ARTICLE

The policies of ethics committees in the management of biobanks used for research: an Italian survey

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Gaps in regulations pertaining to the collection and storage of biological materials in a biobank, at least in the European context, have made the writing of local guidelines essential from an ethical point of view. Nevertheless, until recently, the elaboration of local guidelines for the collection, use and storage of biological materials in a biobank has been the exception in Italy and all European countries. In this context, it is of value to know the policies, even if they are unwritten, of local ethics committees (ECs) engaged in the evaluation of research protocols involving biobanks and biological materials. This paper presents the results of a survey carried out among local Italian ECs (229) to document their attitudes and policies regarding the management of the ethical issues related to biobanks and the use of biological materials. A questionnaire was developed to investigate the areas regarded as critical from an ethical–legal point of view: informed consent and information to the subjects; protection of confidentiality; communication of research results; access/transfer of biological materials and related data; ownership of samples and data and intellectual property rights; and subjects' remuneration and benefit sharing. Twenty-six ECs from the Italian Institutes for Research and Care (62%) and 26 other ECs (14%) participated in the survey.

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INTRODUCTION

Developments in genetics have promoted large-scale genetic research efforts and the creation of large biological banks at international, national and local levels.

The scientific value of biobanks is evident in that increases in genetic knowledge arise from the possibility of using larger numbers of biological samples and the planning of future studies using those same samples that are not conceivable today. The creation of biobanks also has implications for human-value issues in that the progress in biomedical science and practice, which also depends on research involving the use of human biological materials, may contribute to fighting diseases and improving the quality of human lives.

Nevertheless, the creation and management of biobanks raise profound ethical and legal issues concerning informed consent, confidentiality, ownership of biological materials (and related information), access to the bank, commercial interests and discriminatory use of research results.^{1,2}

The ethical sensibility towards the issues raised by the creation and management of biobanks and by biological research has greatly increased in recent years; however, regulations concerning the storage of human biological materials and genetic data are still evolving in most European countries, and there are many variations in the definitions, scope and purpose of guidelines and legal instruments in Europe.³ The legal and regulatory frameworks that apply to biobanking are fragmented, and the development of common guidelines is crucial.²

The need of a regulatory system for biobanks is clear from the efforts made by the main bodies and societies addressing research on

biological materials in different countries. Regarding the situation in Italy, the documents and guidelines elaborated by the National Bioethics Committee (Comitato Nazionale per la Bioetica), National Committee for Biosafety, Biotechnology and Sciences of Life (Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita), Italian Society of Human Genetics (Società Italiana di Genetica Umana) and Telethon Foundation (Fondazione Telethon)⁴ should be remembered, in addition to those of the Italian Data Protection Authority's General Authorisation for the Processing of Genetic Data (2007, revised in 2011 and 2012).⁵

Furthermore, within the Italian hub of BBMRI – ERIC (Biobanking and Biomolecular Resources Research Infrastructures – European Research Infrastructure Consortium) set up at the Italian National Institute of Health,⁶ whose mission is to activate any initiative necessary for the coordination of the Italian biobanks participation to the European consortium, a working group has been established to discuss and suggest solutions to the legal and ethical issues associated with the management of biobanks.

Gaps in regulations pertaining to the collection and storage of biological materials in a biobank, both in Italy and in the European context, made the writing of local guidelines essential from an ethical point of view. Nevertheless, until recently, the elaboration of local guidelines for the collection, use and storage of biological materials in a biobank has been the exception in Italy and all the European countries.

Thus, it is of value to know the policies, even if unwritten, of local ethics committees (ECs) engaged in the evaluation of research protocols involving biobanks and biological materials.

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In this paper, we present the results of a survey conducted among Italian ECs, documenting their attitudes and policies regarding the management of ethical issues related to biobanks and the use of biological materials.

METHODS

Survey

A questionnaire-based survey was conducted among local Italian ECs. The first phase of the survey ranged from December 2009 to June 2010 and involved the ECs (42 for 43 institutes) of the Italian Institutes for Research and Care (IRCCS) that are recognised by the Italian Ministry of Health as national institutes of excellence. From November 2010 to June 2011, the survey was extended to all the other ECs (187) included in the register of the Italian Medicine Agency as of 29 October 2010.

The questionnaire was submitted to the Italian ECs by e-mail; the IRCCS ECs answered the questionnaire during a telephone interview with the EC chief or her/his delegate, whereas the other EC chiefs or delegates were asked to complete the questionnaire and return it by e-mail (with the option of a telephone interview). The person in charge of answering the questionnaire was asked to refer to the policies of her/his EC that, where not written, could be inferred from the opinions previously given by the EC on research protocols involving the use of biological materials and biobanks. For the aspects on biological material management not previously taken into consideration by the EC, no answer was provided.

