

Modeling Professionalism and Interpersonal Skills as a Clinical Research Professional

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Session Objectives:

- Describe and apply the principles and practices of modeling professionalism and mentorship in clinical research
- Identify ethical and professional conflicts associated with conduct of clinical studies and implement procedures for their prevention or management
- Identify and apply the professional guidelines and code of ethics that apply to the conduct of clinical research.



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The Power of Professionalism



What is Professionalism

- Treating others with respect, valuing people's time, keeping commitments and acting with integrity

Why It Matters

- Builds trust and respect
- Enhances personal growth and career development
- Contributes to a positive work experience for everyone
- Supports reputation management and effective communication

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Professionalism in Action



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What does professionalism mean to you? Use one word.

(Responses are anonymous; you can submit multiple responses)

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The Legacy of Professionalism

- People remember how you made them feel
- Consistency in professionalism builds a lasting reputation
- Enhances individual growth, teamwork, and collaboration
- Promotes participant safety and experience

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From Professionalism to Leadership Impact

Professionalism is more than behavior—it's the foundation of leadership.

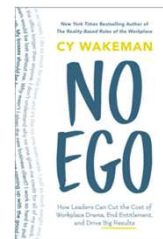


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Leading at Any Level

HOW YOU SHOW UP EACH DAY SAYS MORE ABOUT YOUR LEADERSHIP
THAN ANY JOB TITLE EVER COULD.



Inspired by Cy Wakeman's
Reality-Based Leadership

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Why Leadership Matters at Any Level

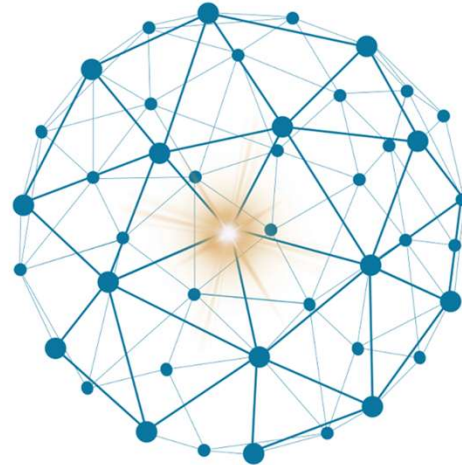
Why It Matters

- Leadership is a daily choice, not a job description
- You influence others through your actions, not your position
- Organizations thrive when everyone leads

"Your value is not in your opinion, it's in your ability to deliver results without drama."

-CY

Wakeman, No Ego



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Leadership is a Choice, Not a Title

These are
leadership behaviors—
not job requirements.

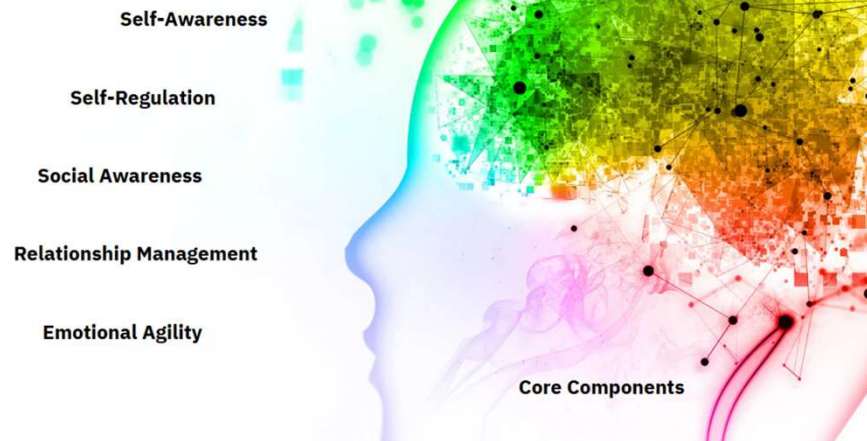
Wakeman:
"Stop judging, start helping."



