HEALTH AND RESEARCH IN THE GENERAL DATA PROTECTION REGULATION

BASED ON ANALYSES BY JANE REICHEL,
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Timeline

- Commission proposal, January 2012
- European Parliament's first reading March 2014
- Council General Approach, June 2015
- European Parliament and Council Compromise Text, December 2015
- Final enactment expected spring 2016
- Regulation in force 2 years after

Main concerns during the process

- Regulation: no national implementing rules, thus no accustomizing to national research traditions?
- Stricter rules on informed consent?
- Stricter rules on purpose limitation, storage limitation?
- A widened right to be forgotten?

Potentially no major differences from today?

- General exceptions for processing of health data in research are to be laid down in EU or Member State law, requiring ”appropriate safeguards”
- Specific exceptions for purpose limitation, storage limitiation, informational requirements are provided for in the Regulation, but not for consent

Exceptions for processing of personal data in research

Article 5.1 b) Purpose limitation

- further processing of personal data for scientific and historical research purposes

Article 5.1 e) Storage limitation

- Further storage of personal data for scientific and historical research purposes

If in accordance with Article 83

Exceptions for processing of personal data in research

- Articles 14 , 15, 16, 17 , 17a , 19 and recital 125
  - Exceptions from the information requirements,
  - rectification,
  - erasure,
  - to be forgotten,
  - restriction of processing and
  - the right to data portability and
  - the right to object when processing personal data,

  if processed in accordance with Article 83

Specific categories of data; health

- Article 9.1 general prohibition in regards to data on [….] genetic data, biometric data in order to uniquely identify a person or data concerning health or sex life and sexual orientation shall be prohibited.
- Article 9.2 i, exceptions for research
  - Data may be processed for research purposes in accordance with Article 83
  - Based on EU law or Member State law
- Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or health data.

Exceptions for research

- Article 83 research exceptions
  - Shall be subject to “appropriate safeguards“
  - Ensure that technical and organisational measures are in place to protect data
  - “May” include pseudonymisation
  - Only if identifiable data is strictly necessary

Processing without consent for public health reasons

Preamble recital 42 b

The processing of special categories personal data concerning health may be necessary for reasons of public interest in the areas of **public health**, without consent of the data subject. This processing is subject to suitable and specific measures so as to protect the rights and freedoms of individuals.

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Broad consent for research?

Recital 25aa

It is often not possible to fully identify the purpose of data processing for scientific research purposes at the time of data collection. Therefore data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

Remaining challenges

- It is still unclear how the exceptions for research will be implemented, and whether via EU law or Member State law
- According to recital 25a, genetic data (DNA/RNA) should be defined as personal data
- A strong adminstrative structure is built, with supervisory authorities with effective tools and the competence to fine controllers – how will research be assessed?

Feedback from RD-PEC

- PEC takes ethical questions from researchers or patient organisations: from NeurOmics – extension of embargoes & countries which exclude sharing outside disease area
- Return of results and unexpected findings
  - Disagreement around practices
  - Individual projects decide consent processes
  - RD Connect description of spirit of platform and signage to IC guidelines
  - Responsive governance for areas which are shifting

Feedback from RD-PEC

- Governance
  - Patient Organisations' (PO) inclusion in governance
    - Current PAC keen to be involved in ongoing governance of platform, also a finding from focus groups
    - Short paper on possible models. Further work to gather examples of where different models are used to present to PAC who will continue the discussion and take solutions to EMC
  - Can the POs be involved in a system of responsive governance?
    - Possibility of drawing up a procedure like that used in risk management – instead of possible risks, it's possible changes
    - And/or include periodic review of ELSI elements in platform governance

Patient Centred Approach

- Patient Centred Approach – 2 stages
- Stage 1 – gather evidence and synthesise knowledge about patient expectations and preferences for RD Connect platform
- Stage 2 – use this evidence to assist platform operation, processes follow a patient centred approach
  - Task 6.6. Implement a patient-centred approach throughout RD-Connect Lead: UNEW-PEALS, Participants: EURORDIS plus all full RD-Connect partners
  - Task 6.7. Develop training materials and hold training workshops Lead: UU. Participants: UNEW-PEALS, EURORDIS

Why is this important?

