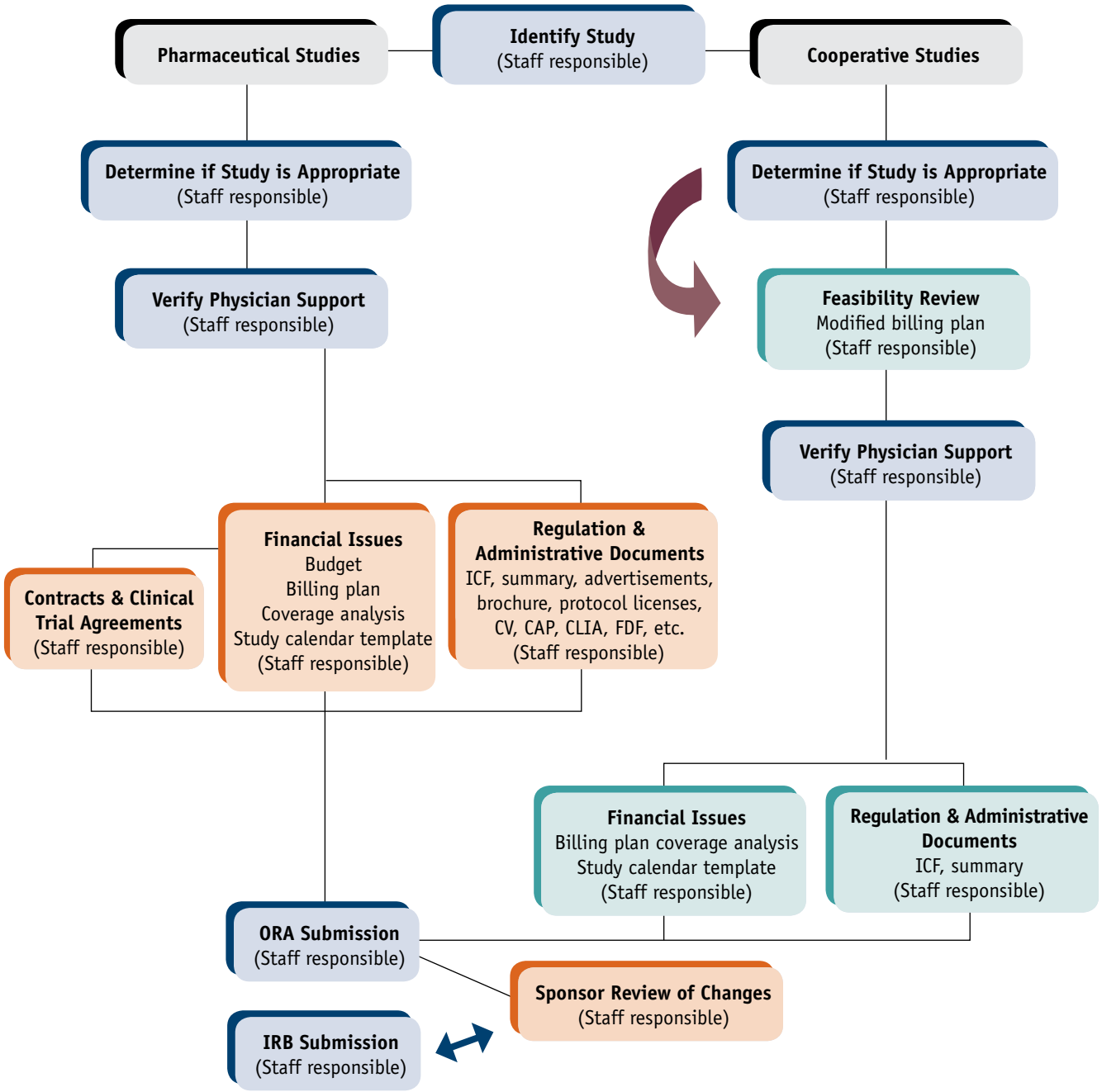
Figure 1. Process Flowchart for New Adult & Pediatric MSTI Protocols