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Emotional Intelligence (EI) Supports Leadership at Any Level



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It is about: How we Show Up, Connect, & Respond

Managing Conflict
Resistance & Change

Supporting well-being
of ourselves and others

Enhancing motivation
Creativity
Decision Making

Delivering feedback effectively

Navigating difficult conversations
Emotional dynamics



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Leading with EI Means Recognizing/Managing Our Emotions and Understanding Others



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Your Leadership Ripple Effect

- Your behavior sets the tone for others
- Leadership creates momentum—
 - a. Others follow your lead
- You're already leading—
 - a. The question is how

WAKEMAN "GREAT LEADERS DON'T INSPIRE FOLLOWERS.
THEY INSPIRE OTHER LEADERS."



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Call to Action



Ask Yourself!

What kind of leader do I want to be?

How can I lead today, right where I am?

WAKEMAN "THE FUTURE OF WORK IS PERSONAL ACCOUNTABILITY."

Leadership starts with you-no title required.

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Professionalism in Action

7.1 Describe and apply the principles and practices of leadership, management and mentorship in clinical research

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Demonstrating Professionalism



- Initiative and proactive thinking



- Emotional intelligence and empathy



- Being a mentor and offering support



- Maintaining vision and perspective

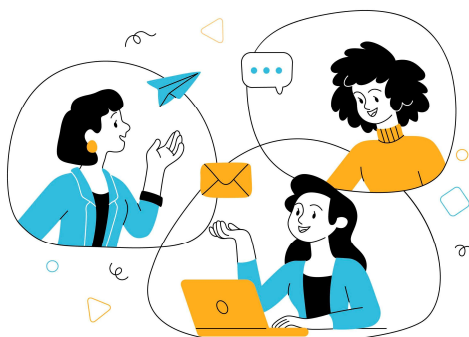


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Communication

...the foundation of professionalism



- The way you talk, type, and behave
- Know how to address different audiences
- Your communication affects others

https://www.freepik.com/free-vector/hand-drawn-business-communication-concept_20286028.htm>image by pikisuperstar on Freepik

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Leadership

*Leadership is an **action**, not a position...*

1) Lead from where you are

- Speak up!
- Take initiative
- Focus on problem-solving

2) Effectively communicate!

- All types – written, oral, documentation

3) Respect the existing leadership structure

- Know where to go to address challenges
- Know what is appropriate and what is not

4) Lead by example

- Understand how your behavior affects your team
- Demonstrate basic professionalism

"If your actions inspire others to dream more, learn more, do more, and become more, you are a leader."

- John Quincy Adams


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Please share an example of when you or a colleague demonstrated leadership, regardless of your role or title?

(Responses are anonymous; you can submit multiple responses.)

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Management

*...of your **professional** life!*

Basic Professionalism	Demonstrating Initiative	Time Management
<ul style="list-style-type: none">• Attitude• Personal presentation• Work ethic• Follow processes	<ul style="list-style-type: none">• Prove your value• Step up• Ignore imposter syndrome!• Further your knowledge	<ul style="list-style-type: none">• Enhances work quality• Prioritization and organization• Demonstrates respect

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Mentorship

Find a mentor – it doesn't have to be a formal partnership

Don't be afraid to ask questions!



Learn by observing

Be a mentor – use YOUR leadership + professional skills to help the next generation

https://www.freepik.com/free-vector/help-support-climbing-employee-from-mentor-leader-hand-team-corporate-people-walking-up-ladder-together-flat-vector-illustration-success-career-growth-leadership-teamwork-concept_22343850.htm>Image by pch.vector on Freepik

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Professionalism and the Research Professional (RP)

- Back to the basic definition of professionalism:
“Competence or skill expected of a professional”
- Skills of the role (the things RPs **do**):
 - Consent subjects
 - Take vital signs/draw blood
 - Administering the research intervention
 - IRB submissions
 - Developing/carrying out recruitment plans
 - Recording data; Documenting the study
- Skills also include (the way we should **be**):
 - Emotional intelligence
 - Meeting deadlines
 - Being honest/trustworthy
 - Respect for others
 - Good follow-through
 - Say what you do; Do what you say
 - Practice integrity
 - Accountability



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Professionalism and the RP

- Five (5) Clusters of professionalism in healthcare [substituting in “research”] setting:
 - Adherence to ethical practice principles
 - Effective interactions with [research participants] and with people important to [research participants]
 - Effective interactions with other people working within [AMCs where the research is being carried out and the greater research enterprise]
 - Reliability
 - Commitment to autonomous maintenance and continuous improvement of competence



From: Professionalism: What is it? Roger Collier
CMAJ Jul 2012; 184 (10) 1129-1130; DOI: 10.1503/cmaj.109-4211

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Professionalism and the RP: What's in it for you?

