STEP 1: DESCRIBE EXPERIMENT

STEP 2: SPECIFY STATISTICAL MODEL

STEP 3: DEFINE STATISTICAL QUERY
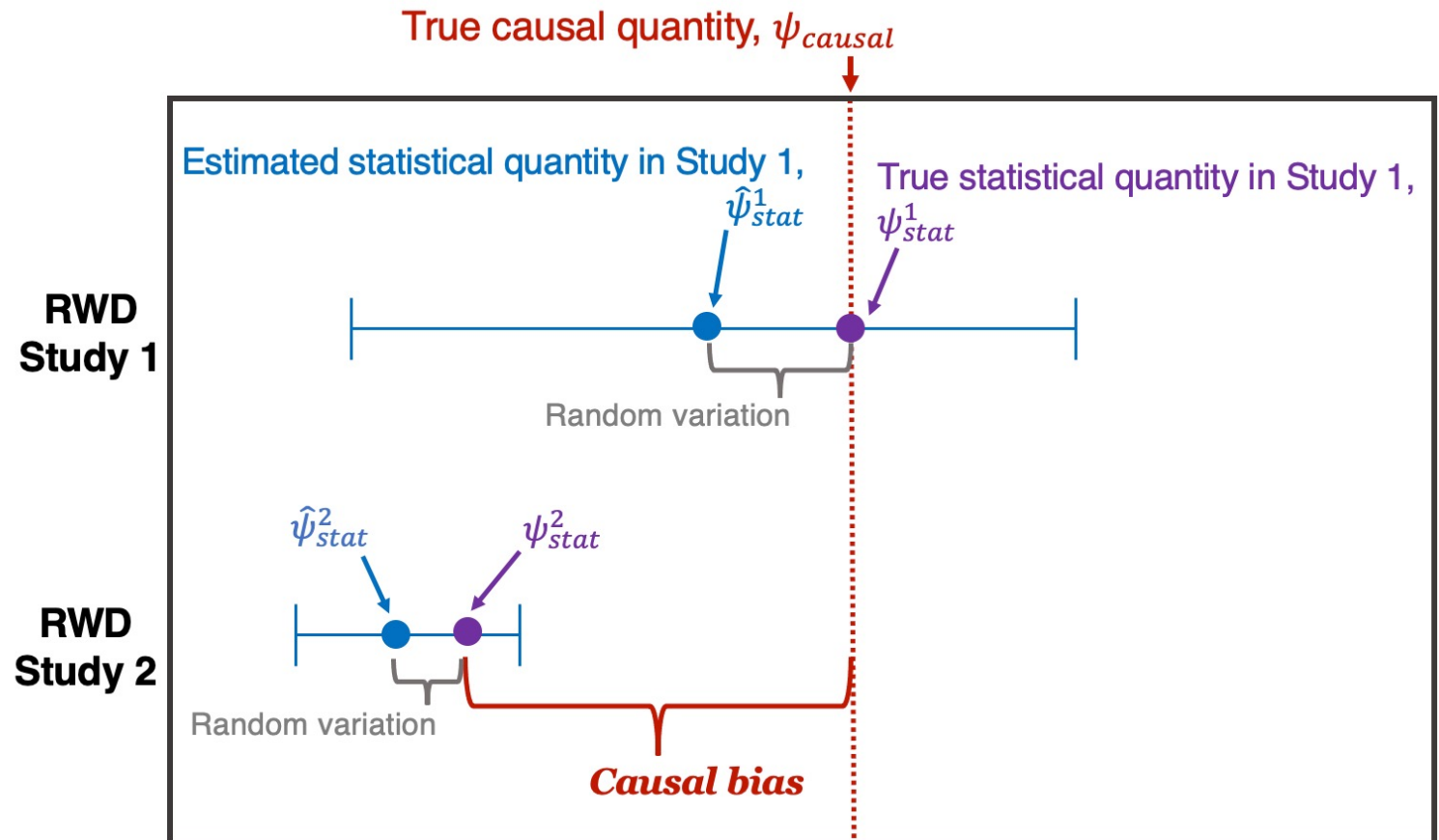
STEP 4: CONSTRUCT ESTIMATOR

STEP 5: OBTAIN INFERENCE

STEP 6: MAKE SUBSTANTIVE CONCLUSION

Investigate causal bias with sensitivity analysis

Causal bias: Gap between estimate and truth due to violations of any of the causal assumptions (e.g., unmeasured confounding)*

True causal quantity, ψ_{causal}

Estimated statistical quantity in Study 1, $\hat{\psi}_{stat}^1$

True statistical quantity in Study 1, ψ_{stat}^1

RWD Study 1

Random variation

$\hat{\psi}_{stat}^2$ ψ_{stat}^2

RWD Study 2

Random variation

Causal bias

Sensitivity Analysis: Model-free assessment of how reasonable departures from causal assumptions would impact study findings

* Sensitivity analysis can be extended to incorporate statistical bias