

# *CARTaGENE*

## Governance Mechanisms: Past, Present and Future

Susan Wallace

Director, CRDP Ethics & Policymaking Core, Université de Montréal

Karine Bédard

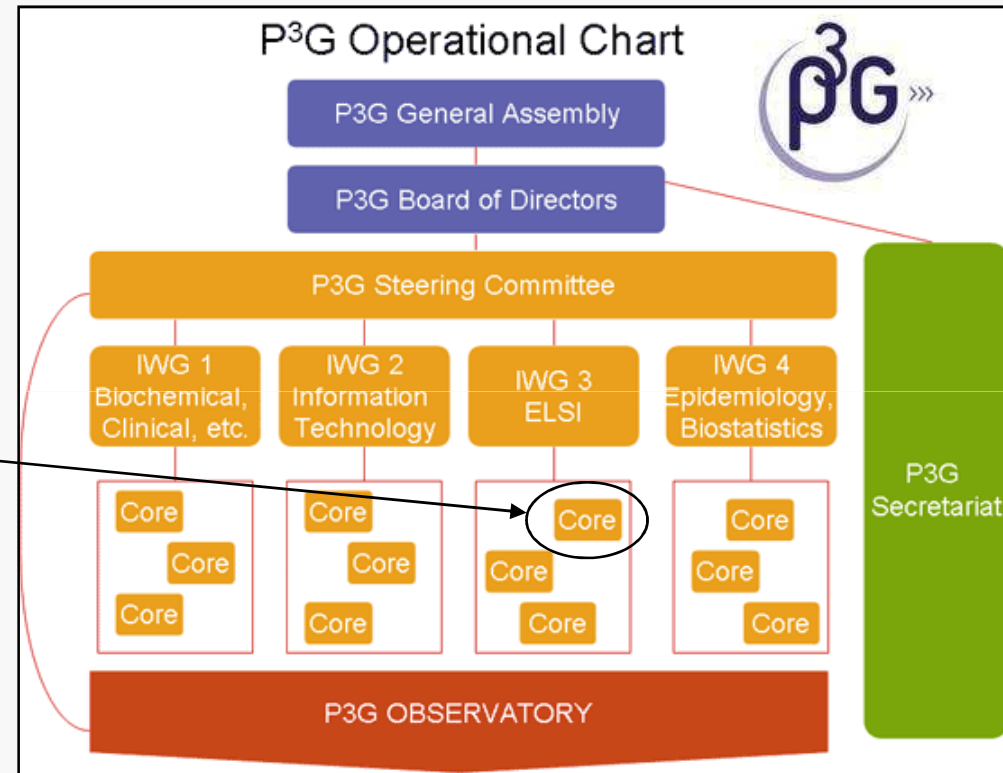
Research Associate, CRDP, Université de Montréal

Saminda Pathmasiri

Research Associate, CRDP, Université de Montréal

# CRDP Ethics & Policymaking Core

- Located at Centre de recherche en droit public (CRDP), Université de Montréal, Montréal, Canada
- Work with the IWG3 on Ethics, Policy and Public Engagement
- Governance and access issues