- Trustworthy ‘keeper’ of patient data and samples
- Can not give too much reassurance on security and privacy
- Research/clinic divide affects notion of choice
- Patients unaware of their inclusion in research - cultural assumptions in receiving country
- ISS survey on EURenOmics partners – confusion if submitters are unsure of their responsibilities
- Better uptake of the platform if backed by and promoted by patient organisations

Patient centred approach

Sources of knowledge

- Patient/participation research (Focus Groups, Delphi)
- Ethical framework (consents, children, carrier status)
- PAC (available for opinion on ad hoc questions which arise)

Prioritisation of Issues

- Patient concerns on security, privacy, trust
- Moveable environment on eg: return results/incidental findings
- Lack of awareness around ELSI requirements for platform

Patient Centred Approach

- Integration of ethical framework into SOPs, help system, during submission
- Model of patient inclusion in governance + specifics eg: biobank assessment
- Responsive governance model

Research involving children

- Children are regarded as vulnerable subjects in the legal and ethical framework of research and should receive protection. At the same time they are not able to make legal decisions on their own.

- This makes all research involving children more challenging from an ethical standpoint.

Involving Children is important

- Excluding children from research, especially low risk research, carries ethical backdraft: it may lead to children's health being under researched.

- Paediatric biomedical research within the field of Rare diseases (RD) is especially crucial if we are to gain insight into early onset pathologies, detect carrier status and develop new therapies.

Children Involvement Research: assent

- There is increasing agreement on the need for children to be part of the consent process (N. A. Giesbertz, Bredenoord, & van Delden, 2014; Wellcome Trust statements etc.).

- We agree with the above statement especially if pain or immediate risk is involved.

Children Involvement in Longitudinal research: From assent to Consent

- Should assent be an absolute requirement?
- Should dissent be always binding?
- Is assent in the best interest of the child?

Taking assent seriously: conveying age appropriate messages

- Contents should be conveyed depending to age maturity when the child or the young can make sense of the information.
- In the workshop there was complete agreement that this threshold should be determined by the child's decision making capacity and maturity.
- In the literature there is not agreement on clear age maturity thresholds related to assent capacity.

Is assent in the best interest of the child? Taking assent seriously.

Is requesting assent when the child has no chance to understand the implications in the best interest of the child?

- Assent may become more a justification than a protection for the child.
- Experts in children research reports confusion and fear being generated by concepts that were alien.
- Assent not measured to age maturity may lead to abuse the child in order to get an official ok for research.
- Assent should be sought at appropriate age if a child is in contact with the research facility (often the case in rare disease)

Children Involvement in Longitudinal research: From assent to Consent

- Children who have donated samples and data for research should be contacted to legally consent when they reach majority.
- The practical side for re-contact could easily be solved using already existing IT-solutions where contact information can be kept updated (for example using a system like the Rudy study).
- For already existing collections, offering participants the possibility to opt out should be the minimal requirement, whereas consent should be the best choice

Genetic data in public research databases: Which governance mechanisms should apply?

International meeting open to stakeholders. WP6 educational training (27/28 April 2016) in collaboration with CHIP ME (EU cost action)

- to explore ethical and especially legal challenges that may arise when researchers are required to deposit genetic and genomic research data in public research databases
- investigate governance mechanisms that may support ethically and legally compliant data deposit

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ARTICLE

Improving the informed consent process in international collaborative rare disease research: effective consent for effective research

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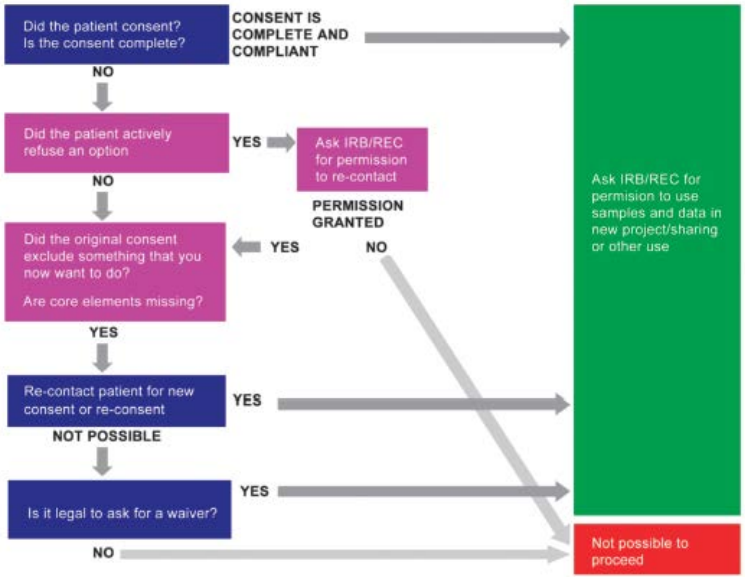


