Obtaining cells for biomedical research and innovative therapies: which regulatory pathways in France?

Adrien Bottacci[1], Guylène Nicolas[2], Aurélie Mahalatchimy[3]

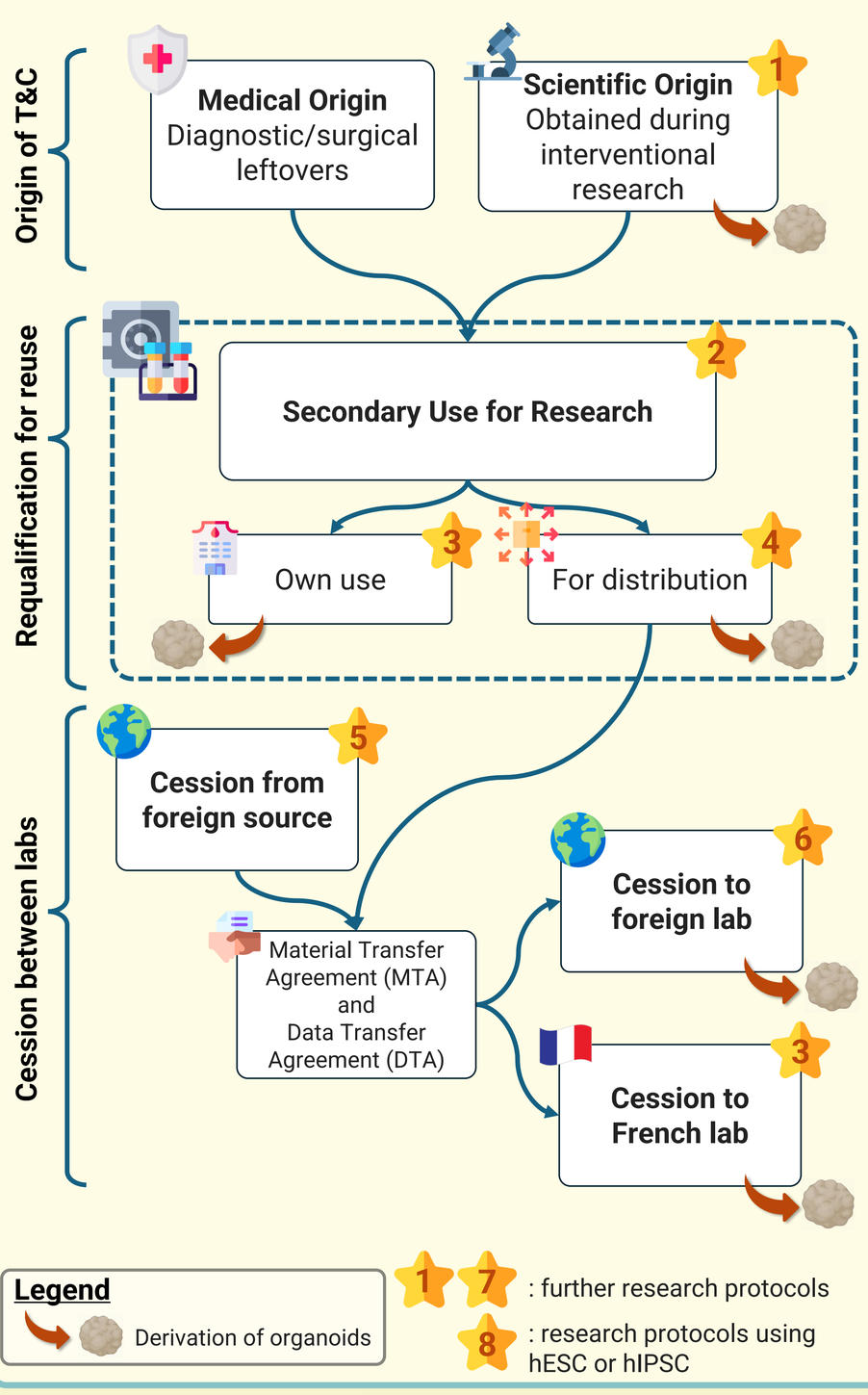
[1]PhD Student, UMR 7268 ADES, CDSA Health Law Centre - UMR 7318 DICE CERIC International, Comparative and European Laws, Aix-Marseille Université – CNRS, Aix-en-Provence, France ; [2] Professor, UMR 7268 ADES, CDSA Health Law Centre, Aix-Marseille Université, Aix-en-Provence, France ; [3]CNRS Researcher in law, UMR 7318 DICE, CERIC International, Comparative and European Laws, Aix-Marseille Université – CNRS, Aix-en-Provence, France

Introduction

- **Human cells** procurement lies at the foundation of biomedical research and bioproduction of innovative therapies.
- The process involves **multiple regulatory procedures** that are interwoven to form a complex web.
- This leads to areas of uncertainty for researchers and lawyers.