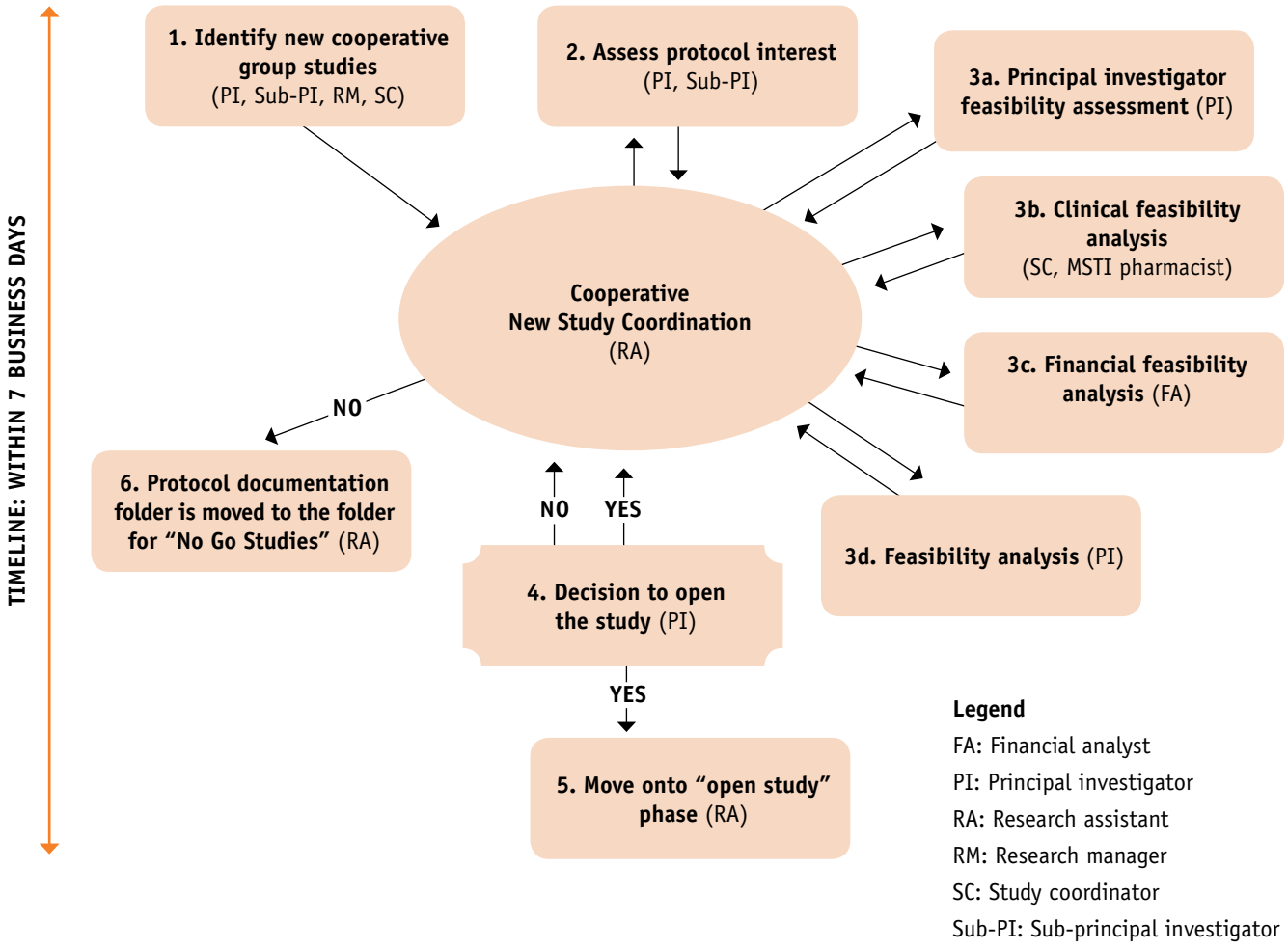
Key

- Blue box applies to all new studies
- Green box applies to only cooperative studies
- Orange box applies to only pharmaceutical studies

Legend

CAP: College of American Pathologists certification
CLIA: Clinical Laboratory Improvement Amendments
CV: Curriculum Vitae
ICF: Informed consent form
FDF: Financial disclosure forms
ORA: Office of Research Administration

Figure 2. Process Flowchart for New Review of Cooperative Group Studies



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RA had created the study tracker a few months prior. As the focus group created the two new flowcharts for cooperative group and industry-sponsored studies, they recognized the value of the study tracker to the overall process improvement development. The updated study tracker now separates out pharmaceutical study tracking (Figure 5, page 33) from cooperative group tracking (Figure 4).