Box 1 Essential elements of IC documents for International Consortia on RD

Information elements that are relevant in IC documents for biobank and observational studies in RD Research

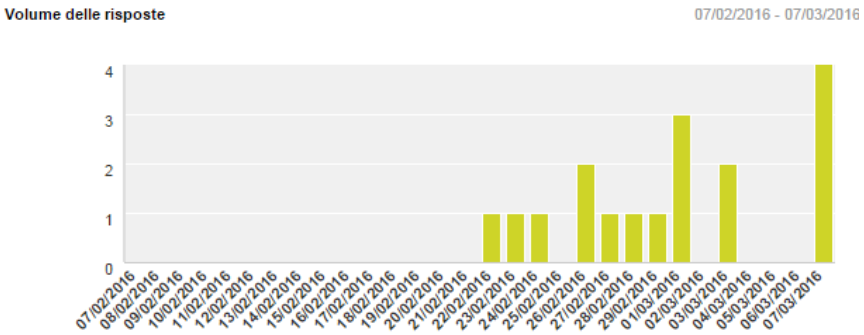
- General (name of the PI, Institution, funding, duration, oversight, contact persons)
- Aims, research uses of data (eg, cancer research and RD research)
- Voluntariness of participation and possibility to withdraw
- Procedures involved in participation, including interviews and blood taking
- Kinds of samples and data that will be collected
- Potential physical, psychological and social risks (informational risks)
- Potential benefits of participation
- Protections in place locally to ensure the confidentiality of samples and data
- Access to data/samples for research purposes: who will have access, who should control and what the procedures in place (data access committee)
- Access to data/samples for purposes such as validation and quality control
- Study oversight
- Compensation/reimbursement
- Custodianship of samples
- Study dissemination plans (professional journals/lay versions/codified or aggregated results only/specific results/patient pictures and occasionally short professional video sequences).

CEs for the IC of studies participating to international RD research

- Possibility of data sharing across research groups and national borders
- Possibility of large-scale genome sequencing techniques
- Return of secondary findings
- Hosting of the data in open access database (eg, in RD-Connect the European Genome-Phenome Archive)
- Use of interoperable identifiers for the de-identification of participants
- Access by industry if foreseen and prospects for third-party commercialisation and intellectual property
- Possible linkage to different data (registries, medical records, etc.)
- Withdrawal procedures, such as sample retrieval and/or destruction and difficulties in ensuring the right to withdraw for the data already shared
- Permission to re-contact