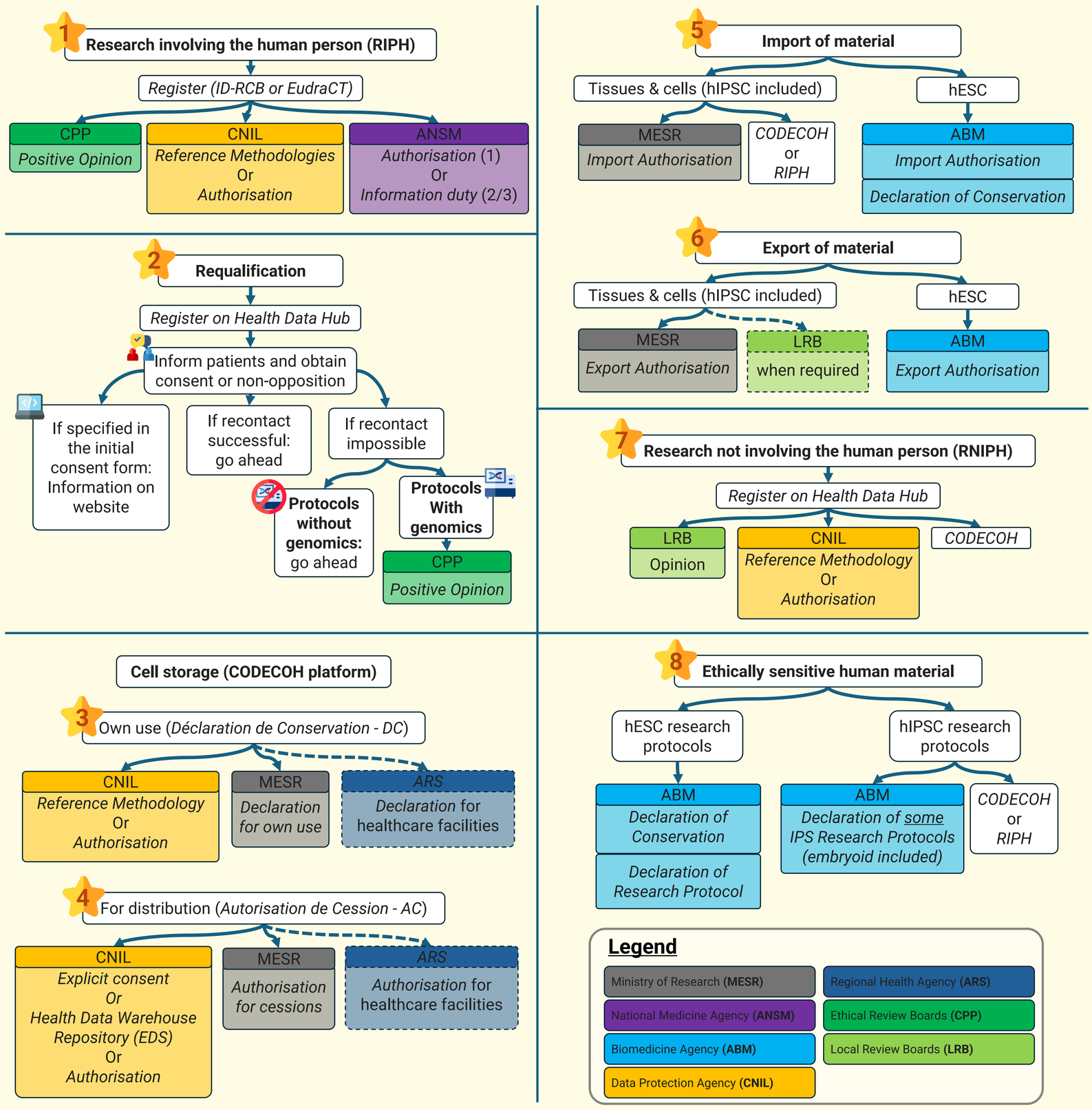
Objective of this poster: to provide a clear overview of the **regulatory pathways for cell procurement,** easily identify the most relevant for a researcher use-case. Additionally, to identify procedures relevant to the production of **organoids for research purposes.**

Journey of a Cell



- **Storage of cells usually managed by biobanks** (*Centres de ressources biologiques)* that interface with other services of the organisation and with external actors (clinic, production platforms, researchers, industry partners…).
- **Contractual agreements** in addition to administrative procedures
- **Organoids** can be derived at multiple stages, without being the target of the procedure.

Procedures in Detail



- **Data**
  - GDPR does not apply when samples are fully anonymised
- **Not pictured:**
  - GMO procedures
  - Animal research procedures

Conclusion

- **Everything starts with donors:** they make research on human material possible. Their will must be respected. Thus, the link between them and their donation is primordial. But it can be severed (loss of contact, incapacity, death). Complex questions arises when diagnostic or surgical samples become research samples. Especially when cell lines are immortalised.
- **Regulatory rationale:**
  - French framework rooted in a strong ethical commitment but pressure for a more competitive research environment. **Balance** between freedom of research and protection of individuals and society.
    - Calls for **simplification** by relying more on accountability of stakeholders.
  - Ensure security and quality of human material
    - Maintain **separation** between cell lines used for research and for therapeutic uses.
- **Determining factors**: sample collection, personal data, stem cells, genomics, biobanking and final uses…
  - **Obtaining substances of human origin: procurement, consent, requalification etc.**
  - **Type of substance of human origin: tissues and cells (T&C), stem cells etc.**
  - **Persons: adults, children, vulnerable persons, deceased persons etc.**
  - **Uses: clinical trials, non-interventional research, genomics, exports and imports, production etc.**
- **Limitations**
  - Complex procedures : difficulty of revision ; classification difficulties with new research artifacts.
- **Open questions**
  - Until when is it still an element of the human body? When does it become a thing?
  - **Complex regulatory frameworks create a market for compliance services**, increasing cost, discouraging sharing of practices

This work has been supported by the ANR-funded Organact project (ANR-22-CE41-0012) and the ANR-funded I-BioLex project (ANR-20-CE26-0007-01).