# Governance: Project Background

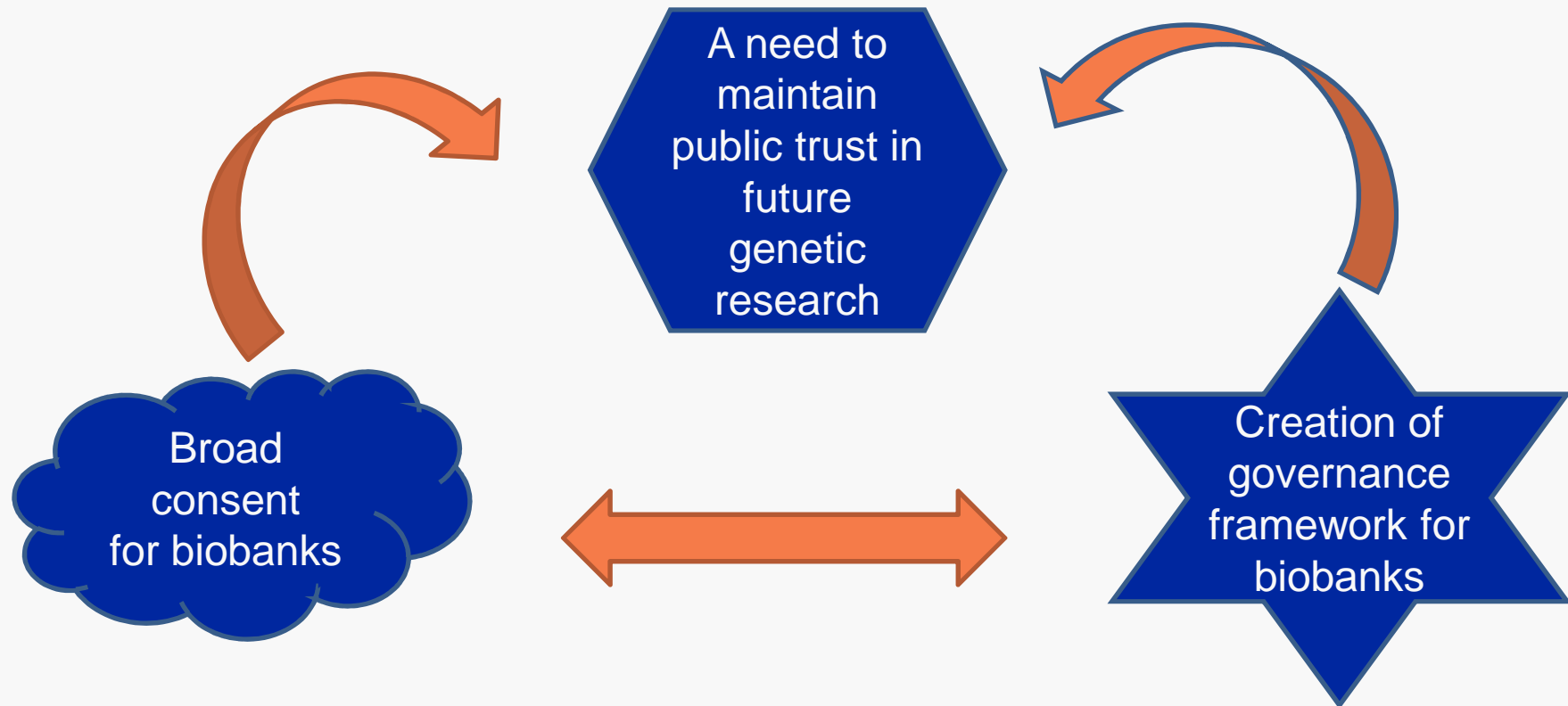
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- **Examining governance in relation to population biobanks**
- **Soliciting data from P<sup>3</sup>G-member biobanks and comparing the mechanisms used by biobanks**
- **Will be presenting/discussing our proposed model framework for governance at P<sup>3</sup>G meeting, Philadelphia, PA, November 2008**



# Need for Governance

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# Governance and its importance for biobanks

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- **“One important and vital avenue for biobanks to maintain and honour public trust is through the creation and use of governance mechanisms within broader frameworks. Governance allows people and institutions to act by constraining behaviour within an agreed social framework. Such frameworks reflect the society in which they are situated and may consist of laws, social norms, ethical codes, etc.”**

# Lifecycle of a Biobank

## **‘Before’**

### Planning/Creation:

- Public Engagement
- Legislation
- Funder Requirements
- Scientific Peer Review
- Ethics Review

## **‘During’**

### Set-up/Operations:

- Executive Committee
- Scientific Oversight
- Ethics Oversight
- Sample Handling
- Data Management
- Communication with Participants