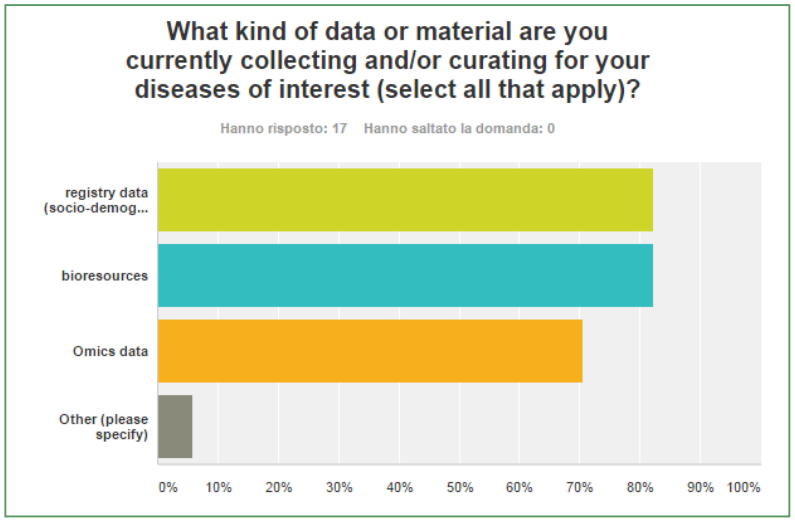
RD Connect

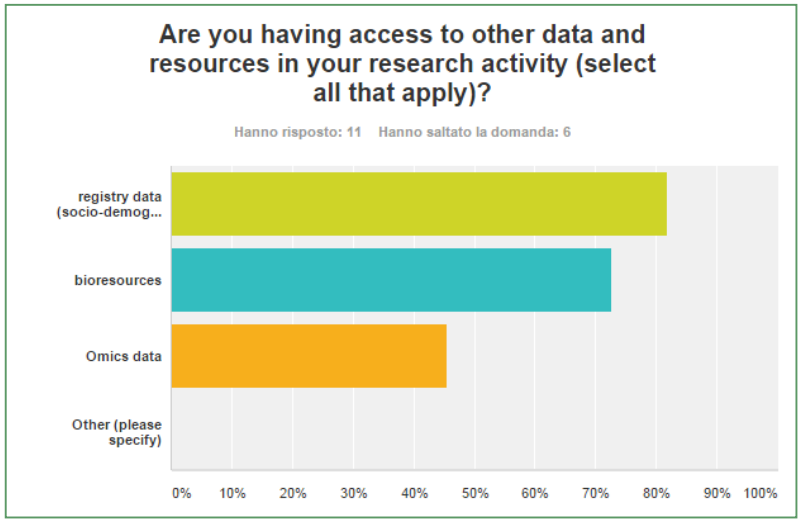
EURenOmics survey on informed consent and re-consent (n=17/37)



France (4)
UK (3)
Netherlands (2)
Belgium(1)
Italy (1)