With the new flowcharts and study trackers in place, the focus group created a research resource utilization form (originally titled protocol feasibility review form) to clearly articulate the responsibilities assigned to each research staff position involved in the new process. Known as the RRUF, this form (Figure 6, page 34) incorporates the due diligence requirements for each new study review. Research team members responsible for completing elements of this review include the study-specific principal investigator, research nurse coordinator, MSTI pharmacist, and research financial analyst.

As part of this formal review process all five MSTI sites (Boise, Fruitland, Meridian, Nampa, and Twin Falls) are evaluated on the same criteria to determine feasibility of individual site participation. This portion of the review is completed using the MSTI adult research site resources list, a companion document to the research resource utilization form. The review areas include but are not limited to:

- Identifying any potential competing studies
- Assessing adequacy of patient population for enrollment into the clinical trial, therapeutic intent, patient considerations (financial impact, visit flexibility, patient responsibility requirements, etc.), and institutional resources (lab, pathology, imaging, pharmacy, radiation therapy, etc.)
- Evaluating the cost effectiveness of opening and managing the specific clinical trial.

For due diligence, individuals are required to sign-off on each section they complete on the RRUF. If it is determined that the study may require time from another department that is

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Figure 3. Process Flowchart for New Review of Pharmaceutical Group Studies