The present study was favourably reviewed by the IRCCS Fatebenefratelli EC.

Questionnaire

The questionnaire was developed by identifying areas related to the management of biobanks that are regarded as critical from an ethical-legal point of view and by taking into consideration analogous instruments used in European research projects,⁷ primarily the BBMRI Supplementary Questionnaire Legal, Ethics and Governance.

The questionnaire is organised into the following areas: informed consent and information provided to the subjects; protection of confidentiality; communication of research results; access/transfer of biological materials and related data; ownership of samples and data and intellectual property rights (IPR); and subjects' remuneration and benefit sharing. Essential information regarding the ECs taking part in the survey was also collected.

The initial version of the questionnaire was tested for face validity through submission to five researchers and four ECs asked to comment on the clarity of the questions. A final version of the questionnaire was developed after the test and used in the survey.

Italian ECs

The ECs included in the registry of the Italian Medicine Agency (a body working on the basis of the Italian Ministry of Health directives) were involved in the survey. The Italian ECs are independent bodies set up in local health units, hospitals and institutes that are public or, as for private IRCCS, equivalent to the public.

There is no difference between IRCCS ECs and the other ECs in terms of role, composition and normative framework. Their task regards, but is not limited to, the evaluation of clinical trials with medicinal products for human use under the Directive 2001/20/EC.⁸ Their role may also include the evaluation of all other kinds of biomedical research. The differences in the activities between IRCCS ECs and the other ECs are mainly due to the different amount and type of biomedical research performed in the hospitals/institutes of reference, IRCCS being the national institutes of excellence for translational research and cure.

RESULTS

Twenty-six IRCCS ECs (62%) and 26 of the other ECs (14%) took part in the survey. Four of the other ECs completed only the section on EC information, declaring that they are not involved with research protocols on biological materials; these ECs were not included in the data analysis. We received answers from 67% of the private IRCCS

ECs and 53% of the public IRCCS ECs. Survey participation varied across the country, with 71% of IRCCS ECs and 22% of the others ECs in northern Italy taking part in the survey, whereas 44% of IRCCS ECs and 13% of the others ECs participated in central Italy. In southern Italy, 56% of IRCCS ECs and 5% of the others ECs participated (Table 1). According to a logistic regression, the acceptance rate was significantly related to the type of institution (greater in IRCCS, $P < 0.001$) and geographical location (greater in northern Italy compared with central Italy, $P = 0.064$, or southern Italy, $P = 0.004$). To take into account the potentially biasing effect of type of institution, we stratified the analysis by type of institution. As concerning the effect of geographical location, we should bear in mind that institutions located in southern Italy are under-represented.

The number of biobanks is greater in IRCCS (77%) than in other centres and hospitals (41%). The ECs always had a role in the evaluation of research protocols on biological materials (100%) and, in half of the cases, also had a role in monitoring the research. To give opinions on the transfer of biological materials was a task for 20 ECs (42%), whereas 11 ECs (23%) provided opinion on the use of samples without informed consent. Even though not required by the current Italian regulation, 24 (50%) of the ECs include a geneticist or another expert in research on biological materials as a regular member of the committee, and other 7 ECs (15%) always or sometimes involve an external expert when discussing research protocols on biological materials.

Informed consent and information provided to the subjects

The ECs were asked which type of informed consent for research on biological materials they regard as suitable (more than one option could be selected). The different types of consent⁹ included the following options: (1) broad consent, which allows the use of biological specimens and related data for current research and future investigations of any type at any time; (2) partially restricted consent, which allows the use of biological specimens and related data for specific current research and future investigations directly or indirectly associated with current projects; (3) multi-layered consent, which requires several options to be explained to the research subject in a detailed form; (4) specific informed consent, which allows the use of biological specimens and related data only for current research and forbids use for any future study that is not foreseen at the time of the original consent; and (5) presumed consent.

The IRCCS ECs show a clear preference for partially restricted consent (50%) followed by multi-layered and specific consent (35%), whereas the large majority of the other ECs expressed a preference for specific consent (73%). Broad consent is regarded as acceptable by a low number of ECs (8%), as is presumed consent (4%) (Table 2). The differences between IRCCS and other ECs were statistically significant for partially restricted consent (higher in IRCCS ECs, $P = 0.049$) and specific consent (higher in other ECs, $P = 0.008$). For the use of

Table 1 Number of participating ECs (four of the other ECs only completed the section on EC information)

