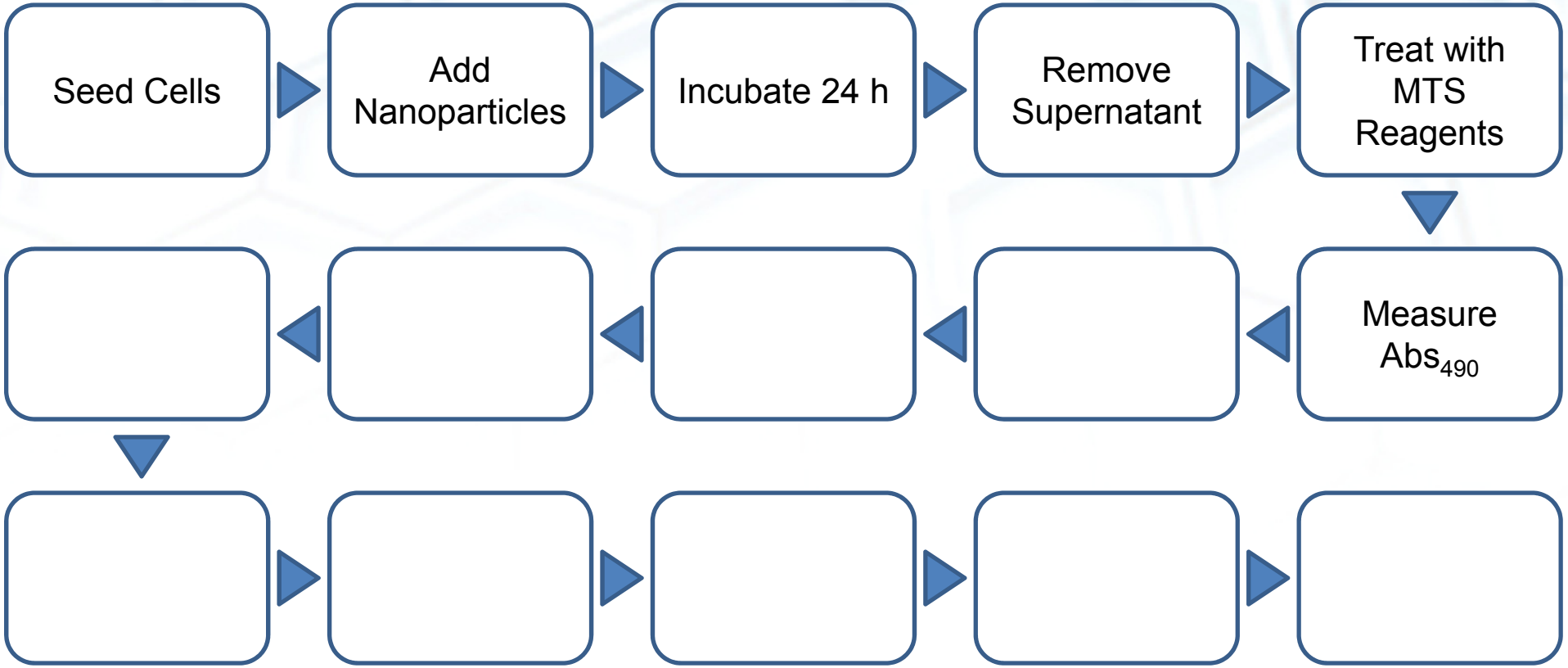
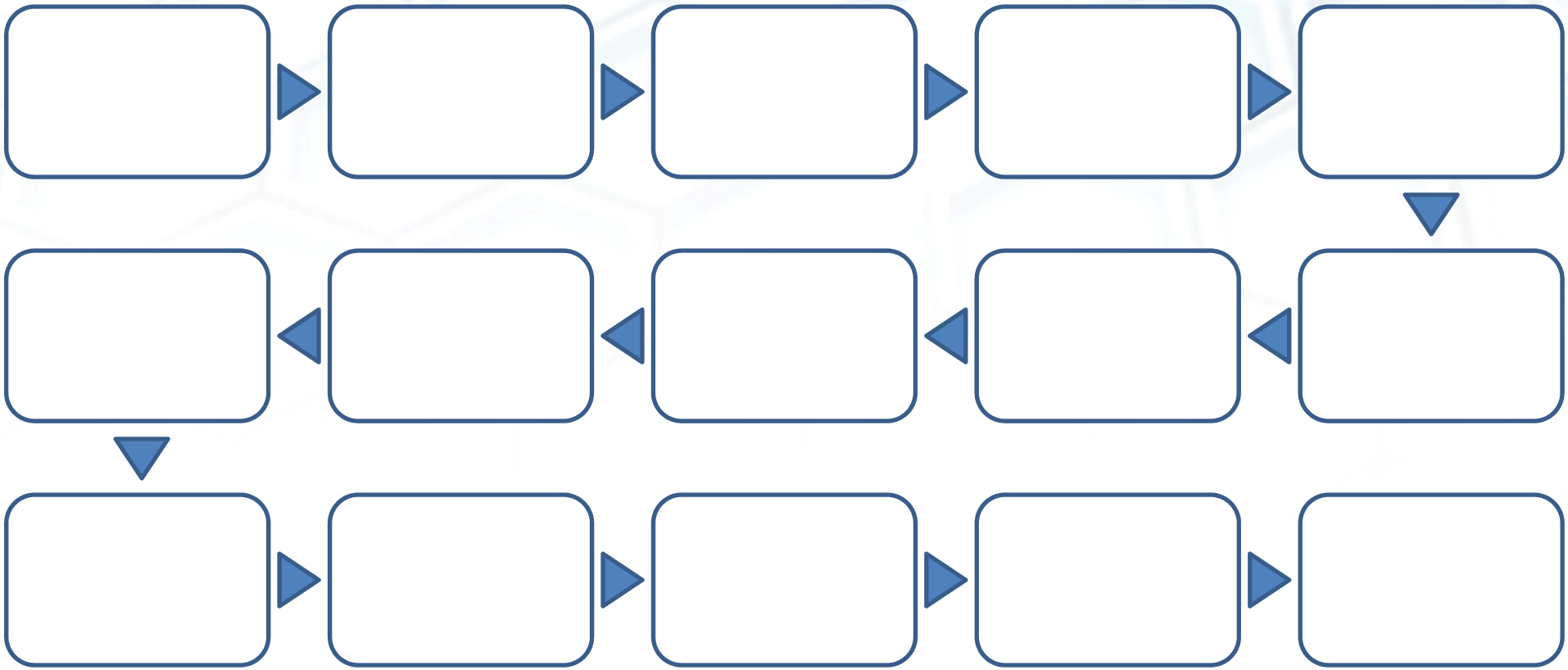
Measurement Process Flow Chart (EXAMPLE: Nanotoxicity Assay)