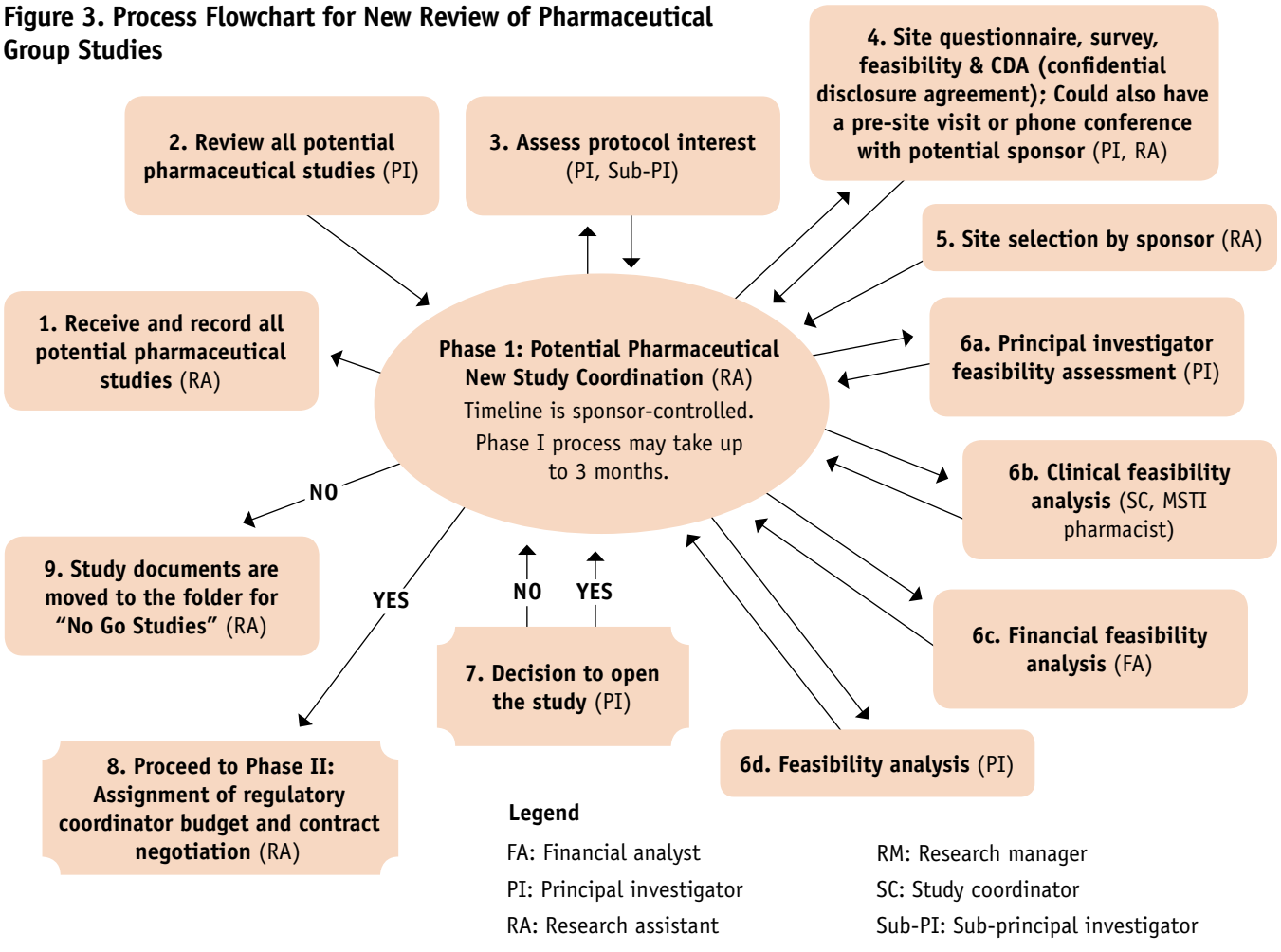

Figure 4. Cooperative Tracking Worksheet

Item or Action	RA Received from & Date	RA Sent to	RA Date Sent	Date Due	Date Completed	Status	Notes
New cooperative study identified							
RA sets up folders							
PI feasibility							
Clinical feasibility							
Financial feasibility							
Pharmacy feasibility							
Sub-PI feedback							
Signed research resource utilization form (RRUF)							
Decision to open study							
Regulatory team alerted to begin study							
RA begins to upload COIs (conflict of interests) into IMedRIS							
Regulatory submitted draft in IMedRIS							
IMedRIS notification study is presented to IRB							

Figure 5. Pharmaceutical Tracking Worksheet

Item or Action	RA Received from & Date	RA Sent to	RA Date Sent	Date Due	Date Completed	Status	Notes
Study information received							
RA sets up folders							
Site questionnaire							
Pre-site visit							
Phone conference							
Confidential disclosure agreement (time received to approved CDA)							
Signed CDA							
Site selection							
PI feasibility							
Clinical feasibility							
Financial feasibility							
Pharmacy feasibility							
Sub-PI feedback							
Signed research resource utilization form (RRUF)							
Decline study							
Regulatory team alerted to begin study							
RA begins to upload COIs (conflict of interests) into IMedRIS							
Financial disclosure forms							
Regulatory submitted draft in IMedRIS							
IMedRIS notification study is presented to IRB							

Figure 6. MSTI Research Resource Utilization Form (RRUF)

Study:
Patient: Clinical Research Manager: Study Coordinator: Financial Analyst:

Line of Treatment: ☐ Neo-Adjuvant ☐ Adjuvant ☐ 1st Line ☐ 2nd Line ☐ 3rd Line ☐ Metastatic ☐ Recurrent ☐ Preventative ☐ Other

Investigator Considerations	PI			Coordinator			Coordinator			Financial Analyst		
	Y	N	N/A	Y	N	N/A	Y	N	N/A	Y	N	N/A
Does this study compete with any opened studies? If yes, which study?												
Do we have adequate patient volumes for this study? If yes, how many?												
Please list all treatment drugs that are considered investigational in this study:												
Study Coordinator Considerations	Y	N	N/A	Y	N	N/A	Y	N	N/A			
Does the study provide for flexibility in visit scheduling?												
Are the inclusion and exclusion criteria too restrictive?												
Are patient responsibility requirements too burdensome?												
Do we have experience in the therapeutic area under investigation?												
Do we have adequate staffing for the trial?												
Are the procedures consistent with standards of care?												
If there are sub-studies, are they feasible?												
Are sponsor pathology requirements feasible?												
Are sponsor laboratory requirements feasible?												
Are sponsor imaging requirements feasible?												
Study Coordinator: Special Considerations				Y	N	N/A	Y	N	N/A			
Is any special equipment required? (Steps, EKGs, etc.)												
Special coordination with other departments or services?												
Are investigators able to complete sponsor required credentialing?												
Does the length of the total clinic visit (lab, MD, treatment) meet the current clinic hours of operation?												
Any special (CIC) training involved?												
Do you have previous experience with the sponsor or CRO?												
Pharmacy Considerations	Y	N	N/A	Y	N	N/A	Y	N	N/A	Initials of Pharmacy Personnel		
Are there special requirements from Pharmacy? If yes, please explain.												
Is Pharmacy in agreement with sponsor requirements?												
Special Pharmacy Notes:												
Department Specific Specialized Tests (Completed by designated individual or departmental representative)	**Concern**						Y	N	N/A	Initials of Individual or Dept. Rep. Consulted		
Is radiation therapy in agreement with sponsor requirements?												
Is imaging in agreement with sponsor requirements?												
Is laboratory in agreement with sponsor requirements?												
Financial Analyst Considerations	Y	N	N/A	Y	N	N/A	Y	N	N/A	Y	N	N/A
Does the Medicare coverage analysis support the study being done?												
Is there Federal funding involved with the study? (Pertains to Cooperative Groups) GGA notified (date): / /												
Study Review Team Recommendations to PI to Proceed to Open?				Y	N		Y	N		Y	N	