Just a quick overview





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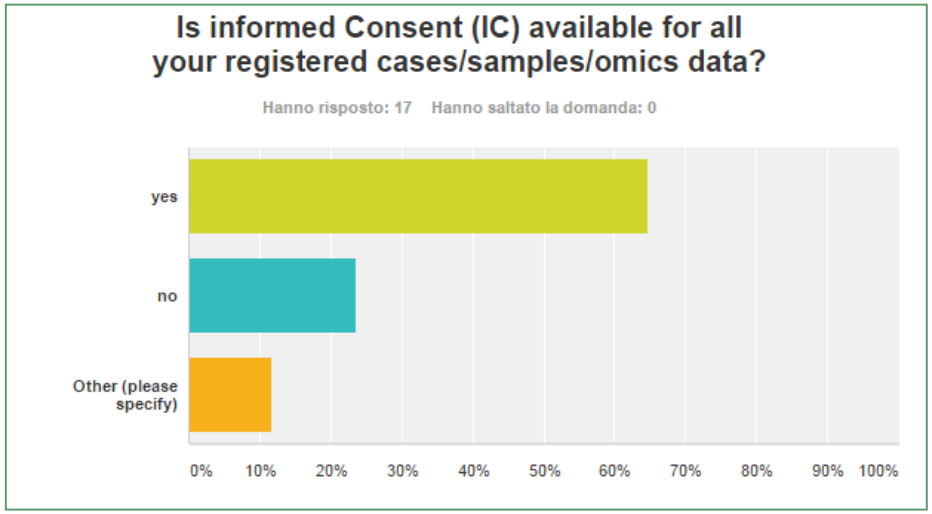
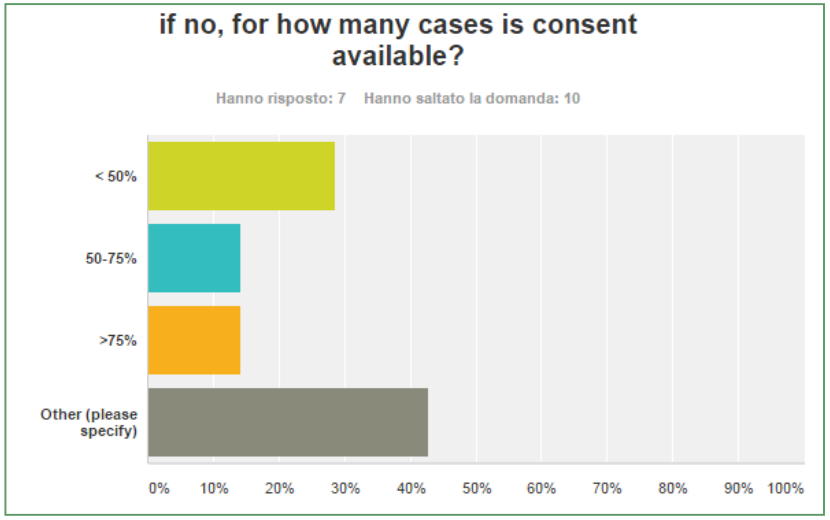
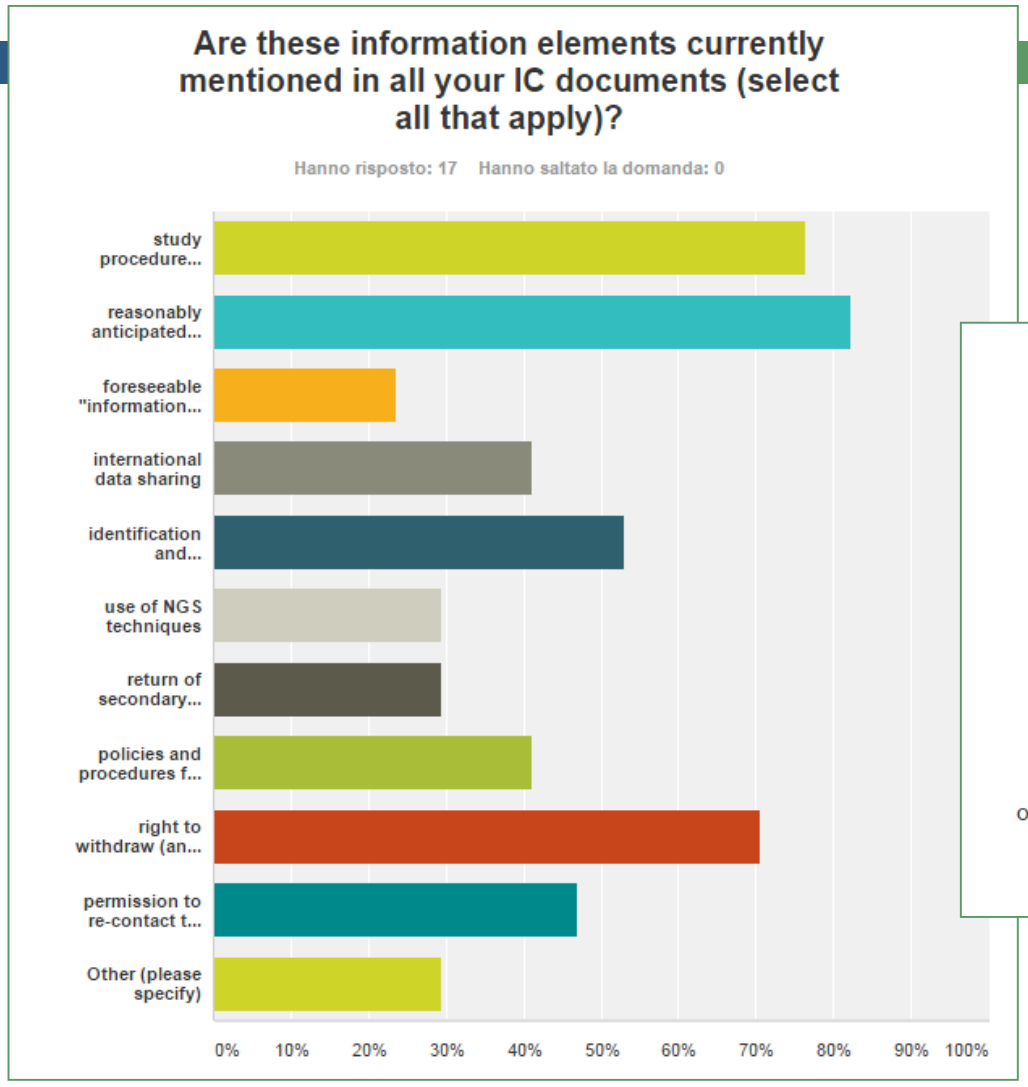