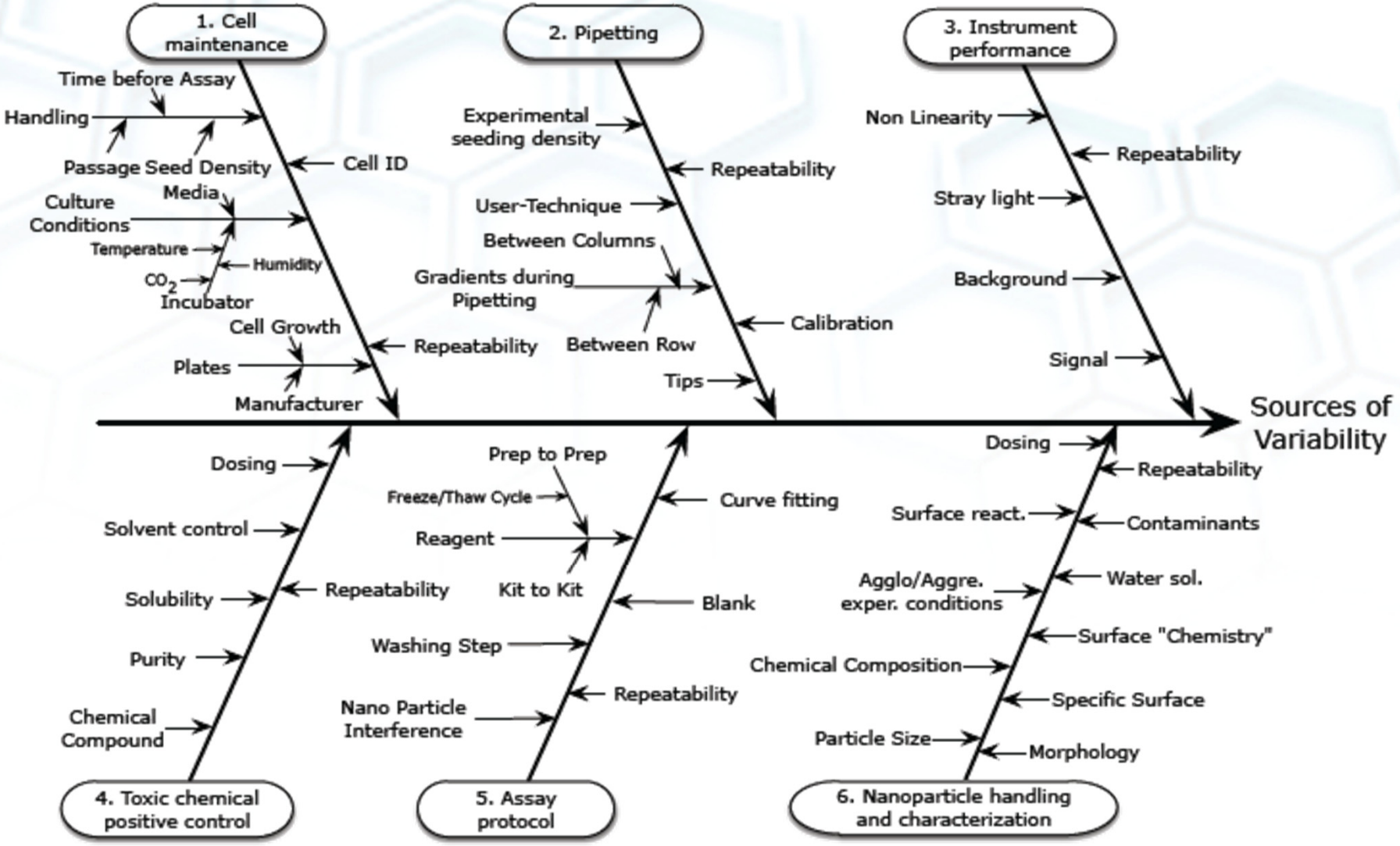
Measurement Process Flow Chart (TEMPLATE)



