

Summer Seminar “Copyright in Motion”

Centre d'Etudes et de Recherche en Droit de l'Immatériel (CERDI),
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Copyright and Biobanks:

Close Encounters of the Third Kind

The sui generis right in the context of biomedical databases

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Biobank

- **Definition**
- Content and data**
- Legal aspects**



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Full List

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- Africa, Business Destination
- Country
- Biobanks
- Stores
- Ecological Intelligence

The TIME Android App



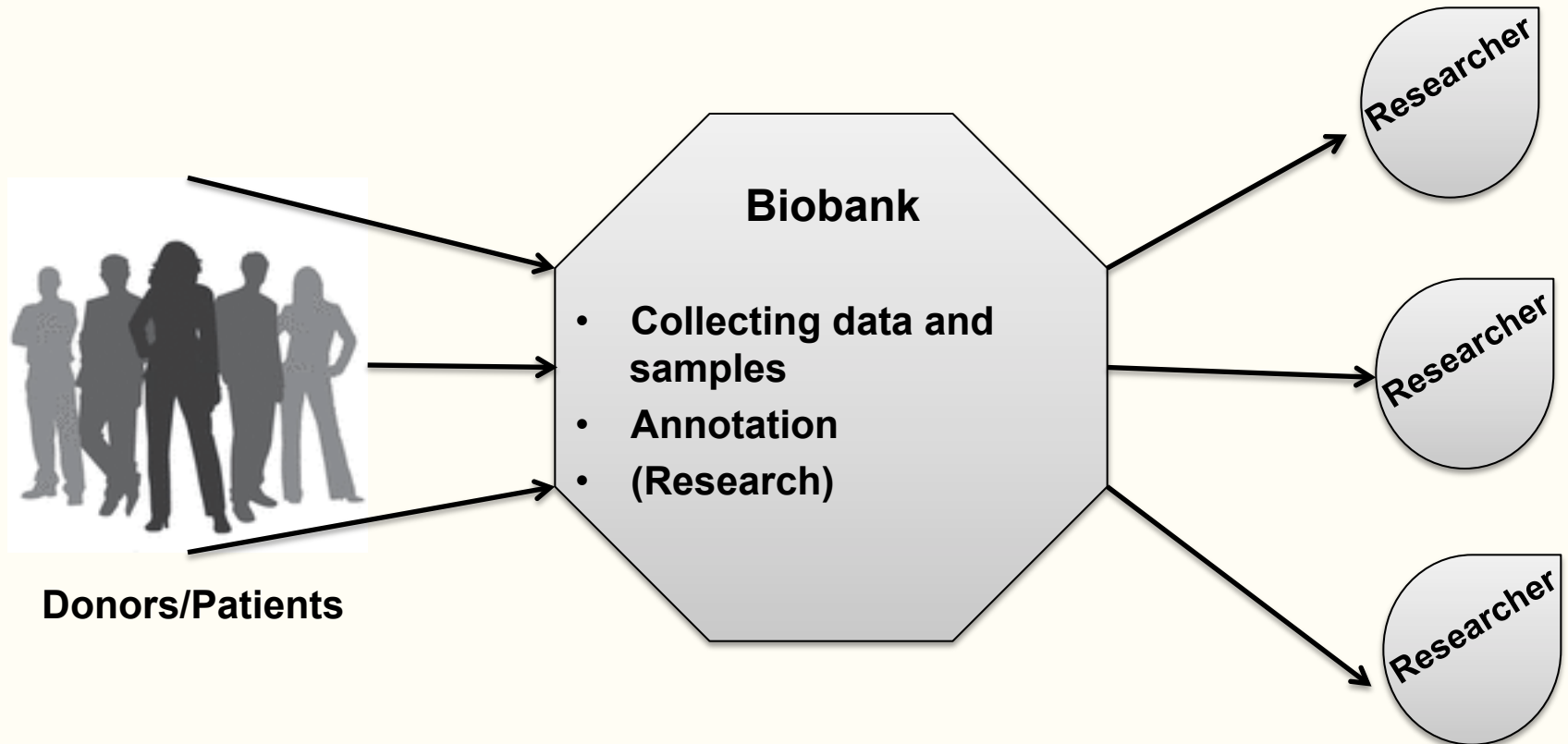
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Special Features:



Photos: Stores That Are No More

1. What is a research biobank?

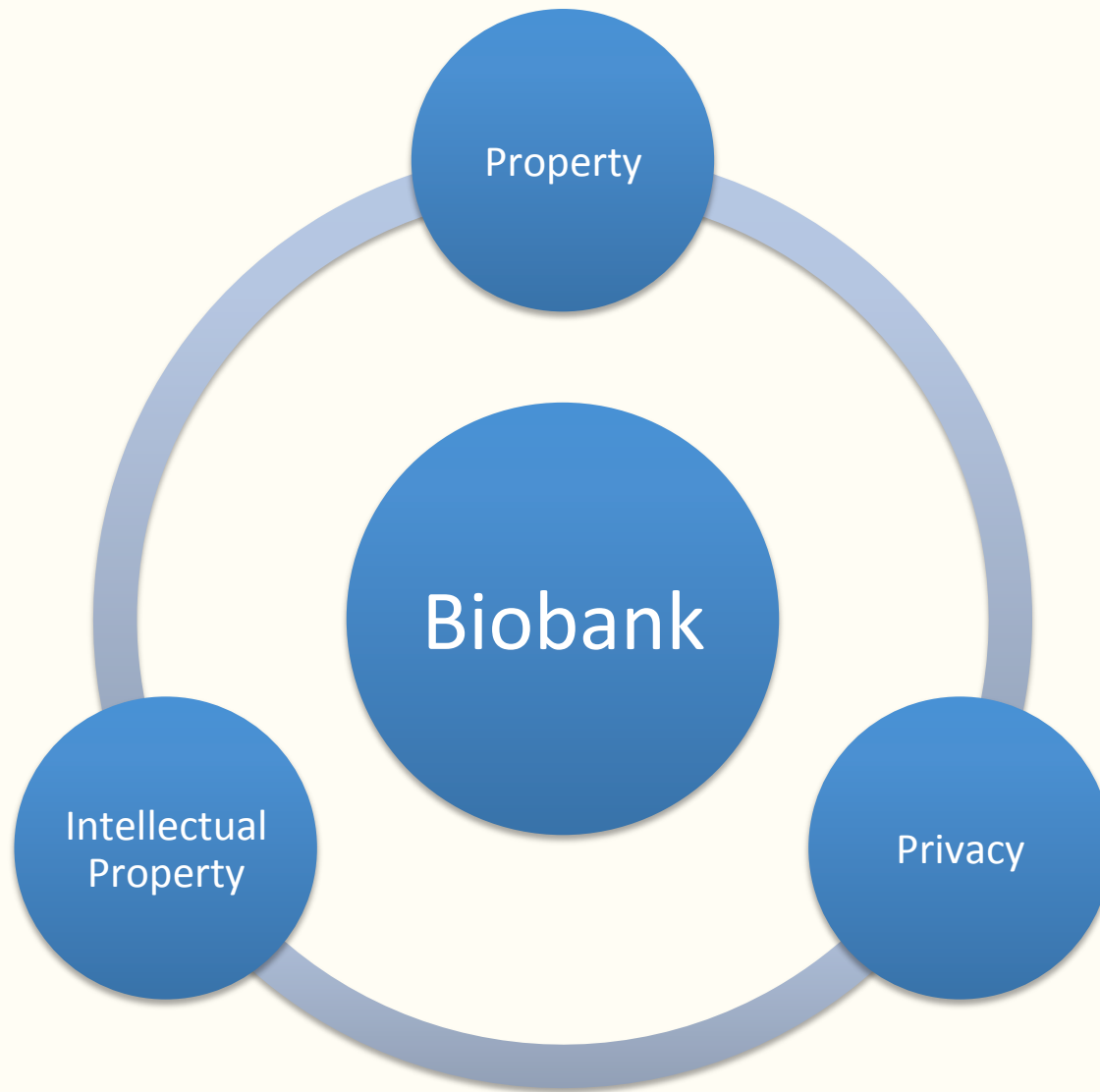


Why biobanks are strategic assets?

- Critical mass of samples and data
- Annotation of phenotype, familial and environmental data
- Follow up data
- Compliance with the necessary legal requirements

2.The double nature of the biobank





3. Legal aspects

Content of the biobank	Legal meaning
Biological samples (res)	Property
Data Personal data Sensitive data Genetic data	Privacy and Data protection
Elaboration of material collection + aggregate data	IP Invention → patent/trade secret Publication → copyright
Data obtained by biobank	Database → Sui generis right

A movie poster for 'Close Encounters of the Third Kind'. The background is a dark night sky filled with stars of various sizes and colors, including some bright yellow and white ones. In the lower half, a road with a dashed white center line leads from the bottom towards a bright, glowing horizon line. The overall mood is mysterious and otherworldly.