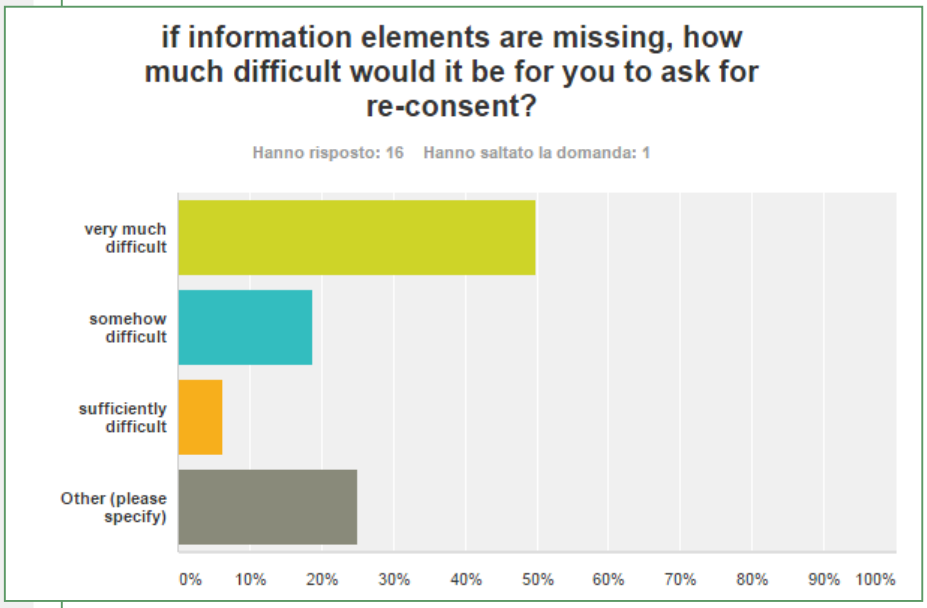


depending on the data; for blood > 80%, for DNA 100%, for clinical data < 50%

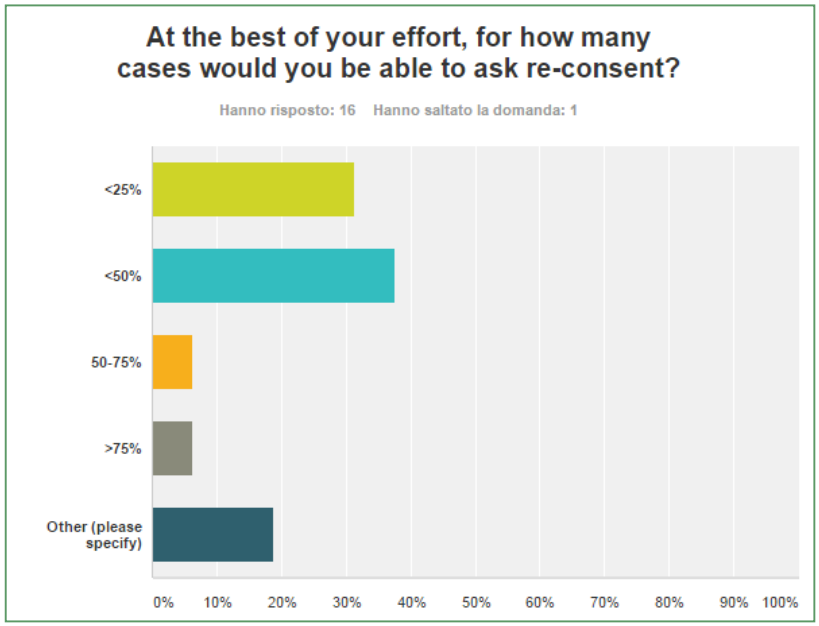
I cannot answer this question since it depends of the type of consent you mention: if it is consent for genetic testing we have consents in approximately 90% of cases, for data sharing it is below 10%

