



Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Acting Executive Deputy Commissioner

New York State Tissue Resources Program

Policy – Regulation of Pluripotent Stem Cell products

Effective date – November 17, 2023

Valid until – Regulatory or policy change supersedes this policy

Policy:

Pluripotent stem cell (PSC)-derived products are not regulated by the Department as a tissue, nor subject to licensure under 10 NYCRR Part 52, if the product is subject to an FDA-allowed Investigational New Drug (IND) application or a Biologics license.

Procurement of the cell(s) of origin of the PSCs is subject to the licensure requirements in 10 NYCRR Part 52 if the procurement occurs in New York State.