## **‘After’**

### Access to/Use of Resource:

- Data/Sample Access/IP Procedures
- Public Outreach

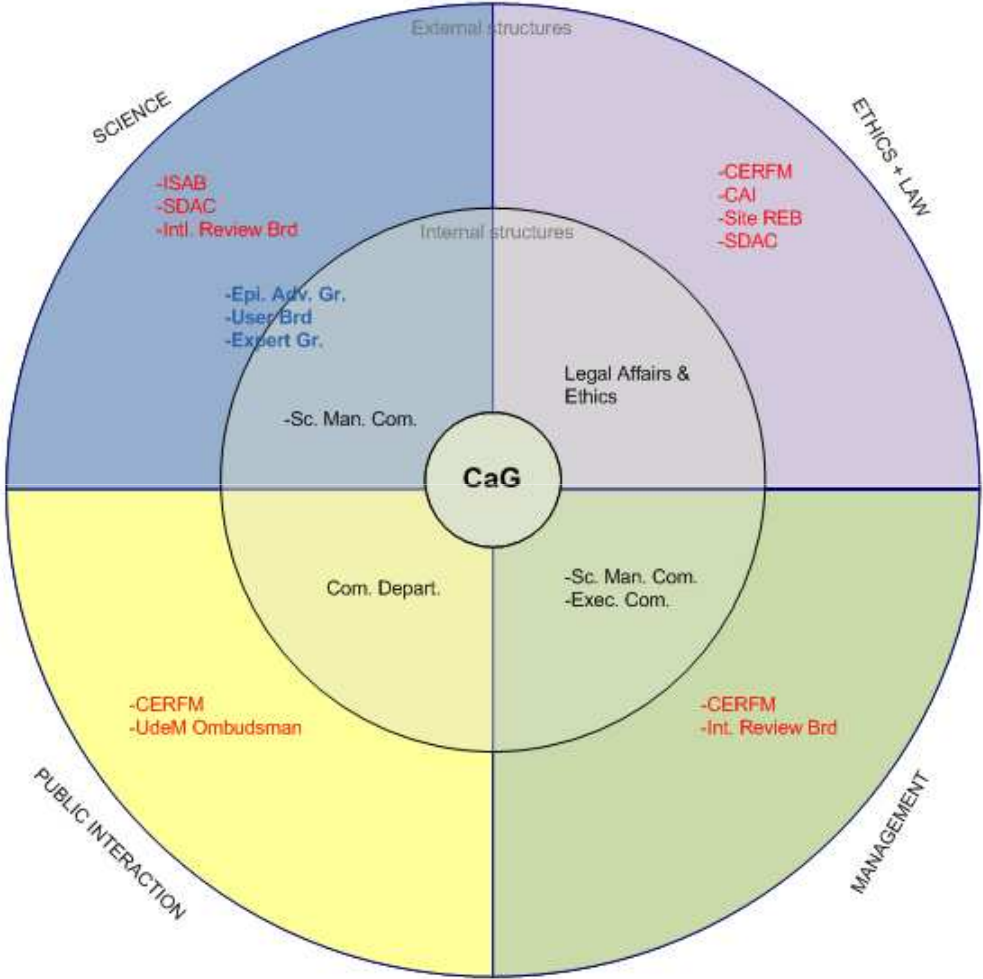
# CARTaGENE (CaG) as a Model

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- **CaG funded in 2007 by Genome Canada and Génome Québec**
- **CaG serves as a project for testing P<sup>3</sup>G tools; important that recommendations be useful for other biobanks/resources**
- **What governance mechanisms has CaG been using?**
- **What will they use in the future?**
- **Are they the same?**



# CARTaGENE Governance





# CaG: Past (before)

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- **External bodies**

- International Review Board (A) (link with funders, GQ and GC)
- User Board (K) (needs of the researchers)
- Epidemiology Advisory Board (best practices in epidemiology)
- Expert Groups (advice on biological and physical measurements)
- Funders (Genome Québec and Genome Canada) (governance of the project)
- Access Commission

- **Internal bodies**

- Core investigators (C) (development of project)

# CaG: Present

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- **External bodies**

- UdeM Research Ethics Board (CERFM) (D)
  - Ethics oversight
- International Scientific Advisory Board (ISAB) (G)
  - Six expert members from outside of Canada
  - Advise on development and strategic direction; milestones and deliverables
  - Alert the project of any changes and technical developments that may affect the goals and the development of the project
- International Review Board (A)
  - Members named by the funders (Genome Quebec and Genome Canada) to review CARTaGENE
- UdeM Ombudsman (J)
  - Manages complaints and comments from the public

# CaG: Present

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- **Internal bodies**

- Scientific Management Committee (N)
  - In charge of managing the scientific aspect of the project
- Liaison Committee (MSSS) (O)
  - Facilitates discussions with the host (University of Montreal)
- Operation Committee (P)
- Executive Committee (Q)
- Coordination Committee (UdeM) (R)
- Legal and Ethics Department (S)
- Communication Department (T)

# CaG: Future

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- **Unknown what governance mechanisms will be necessary for CaG in the future**
- **Once political-ethical “comfort” is achieved, it is hoped that the system can be streamlined**
- **Governance mechanisms must be flexible to reflect the changing nature of the biobank and public expectations**



# Future of CaG

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- **Pilot tested in 2008**
- **No major problems (except the snow!)**
- **97% agreement to be re-contacted for further questions, other studies, etc.**
- **Protocol for phase A (20,000 target population) under ethics review [age 40-69]**
- **Role-out January 2009**
- **Harmonised with core reference set with ...**

# CRDP Ethics & Policymaking Core



**Bartha Maria Knoppers**  
Canada Research Chair in Law and Medicine  
Faculty of Law, CRDP, UdeM



**Susan Wallace**  
Director, EPC  
CRDP, UdeM



**Karine Bédard**  
Research Associate  
CRDP, UdeM



**Saminda Pathmasiri**  
Research Associate  
CRDP, UdeM

*Thank you to our funders*

**Canada Research Chair in Law and Medicine, Genome Canada, Génome Québec and the Centre de recherche en droit public, Université de Montréal**