CLOSE ENCOUNTER
OF THE FIRST KIND
Sighting of a UFO

CLOSE ENCOUNTER
OF THE SECOND KIND
Physical Evidence

CLOSE ENCOUNTER
OF THE THIRD KIND
Contact

CLOSE ENCOUNTERS

OF THE THIRD KIND

Databases' legal protection

Directive 96/9/EC

- Copyright
- Sui generis right

Directive 96/9/EC

Double track of protection

Copyright

Sui generis right

Database which “by reason of the selection of arrangement of their contents, constitute the author’s own intellectual creation”	Any database where “there have been qualitatively and/or quantitatively substantial investments in either the obtaining, verification or presentation of the contents”
Author	Maker of the database
“expression” of the database <ul style="list-style-type: none">• originality of its systematic organization• no mere alphabetical or chronological order	No minimum standard of creativity
Duration: 70 years after author’s death	Duration: 15 years (see art. 10.3)

Database sui generis right is
*“one of the least balanced and
most potentially anti-competitive
IPRs ever created”.*

Reichman and Samuelson, 1997

The Italian case

Legge 22 aprile 1941, n. 633

	Copyright	Sui generis right
Exclusive right of the author/maker	<ul style="list-style-type: none"> • Reproduction; • Translation, adaptation, elaboration; • Distribution to public; • Communication to public; • Riproduction, distribution, communication of the translation, adaptation, elaboration 	<ul style="list-style-type: none"> • Extraction • Re-utilization of a substantial part
Free uses	<ul style="list-style-type: none"> • Education and scientific research 	<ul style="list-style-type: none"> • Extraction and/or re-use of an insubstantial part of the database

The Italian case

art. 171 bis, L. 633/41

“Whoever [...] extracts or re-uses the database in violation of the provisions of Articles 102-bis and 102-ter, or distributes, sells or rents a database, is subject to **imprisonment from 6 months up to 3 years and to a fine from 2,582 Euros up to 15,493 Euros**. The minum sanction is two years' imprisonment and a fine of EUR 15,493 if the offense is serious”.

General criticisms regarding sui generis right

- Dynamic database and the “rolling” duration of sui generis right (*art. 10.3 Directive; art. 102 bis L.633/41; BHB v. William Hill Organization Ltd*)
- Sui generis right do not fulfill the scope of the Directive (*ICSU, 2004; EU first evaluation report, 2005*)
- NO research exemption in the Italian transposition (*art. 102 bis L. 633/41*)

Enclosure v. Open Science

- Trend toward a “second enclosure” (Boyle, 2003)
- Barrier to full and open access to data for scientific purposes
- Sui generis right: stumbling block for scientific research
 - the protection covers basic information and raw data (pre-competitive nature)



lawtech

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Sui generis right

IS THIS REALLY THE BEST WE CAN DO?

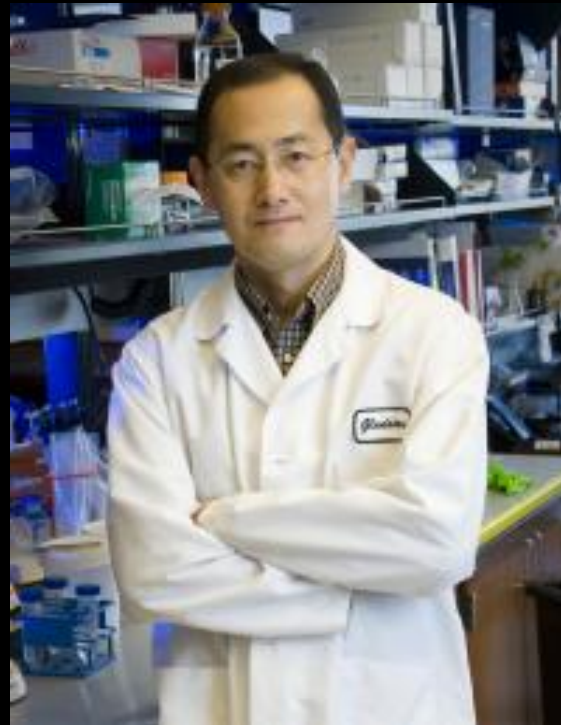
Possible contrasts

- Institutional goal of the biobank
 - a strategic source of information and assets for biomedical research
 - the steward of a common resource
 - an independent entity with the institutional goal of fostering scientific research for the common good
- Social norms of scientific community
 - Data sharing and collaboration

Ilaria Capua



Shinya Yamanaka



Conclusion

- Exclusive rights (copyright/sui generis right) over a biobank's collection can negatively affect the scientific progress
- Open models for research biobanks
- Think up novel solutions, considering the role of social norms and the flexibility offered by contractual tools

Thank you for your attention!



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