Which MSTI location(s) are able to participate? ☐ Boise ☐ Meridian ☐ Twin Falls ☐ Nampa ☐ Fruitland
PI Evaluation: ☐ Feasible ☐ Feasible with considerations ☐ Not recommended ☐ Other:

Principal Investigator Sign-off

Principal Investigator Signature: Date: / /

Regulatory Notified Date: / / Anticipated IMedRIS Submission Date: / /

Special Consideration Explanation:	**Special Consideration Resolution:**

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outside their normal scope of function and/or practice, an additional sign-off and marked check-box will be required by a representative from that department acknowledging that they have been consulted about study specific requirements. Once reviewers have completed their due diligence, the document goes back to the PI for a final review and sign-off. After the PI has approved and signed off on the RRUF, the new study review process is complete and the clinical research assistant assigns a regulatory coordinator to prepare for IRB review.

The Role of the Clinical Research Assistant in the New Process

During these process improvements, our focus group realized the necessity of designating a research staff position to: 1) serve as a point of contact for sponsors and new study information, 2) conduct the new study review flow process with consistency and continuity, 3) act as gatekeeper to maintaining the new process, and 4) be empowered with the authority to hold staff accountable. The focus group unanimously agreed the staff position best suited for these responsibilities was the newly-added clinical research assistant position. Accordingly, the responsibilities identified above were incorporated into the existing job description.

This "customized" research assistant position was instrumental in assembling adult oncology clinical trials and disseminating the information to the review team. Once the new study review team commits to a feasibility review of a potential new study, the research assistant orchestrates the communication between the sponsor, principal investigator, and various members of the research staff. The research assistant then gathers essential documents and steers the new clinical trial through the review process. The position requires very strong organizational and computer skills. This skill-set allows this individual to keep track of multiple clinical trials in a variety of phases of the review process. The position requires excellent communication skills and the ability to "flex" communication styles to best fit the individual needing the information.

Improved Efficiency & Quality

The well-defined and consistent study review process has lived up to the focus group's hopes of improving the quality and efficiency of new study review, supporting research staff accountability to the process, and improving the number of new studies for review. Further, the new review process demonstrates cost effectiveness for the institution by scrutinizing new studies through a rigorous review. This review begins with assessing the potential MSTI patient population for study enrollment. The MSTI tumor registry department assists us in this area by providing cancer diagnoses data. As required by our new study review process, we now complete a financial feasibility assessment using a Medicare coverage analysis. The financial review scrutinizes which costs are paid by a sponsor versus what is billable to insurance or the patient. In turn, this process helps the MSTI research department better serve its patients by offering research studies at minimal financial hardship to patients.

Key Challenges, Successes, & Lessons

Study sponsors may have their own ideas and/or expectations for review and IRB preparation, and their ideas and expectations may not align with our new process. Our clinical research assistant has been very successful in communicating to the sponsor the importance of working with our process, and why it is important for them to do so. Our department has found when we stray from this new study review and flow process, we lose our focus and efficiency. The new process is an efficient use of our study review team's time and efforts.

The overall project goal identified at the outset was to evaluate possible MSTI research department barriers to efficient IRB review; our focus group achieved this goal. Internal evaluation helped the focus group identify inefficiencies and develop a new study review process that has had a positive impact on the MSTI adult research program.

In November 2011, MSTI adult research implemented the practice of metrics. Metrics collection and reporting provide an objective tool for evaluating inter-departmental work practices and process improvements. Metrics are collected for research coordinator clinical practices, regulatory practices, and research financials. Data are presented and reviewed quarterly to the research department staff, MSTI research director, and MSTI director of clinical support services during a department meeting. The data presented facilitate questions from and discussion within the group. If needed, further strategies are identified for minimizing barriers to successful outcomes. OI

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