- Satisfaction of doing a job well
- Team asset: You become someone that others can count on
- Gaining respect of colleagues (builds trust and credibility)
- Feeling great about work!
- Booster of productivity and job satisfaction
- Being a model of excellence
- Future opportunities within current role
- Future promotion



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Professionalism and the RP: What's in it for others?

For our research participants... ensuring:

- Quality of the conduct of your research studies
- Safety, rights, and welfare of research participants in the studies you work on

“Professional integrity is vital in forging an ethically sound relationship between investigators and patient volunteers, a relationship that differs in important ways from the patient-physician relationship in standard clinical practice.”

*Miller, Rosenstein & DeRenzo,
Professional Integrity in Clinical Research
JAMA 1998 Oct 28;280(16):1449-54*



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The RP Role, Professionalism, Leadership, and Communications



- Conduct of a clinical trial → Managing a large, complex project
- Organizational structure (people) and operational structure (processes)
- Diverse team: different roles, different departments, different institutions, different parts of country or world, different perspectives
- Multiple stakeholders
 - At the site: PI, co-I, staff, local IRB, lab, pharmacy, imaging
 - Beyond the site: other sites, staff, DSMB, steering committee, reviewing IRB, lead site
- Even a smaller single site trial involves much complexity and uncertainty

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The RP Role, Professionalism, Leadership, and Communications



- RP has the role of “The Connector” – within teams and between stakeholders, and serves as a project leader
- Successful projects: require “skill/competency in the doing” but ALSO high dependence on “people skills” (aka “soft skills”) related to Emotional Intelligence
- Role of project leader
 - Team engagement
 - Managing conflicts
 - Managing resistance
 - Ensuring effective communication
- How? Motivation, Encouragement, Mentoring, Active listening, Respectful communication, Constructive feedback, Positivity, Kindness (to name a few! 😊)

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What barriers work against our ability to put “**professionalism-promoting behaviors**” in place?

- Fast-paced environment
- Many stakeholders
- Lack of time
- Many things unexpected; putting out fires
- Not knowing how to handle a given situation

What can we do about it?

- Self-reflection
- Take a beat before you act
- Be intentional
- Always consider others’ perspectives
- Play the long game
- Employ active listening
- Realistic planning

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Professionalism in *Action!*



- Let’s try to solve some issues using concepts from today’s workshop.
- How can we use elements of professionalism in the context of our work conducting research studies?
- We will use Slido to work on cases!

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Scenarios on RP Professionalism

- It's one thing to hear about all the various elements of Professionalism, but how can we really put these in place in the "real world?"
- The cases can help to reinforce how important these elements of professionalism are and how they can be practiced and used to ensure a cohesive team and good results!
- Each case will be presented briefly, with prompts.
- Then we will use Slido to respond (open text answers, ranking, rating, etc.)
 - All Slido answers are anonymous!



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Scenario 1: Colleague Vacation

You are covering coordinator for your co-worker as they are about to take a two-week vacation. When demonstrating professionalism, consider what should be put in place by you and your co-worker.

The coordinator(s)

- Ensured that the covering coordinator is:
 - Listed as Key Personnel on the study
 - Appropriately trained for covering coordinator role and the training has been documented on the training log
- Ensured DOA is complete (including covering coordinator and role)
- Reduced scheduling subject visits, if possible
- Signed out to covering coordinator/team
- Emailed the full study team/key stake holders regarding absence and coverage plan

Prompt:

How would you rate what the team did to prepare for coverage while they were away on vacation?

Use Slido anonymous rating response (next slide)



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The vacationing coordinator(s) ensured that covering coordinator is is prepped (see Zoom Chat for the list).

How would you rate what the team did to prepare for coverage while they were away on vacation?

