## Q1: Are there GOF studies that may be conducted but should require an additional level of review or oversight? If so, what should the oversight entail? Should the oversight occur at the federal or institutional level or both?

A1:

- We support the NSABB definition for “GOF studies of concern” and agree with general requirement for enhanced review and oversight.

- We support a model similar to USG Policy for Institutional Oversight of DURC.
    - Adapt DURC regulations?
    - Already include high path flu; add SARS, MERS, other pathogens with pandemic potential.
    - Expand IRE scope of review to include GOF experiments with potential to create pathogen with pandemic potential.

**Jill Taylor, Ph.D.**
Director, Wadsworth Center, NYSDOH

# Q2: How well does the NSABB's draft working paper identify the GOF studies of greatest concern?

A2:

- We support the approach of identifying the highest risk studies as those resulting in key triad of phenotypes that create pandemic risk → transmissibility + virulence + immune/therapeutic evasion.

- We caution, however, that GOF studies that produce pathogens with only one or two of these phenotypic attributes may still present significant biosafety risks.
    - Need to be sure that GOF regulations do not leave "gap" in safety oversight.

**Jill Taylor, Ph.D.**
Director, Wadsworth Center, NYSDOH

# Q3: Are there GOF studies that should not be conducted? If so which studies and why?

A3:

- Banning studies “a priori” is not a good policy.
- Each individual GOF study should be subject to a thorough risk/ benefit review at both the institutional and federal level, taking into account the current scientific and public health context.
- A “one-size-fits-all” methodology with respect to policy approaches should be avoided. Several of the potential policy approaches discussed may be required to cover all circumstances.

**Jill Taylor, Ph.D.**
Director, Wadsworth Center, NYSDOH

## Q4: How well would the NSABB's draft principles and criteria permit the review of GOF studies that have raised concerns and inform decision about whether to fund such studies?

A4:

- Build on the existing DURC/Guidelines programs to create an appropriate review process.
- Weakness in guidance principle "iv" .
  - Need a mechanism to ensure investigator and institution have the appropriate "culture of safety and responsibility"
  - Who makes this determination?

# Q5: Are there specific risk mitigation measures that should be required for certain GOF studies to be conducted?

A5:

- What did we learn from Ebola? For some GOF studies, there will be a need to:
  - Elevate containment requirements.
  - Require a “buddy” system.
  - Elevate occupational health requirements.
- Require on-going internal and external step-wise review of progress.
- Involve local and/or state epidemiology and public health officials in the review process.

➡ Need to strengthen “culture of responsibility” at all institutions.