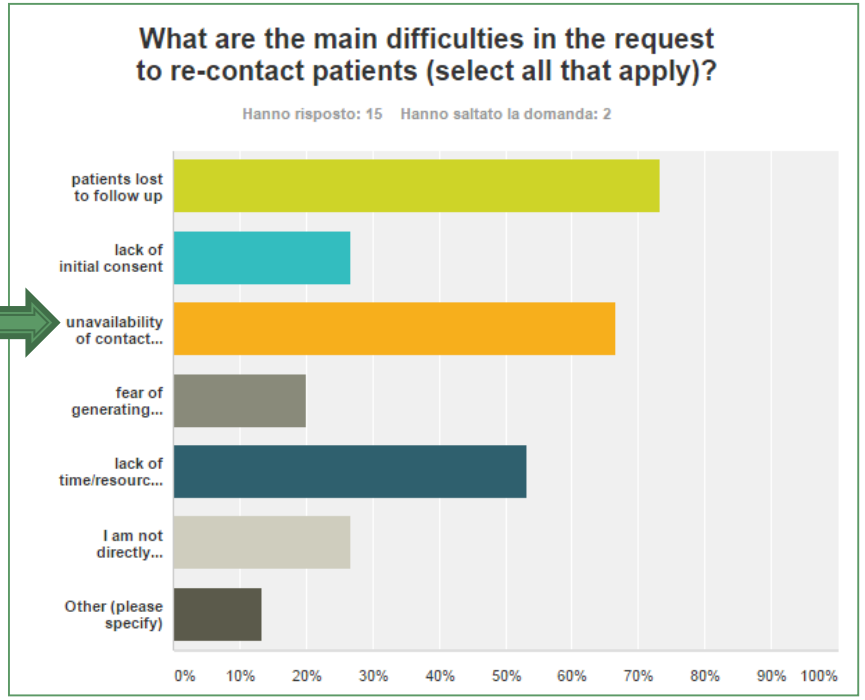
Feasibility of re-consent



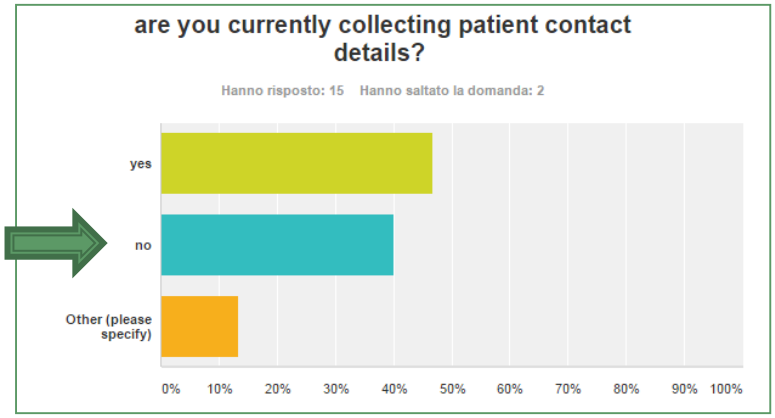


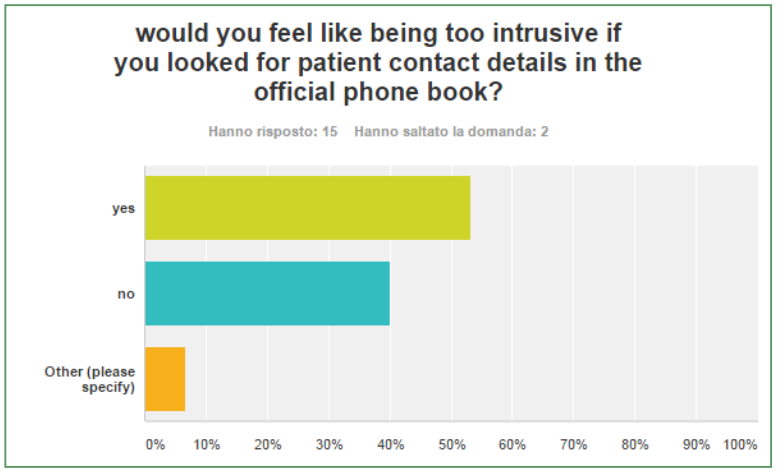
Core information elements missing

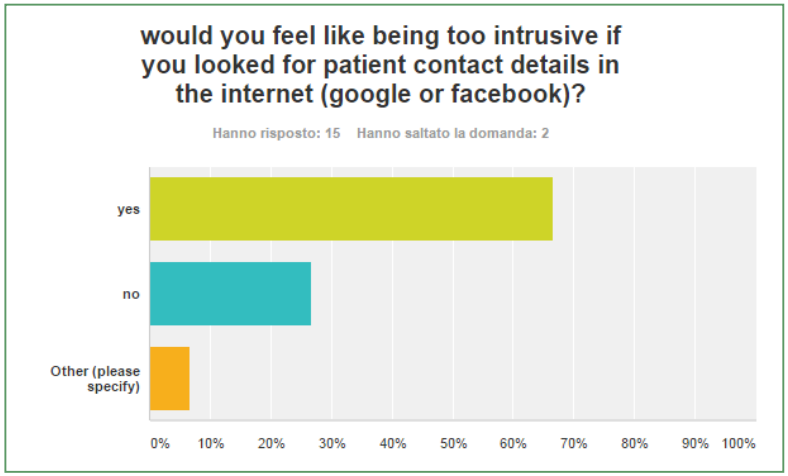




Contact details

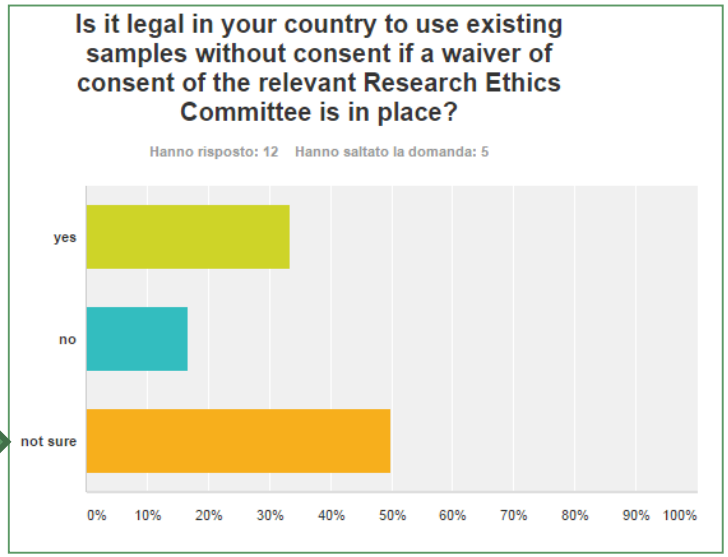


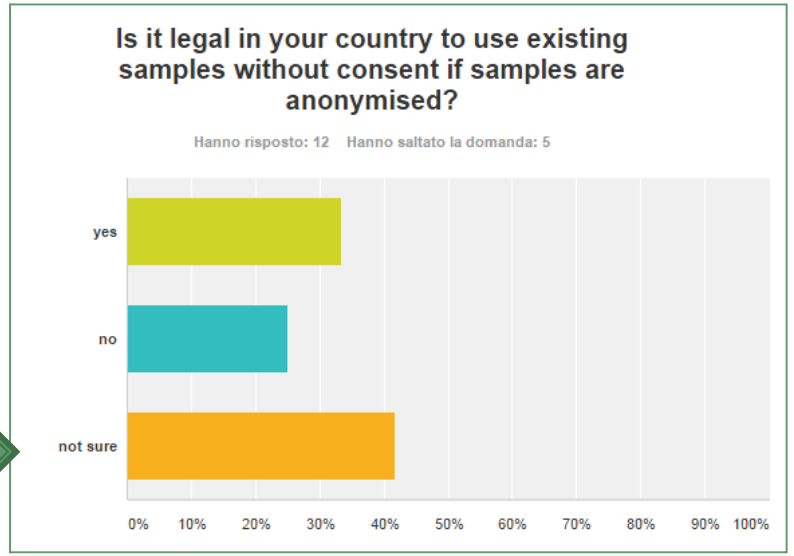




...the most ethically acceptable solutions where re-consent is impossible

Opzioni di risposta	Risposte	
A waiver of consent by the Research Ethics Committee (REC) or Institutional Review Board (IRB)	84,62%	11
Personal notification with the possibility to opt out (presumed consent unless the participant actively requests cancellation)	15,38%	2
Wide dissemination of the information through the work of patients associations and moral endorsement of these	15,38%	2
Anonymisation of data and/or samples	61,54%	8
Other (specify)	15,38%	2
Totale rispondenti: 13		





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SEVENTH FRAMEWORK
PROGRAMME

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NeuroOmics