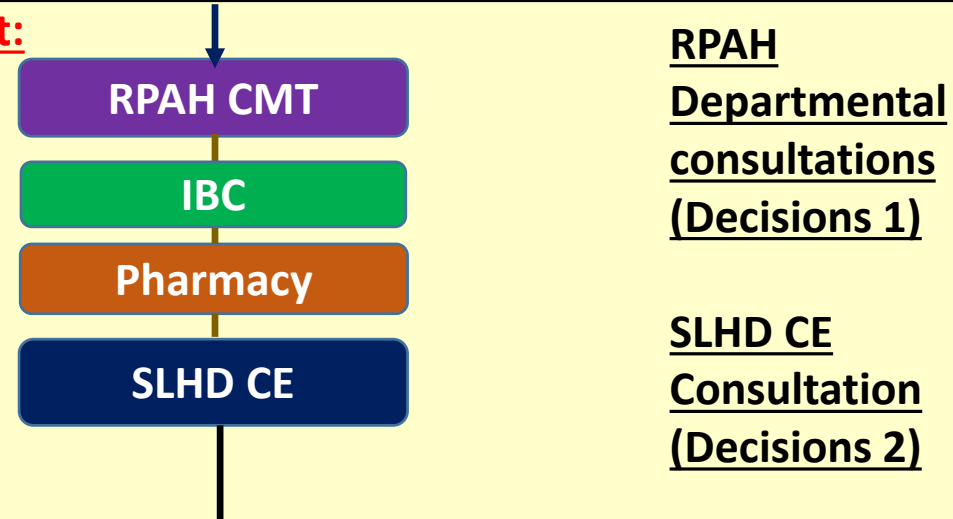


SLHD requirements regarding requests for the use of Advanced Therapy Medicinal Products (ATMPs)

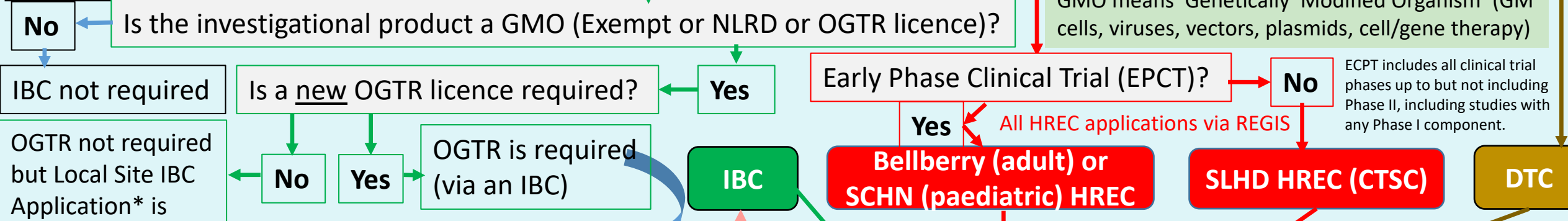
(e.g. GMO, cell or gene therapy, somatic cell or tissue engineered medicinal products)

A. Preliminary early consultations within SLHD - The Principal Investigator must:

1. Consult RPAH Cell & Molecular Therapies (CMT) & RPAH Institutional Biosafety Committee (IBC). Submit the **ATMP Consultation Questionnaire**.
2. Obtain a **Confidential Disclosure Agreement** (signed by SLHD CE & Sponsor)
3. Complete RPAH CMT feasibility assessment
4. Consult RPAH Pharmacy (regarding its requirements & other medications)
5. Consult other Departments involved
6. Complete the **Proposed Site Visit Request Brief** to SLHD CE
7. Apply to relevant Committees (IBC, HREC, DTC) (See below)

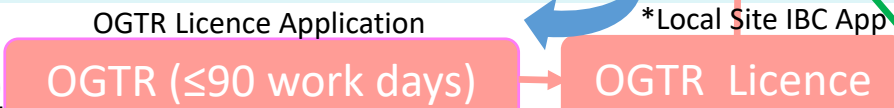


B. Local Committees (IBC, HREC, DTC) (Decisions 3)



C. Gene Technology

Regulator (Decisions 4)



D. Local Governance (Decisions 5)



SCHN, Sydney Children's Hospital Network; CTSC, Clinical Trials Sub-Committee of SLHD HREC; DTC, Drug & Therapeutics Committee; REGIS, Research Ethics and Governance Information System