

NIEHS Translational Research Framework Ring/Node Criteria

Project Title/Description
Reviewer Name

Total Number of Fundamental Question Milestones	
Total Number of Application and Synthesis Milestones	
Total Number of Implementation and Adjustment Milestones	
Total Number of Practice Milestones	
Total Number of Impact Milestones	
Grand Total	

Fundamental (Biological) Questions – Mark if Applicable		Total # of FQs
<i>Note: You may need to make multiple copies of the Fundamental Questions Coding Page</i>		
What kind of question is the research trying to answer?		
Identification	<input type="checkbox"/> Is the research seeking to identify a new biological element (such as a gene, biomarker, etc.)? <input type="checkbox"/> Does the research have a targeted endpoint? <input type="checkbox"/> Does this research incorporate genome wide association studies (GWAS)?	
Observation	<input type="checkbox"/> Is the research seeking to observe a phenomenon? <input type="checkbox"/> Is the research drawing inferences from a sample to a population? <input type="checkbox"/> Is the research organism free from any interference, manipulation or control of the researcher? <input type="checkbox"/> Is this a genome wide association study, with an agnostic question? <input type="checkbox"/> Does the research include assessment of biometric data for measurement purposes (such as measuring breast density?) <input type="checkbox"/> Does the study use a large data set to explore associations? <input type="checkbox"/> Is the research attempting to characterize or measure by source (home, office, car, etc.)	
Understanding	<input type="checkbox"/> Is the study manipulating or perturbing an organism or component of an organism to clarify a process or effect? <input type="checkbox"/> Is a tool, method, technique, (etc.) being developed to conduct or improve a research process or activity? <input type="checkbox"/> Is the objective to calibrate or advance measurement technology? <input type="checkbox"/> Is an intervention being tested?	
What is the organism being studied? (human, mouse, rat, plant, bacteria, yeast, worm, fish, pig, other model organisms, etc.)		

What is the experimental setting?	
<input type="checkbox"/> Group & Population	<input type="checkbox"/> Does the study use a large data set to explore associations? <input type="checkbox"/> Is the research being conducted in a community? <input type="checkbox"/> Is the research being conducted with more than just a small sample of people? <input type="checkbox"/> Does the research study the incidence or prevalence of an exposure or a disease in a population? <input type="checkbox"/> Is the research conducted with a cohort study? <input type="checkbox"/> Does the research require human subjects' approval? <input type="checkbox"/> Does the research include health outcome measures such as caffeine breath tests, heart rate, survey of smoking, nutrition, behavioral, mood or mental health assessments, or other behaviors, or socio/economic factors such as education, race? <input type="checkbox"/> Is a bio specimen being analyzed to assess exposures or other characteristics? <input type="checkbox"/> Is the research attempting to characterize or measure by source (home, office, car)?
<input type="checkbox"/> In vivo	<input type="checkbox"/> Is the research being conducted on a whole, living organism or cell? <input type="checkbox"/> Does the research involve clinical studies? <input type="checkbox"/> Was human subjects' approval obtained? <input type="checkbox"/> Is the subject purposely being exposed or challenged to understand the effect? (chamber studies, functional MRIs, etc.) <input type="checkbox"/> Studies using MRIs (both static and function MRIs – but if the MRI is one aim of a larger project that includes other health outcomes, it would be coded it as population.)
Fundamental (Biological) Questions (Continued) – Mark if Applicable	
<input type="checkbox"/> Ex vivo	<input type="checkbox"/> Does the study remove the biological component from the organism, but keep it alive by placing it in an environment similar to its natural environment? <i>Questions still under consideration...</i> <input type="checkbox"/> <i>Do we need a question to tease out difference related to preserving the ability to return something to the original organism?</i> <input type="checkbox"/> <i>Should we add something about transplanting back into the original organism?</i> <input type="checkbox"/> <i>Do we need a question to help us consider how far removed the biological component is from when it was isolated from the organism – in other words, if you remove cells from a mouse, and culture those cells and keep culturing them – it starts to become a different cell type ... do we want to include a question to capture this kind of thing? Is there a timeframe that the “fundamental question work” (observation or manipulation) has to happen before it is considered in vitro?</i> <input type="checkbox"/> <i>What other questions can we ask to distinguish between ex vivo and in vitro – and does it really matter – are the tools, training, people, equipment, methods different enough between in vitro and ex vivo?</i>
<input type="checkbox"/> In vitro	<input type="checkbox"/> Is the research using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells, or biological molecules? <input type="checkbox"/> Is the component/biospecimen fixed in a culture, slide or other medium designed to preserve it rather than keep it “alive”? <input type="checkbox"/> Does the research involve “omics” techniques? <input type="checkbox"/> If human components, were the cells, biospecimens purchased (such as publicly available cell line or biobanked materials?) <input type="checkbox"/> Does the research use biospecimens to conduct phenotyping or genotyping?
<input type="checkbox"/> In situ	<input type="checkbox"/> Is the research being conducted in the same place as the biological organism? (such as in a river, lake?)
<input type="checkbox"/> In silico	<input type="checkbox"/> Is the research conducted on a computer, using simulated, modeling techniques?