Measurement Controls (TEMPLATE)

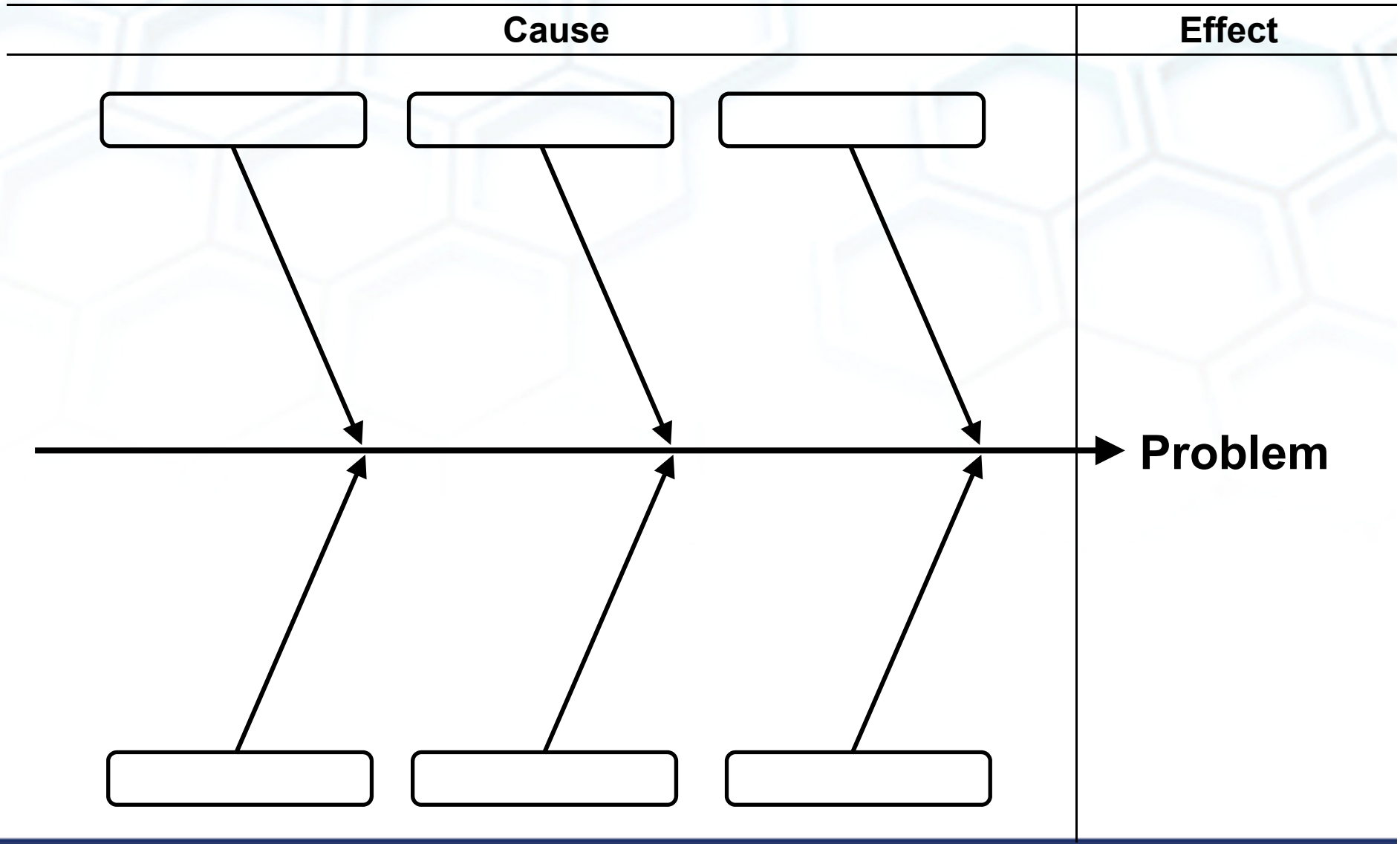
Variables/Factors	Why an Issue?	Control Experiment /Approach	Reference Material?
EXAMPLE: Nanotoxicity assay: Variable: Cell toxicity response	Cell response varies due to many factors (passage, incorrect seeding, variability in medium, contamination, etc.)	Add cadmium sulfate to cells to establish a reproducible “toxic” response in the assay	Cadmium sulfate

Ishikawa Diagram (EXAMPLE: Nanotoxicity Assay)



Rösslein M, Elliott JT, Salit M, Petersen EJ, Hirsch C, Krug HF, Wick P. Use of Cause-and-Effect Analysis to Design a High-Quality Nanocytotoxicology Assay. Chem Res Toxicol. 2015, in press.

Ishikawa Diagram (TEMPLATE)



Reference Materials (TEMPLATE)

1. What reference materials do you employ in your assay. How & why do you use them?

2. What needs do you see for new or better reference materials. How would you use them? Why?

What properties must be specified for the proposed new reference materials?

Inter-Laboratory Studies (TEMPLATE)

1 **What is the goal of the inter-laboratory study? Tech. transfer? Establishing a standard test method?**

2

Participating Labs	
1.	4.
2.	5.
3.	6.
Others?	

4

What process controls should there be?	
1.	4.
2.	5.
3.	6.
Others?	

3

How will the SOP be established?	How will operators be trained?	Parameters that must be tested for sensitivity?	Materials to distribute to all participating labs?	Materials provided by the participating labs?	What level of agreement is adequate? When are we done?