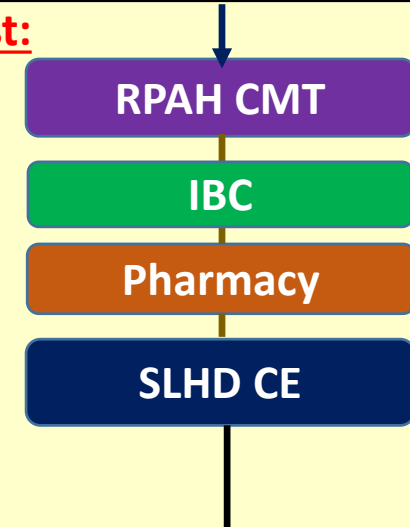


SLHD requirements regarding requests for the use of Advanced Therapy Medicinal Products (ATMPs)

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

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

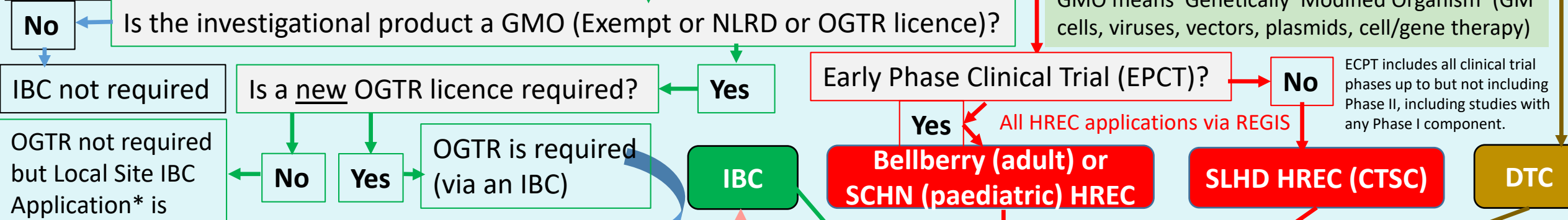
1. Consult RPAH Cell & Molecular Therapies (CMT- See Figure 2) & RPAH Institutional Biosafety Committee (IBC)
2. Obtain a **Confidential Disclosure Agreement** (signed by SLHD CE & Sponsor)
3. Complete RPAH CMT feasibility assessment
4. Consult RPAH Pharmacy (regarding its requirements & other medications)
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)



RPAH Departmental consultations
(Decision 1 Part 1 – CMT Feasibility; Part 2 – Other Departments)

SLHD CE Consultation
(Decisions 2)

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

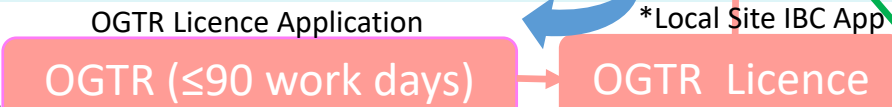


GMO means 'Genetically Modified Organism' (GM cells, viruses, vectors, plasmids, cell/gene therapy)

ECPT includes all clinical trial phases up to but not including Phase II, including studies with any Phase I component.

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