Application and Synthesis – Mark if Applicable	Total # Checked
<input type="checkbox"/> Is the research replicating an experiment in a structured and predictable setting to better understand a process or effect? <input type="checkbox"/> Does the research involve pilot testing an intervention? <input type="checkbox"/> Does the research involve testing a new method, approach, device, or tool (software, product – define more) in a structured, controlled setting? <input type="checkbox"/> Does the research involve testing a new diagnostic approach in a controlled setting? <input type="checkbox"/> Does the research attempt to synthesize or integrate evidence from previous research to inform future research, risk assessment and other decision making? <input type="checkbox"/> Does the research replicate a previously conducted study for the primary purpose of demonstrating reproducibility? <input type="checkbox"/> Is the research a Phase 1 clinical trial?	
Implementation and Adjustment - Mark if Applicable	Total # Checked
<input type="checkbox"/> Is the research assessing implementation of an idea, intervention, approach, or methodology in a real-world setting? <input type="checkbox"/> Does the research attempt to make adjustments to an idea, intervention, approach, or methodology to account for different settings and populations? <input type="checkbox"/> Is the research validating or testing the efficacy or optimal use of a biomarker, assay, or screen? <input type="checkbox"/> Does the research include a Phase II or Phase III clinical trial? <input type="checkbox"/> Does the research attempt to assess the efficacy or optimal use of a tool, device, or methodology in a real-world setting? <input type="checkbox"/> Does the research attempt to make test dose adjustments population or other characteristics?	
Practice - Mark if Applicable	Total # Checked
<input type="checkbox"/> Has the idea moved from research into common practice? <input type="checkbox"/> Has the research been used to inform diagnostic, treatment or other clinical guidelines? <input type="checkbox"/> Have the research products (tools, methodologies, computational programs, sensors, etc.) been used in standard research practice? <input type="checkbox"/> Is the research now routinely used to treat exposures, illness and disease or reduce environmental exposures? <input type="checkbox"/> Did the research result in a standard public health practice? <input type="checkbox"/> Did the research result in standard risk management protocols? <input type="checkbox"/> Did the research inform individual behaviors at the population level? <input type="checkbox"/> Was the research used to inform organizational, local, state, regional or national policy? <input type="checkbox"/> Does the research examine problems with, mechanisms underlying, potential interventions, impact, or real world outcomes (e.g., level of disease prevention, reduced medical costs) of population level practices/interventions?	
<p>Questions below are from CTSA Checklist and are generally specific to health care delivery and practice.</p>	
<input type="checkbox"/> Does the research study inconsistency or variation in the application of a diagnosis or intervention? <input type="checkbox"/> Does the research compare the effectiveness of existing health care interventions to determine which work best for which patients and which pose the greatest benefits and harms? <input type="checkbox"/> Does the research involve interventions in the community with input from community members? <input type="checkbox"/> Does the research determine mechanisms underlying effective health care delivery in practice or community settings? <input type="checkbox"/> Does the research identify problems with effective health care delivery in practice or community settings? <input type="checkbox"/> Does the research test an intervention to improve health care delivery in practice or community settings? <input type="checkbox"/> Does the research study factors that affect interventions (cost, convenience, accessibility, patient preferences?) <input type="checkbox"/> Does the research determine reasons why gaps in care exist?	
Impact – Mark if Applicable	Total # Checked
<input type="checkbox"/> Did the research assess the environmental, clinical or public health impact of a practice, guideline or policy? <input type="checkbox"/> Did the research assess a change in environmental exposures after a population change was made? <input type="checkbox"/> Did the research assess a change in behavior after a population level change was made? <input type="checkbox"/> Did the research assess the economic impact of a population level change? <input type="checkbox"/> Did the research assess the clinical outcomes after a change to clinical guidelines or protocols?	