

Building a Research Enterprise
 Presenter: E. Wesley Ely, MD, MPH

Slide #	Section
3	<p><u>Research Success</u></p> <ul style="list-style-type: none"> • Time • Cross talk • “use what we already know” • 2020 scientists must be 1990 scientists first, then become excellent 2030 scientists
4	<p><u>Considering Scope of Research Along Different Axes</u></p> <ul style="list-style-type: none"> • Axis based on types of clinical and translational research • Axis based on specific clinical disciplines • Axis based on methodological foci (slide 31: design, measurement, analysis)
7	<p><u>T0 to T4 Research</u></p> <ul style="list-style-type: none"> • Infographic depicting research flow
8	<p><u>Careers in Translational Clinical Research</u></p> <ul style="list-style-type: none"> • 11% of U.S. medical school graduates plan careers significantly devoted to research (n=1600) • Clinical researchers are considered by some to be an endangered species • “Serious doubts about the viability of careers based on patient-oriented research” • Without such research, we can’t close the loop on discovery and advancement
14	<p><u>Clinical Research...the path to success</u></p> <ul style="list-style-type: none"> • Protected time (details slide 15) • Tool box formation (details slide 16) • The mentor (details slide 17) • Developing the ??s (details slide 18) • Building the team (details slide 20, 21, 22, 25) • IRB issues • Consent • Study Design • Funding • Other issues
27	<p><u>Major Concepts</u></p> <ul style="list-style-type: none"> • The guiding principle MUST BE the patient • That means it is not career, money, promotion, getting a specific grant, etc. • Driven by passion • Decide in what area you can be THE BEST • Determine how you’d feel if you failed; why would that matter to you?
32	<p><u>Another Axis for Types of clinical research</u></p> <ul style="list-style-type: none"> • Quantitative <ul style="list-style-type: none"> ○ Establish incidence, prevalence, determine treatment effectiveness, measure risk • Qualitative <ul style="list-style-type: none"> ○ Describe phenomenon, understand thinking or behavior, “why” treatments do or don’t work ○ Rigorously done qualitative research provides insights that quantitative research can not ○ Poorly done, qualitative research is as useless as poorly done quantitative research • Quality improvement <ul style="list-style-type: none"> ○ When does it become research?
33	<p><u>Conducting and Analyzing Cohort Studies</u></p> <ul style="list-style-type: none"> • Intensely interdisciplinary and technical • Many things can never be randomized, such as “delirium group” vs. “no delirium group”

	<ul style="list-style-type: none"> • Attributing cause and effect is limited yet robust predictor methodology is available • Key methodological issues must be considered such as time-immortal bias
36	<p><u>Epidemiology</u></p> <ul style="list-style-type: none"> • Changing delirium rates • Subtypes of delirium (septic, pharm, etc.) • Relationship with LTCI • Dementia type (amnesic vs. non-amnesic, vascular vs. AD)
37	<p><u>Tools</u></p> <ul style="list-style-type: none"> • Clinical instruments (ICDSC and CAM-ICU, severity scales) • EEG, fronto-temporal • Neuroimaging (MRI, fMRI, PET) • Biomarkers
38	<p><u>Understanding/Predicting Outcomes (examples)</u></p> <ul style="list-style-type: none"> • Clinical prediction rules for both delirium and LTCI • Caregiver burden • Inter-relationships with other psychiatric illnesses such as depression, PTSD, dementia
39/40	<p><u>Planning an RCT</u></p> <ul style="list-style-type: none"> • Ensure that similar studies aren't ongoing or haven't been completed • If possible, undertake RCT as part of broader research program • Simple rather than complex designs (2 parallel arms vs. factorial) • "Minimal data" collection strategies are often regretted • Primary outcome- patient-oriented rather than surrogates or biological markers • Answer questions that clinicians consider • Important • Select an achievable goal (sample size) • Involve experienced trialists, biostatisticians, and multiple pertinent disciplines
41	<p><u>Clinical Trials</u></p> <ul style="list-style-type: none"> • Pharmacological interventions (sedation and analgesia, antipsychotics, anticholinergic modulation) • Sleep optimization and modification • Multi-component interventions • Physical/cognitive rehabilitation
42	<p><u>Example RCT Organizational Chart</u></p> <ul style="list-style-type: none"> • Infographic flow chart
45	<p><u>As researchers...</u></p> <ul style="list-style-type: none"> • We are not satisfied with status quo • We ask questions and find answers • Driven by the desire to improve the lives of both our patients and those whom we'll never meet • So this is YOUR study, YOUR time, and YOUR vocation
47	<p><u>Miscellaneous issues critical to ensure success</u></p> <ul style="list-style-type: none"> • Database and statistical analysis • Publish (write, write, and write) • Tips for discussion section: Horton R, (editor of Lancet). JAMA 2002;287:2775-2778 • Authorship • Formulate next questions • Modify team for next study
50	<p><u>Institutional Review Board (IRB)</u></p> <ul style="list-style-type: none"> • Know your IRB personnel • Rules are now in evolution and somewhat of an improving target

	<ul style="list-style-type: none"> • HIPPA (health insurance portability and accountability act of 1996), as you know, changed everything! • Never assume you “don’t need an IRB approval”
52	<p><u>Informed Consent in Critically Ill</u></p> <ul style="list-style-type: none"> • Incompetent patient and surrogate consent • Waived consent • Participation of the family (they’ll be under stress, obtaining a 2nd consent form) • Implied (presumed) consent in Emergency Setting (vasopressin and CPR) • Reconsenting the patient • Is consent required for quality improvement projects?
53	<p><u>Funding pros and cons</u></p> <ul style="list-style-type: none"> • NIH (K awards [K23 and K08], loan repayment, R01) • VA • Industry • Foundation • Talk to the institute or granting agency • Grant writing is a “team effort”
54	<p><u>Components of a Grant- selling your idea</u></p> <ul style="list-style-type: none"> • We have the following specific aims • The reason we think this is important is because... • In response to this issue, we, the investigators have already conducted the following germane areas of work • Our plan has the following components • Pros/cons/caveats/timeline