(Responses are anonymous.)

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If not "top notch" what could the team have done to better prepare while the co-worker was away on vacation?

(Responses are anonymous and you can provide multiple responses.)

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Scenario 2: Challenges with the IRB submission

- IRB approved protocol and consent contain provisions for use of data and materials for future research
- Protocol amendment is submitted to include use of data and specimens with a new aim
- IRB Analyst requests that participants in the original study be reconsented for data and specimens to be used in the new research aim
- Reconsent should not be required (per above bullet 1)

Prompt:

How do you best handle this situation? What elements of professionalism would you implement?

Use Slido anonymous open response (next slide)



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Scenario 2: Challenges with the IRB submission.




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How do you best handle this situation? What elements of professionalism would you implement?

(Responses are anonymous; you can submit multiple responses.)

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Scenario 3: Picking up an ongoing study

You are a coordinator being asked to take on a study that has been ongoing for the past three years. What would your approach be to manage this type of transition?

Assumptions for this scenario:

- The current coordinator is available to you for two weeks, will orient you to the study materials and participants
- There are six (6) participants still on study, ten (10) total
- There have been monitoring visits each year
 - Year 3 monitoring visit is scheduled next month

Prompt:

How do you best approach this scenario?
What actions should be taken?

Use Slido anonymous open response (next slide)



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Scenario 3: Picking up an ongoing study

You are a coordinator being asked to take on a study that has been ongoing for the past three years.



What would your approach be to manage this type of transition?

What are a few things you need to consider as you move forward?

(Responses are anonymous; you are able to submit multiple options.)

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Scenario 4: Ineligible enrollment

The Principal Investigator is trying to enroll an ineligible patient/participant on their Study. The RP has several choices for how to proceed.

- Report the PI to the IRB or Compliance Office
- Double check the eligibility criteria to confirm the person is ineligible and talk to the PI
- Talk to a colleague, Research Leadership or IRB – solicit their assistance
- Email the Medical Monitor for confirmation of eligibility/ineligibility
- Do what the PI tells you to do, they are ultimately responsible anyway
- Complain to your peer coordinators what the PI is trying to do

Prompt:

Use Slido "Ranking" to rank the choices (next slide).



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The Principal Investigator is trying to enroll an ineligible patient/participant on their Study.

Rank the following "next step" choices for this scenario.

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Scenario 4 (cont'd.): The Principal Investigator is Trying to Enroll an Ineligible Patient/Participant on their Study

What is key in how you handle this situation?

And how would you “finesse” your approach?

Use Slido anonymous open response (next slide) and/or unmute and share your thoughts

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What is key in how you handle this situation?

And how would you "finesse" your approach?

(Responses are anonymous; you can submit multiple responses)

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Scenario 5: Response to Monitor's Report

- A sponsor monitor had a monitoring visit and provided a report to the coordinator and PI. The report contained multiple findings of deviations and concerns. The coordinator read the report briefly and immediately sent an email to the monitor and PI about perceived inaccuracies with the report and the monitoring.

Prompt:

What do you think is at play here? What approach would you suggest the coordinator take instead?

Use Slido Open response (next slide).

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A sponsor monitor had a monitoring visit and provided a report to the coordinator and PI. The report contained multiple findings of deviations and concerns. The coordinator read the report briefly and immediately sent an email to the monitor and PI about perceived inaccuracies with the report and the monitoring.

What do you think is at play here? What approach would you suggest the coordinator take instead?

(Responses are anonymous; you can submit multiple responses.)

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Ending with a few relevant and inspiring quotes!

"Professional is not a label you give yourself – it's a description you hope others will apply to you."
- David Maister

"How you do one thing is how you do everything!"
- MT's yoga teacher ☺

"Professionalism is knowing how to do it, when to do it, and doing it."
- Frank Tyger

"Being a professional means doing your job on the days you don't want to do it."
- David Halberstam



"Success doesn't come from what you do occasionally; it comes from what you do consistently."
- Marie Forleo

"Professionalism: it's not the job you do but how you do the job."
- Anonymous

"The professional does not wait for inspiration; they act in anticipation of it."
- Steve Pressfield