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)

RPAH Departmental consultations (Decisions 1)

SLHD CE Consultation (Decisions 2)

RPAH CMT → IBC → Pharmacy → SLHD CE

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

Is the investigational product a GMO (Exempt or NLRD or OGTR licence)?

- **No** → IBC not required
- **Yes** → Is a new OGTR licence required?
  - **No** → OGTR not required but Local Site IBC Application* is
  - **Yes** → OGTR is required (via an IBC)

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

Early Phase Clinical Trial (EPCT)?

- **Yes** → All HREC applications via REGIS → **Bellberry (adult) or SCHN (paediatric) HREC**
- **No** → **SLHD HREC (CTSC)**

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

DTC

IBC

C. Gene Technology Regulator (Decisions 4)

OGTR Licence Application → OGTR (≤90 work days) → OGTR Licence

*Local Site IBC App

D. Local Governance (Decisions 5)

Clinical Trial Research Agreement (CTRA) → **Local Governance Officer (Site Specific Assessment (SSA))** → **Authorisation - SIV – Training – Conduct trial**

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