	IRCCS ECs			Other ECs		
	Accepted	Invited	% Acceptance	Accepted	Invited	% Acceptance
Northern	17	24	71%	18	83	22%
Central	4	9	44%	5	38	13%
Southern	5	9	56%	3	66	5%
Italy	26	42	62%	26	187	14%

Table 2 Models of informed consent

	<i>IRCCS ECs</i> (<i>N</i> = 26)	<i>Other ECs</i> (<i>N</i> = 22)	<i>Total</i> (<i>N</i> = 48)
Broad consent	3 (12%)	1 (5%)	4 (8%)
Partially restricted consent*	13 (50%)	5 (23%)	18 (38%)
Multi-layered consent	9 (35%)	3 (14%)	12 (25%)
Specific consent*	9 (35%)	16 (73%)	25 (52%)
Presumed consent	1 (4%)	1 (5%)	2 (4%)

*Indicates items with significant ($P < 0.05$) differences between IRCCS ECs and Other ECs.

Table 3 Key information for informed consent

- Location of biological materials collection
- Type of biological materials taken for purpose of research or a biobank creation
- Purpose for which biological materials will be used
- Solidarity and voluntary character of the participation
- **Right to withdraw consent to the use of samples**
- **Right to withdraw consent to the use of data**
- Authorisation to be recontacted
- Authorisation to contact family members
- Duration of the storage
- Communication of research results
- **Rules to protect subjects' privacy**
- Independent ethics committee review
- Information on samples property
- Information on intellectual property rights and patents
- Prohibition of the commercialisation of samples and related data
- Benefit sharing
- Transfer of samples and related data to other research institutes
- Access to samples and data from external researchers
- Destiny of samples and data after donor's death
- Destiny of samples and data in case of advanced research conclusion

Options chosen by >75% of ECs are in bold; options chosen by 51–75% of ECs are underlined; options chosen by 26–50% of ECs are in normal type; and options chosen by <25% of ECs are in italics.

samples in investigations not included in the original IC form, almost all ECs (90%) ask for re-contacting the subjects.

Table 3 shows the type of information ECs ask being provided to subjects when consent is collected. The possibility for subjects to withdraw consent to the use of samples is required by 98% of ECs. In EC's view, withdrawal of consent leads to sample destruction (75%), prohibition to use the sample in new research (51%) or sample anonymisation (27%).

Protection of confidentiality

Regarding samples and data processing to protect subjects' right to privacy, the Italian ECs primarily ask for the use of a single (55%) or double (40%) code when biological materials are used within the centre that collected the samples, while the request for anonymous use of samples (ie, the irreversible removal of the link with the donor) increases in cases in which research is performed by researchers belonging to other for profit or not for profit organisations (Table 4). In particular, the exclusive option of non-identifiable biological materials was chosen by four ECs (none of them IRCCS ECs) for samples used within the centre and 13 and 14 ECs for the use of samples by not for profit and for profit organisations, respectively.

Table 4 Privacy protection

	<i>Internal use</i> (<i>N</i> = 47)	<i>Not for profit organisations</i> (<i>N</i> = 43)	<i>For profit organisations</i> (<i>N</i> = 43)
Anonymous samples	10 (21%)	17 (40%)	16 (37%)
Double code	19 (40%)	12 (28%)	15 (35%)
Single code	26 (55%)	18 (42%)	14 (33%)

Table 5 Communication of research results

	<i>Research results of general value/yes, N = 26/48 (54%)</i>	<i>Individual results/yes, N = 23/47 (49%)</i>
Web site	4 (15%)	
Direct contact	12 (46%)	
Publication	14 (54%)	
Any type of individual results		9 (39%)
Only health relevant individual results		13 (57%)

Table 6 Conditions for the access to samples and data. Thirty-five ECs answered the question as not for profit and 31 ECs answered for profit

- Access fee (3%; 14%)
- Co-authorship (46%; 26%)
- Citation of biobank in scientific publications (57%; 42%)
- Communication of results to the institute that collected the samples (31%; 36%)
- Return of the remaining biological materials (26%; 26%)
- Destruction of the remaining biological materials (23%; 32%)
- Only anonymous samples and data can be transferred (37%; 42%)
- Only coded samples and data can be transferred (37%; 39%)
- Sharing of possible patents (29%; 19%)

The percentages for not for profit and for profit are given in the brackets.

Communication of research results

Management of research results and communication of findings to the donors are planned by the ECs as follows: 54% of ECs require the communication to the donors of research results of general value either through direct contact or publication, and 49% of ECs require the communication of individual research results to the single subject with a preference (57%) for the communication of results that are relevant for the donor's health (Table 5).

Access/transfer of biological materials and related data

The ECs were asked about access to samples and data by researchers who are not related to the centre that collected the biological materials. The large majority of ECs that answered the question (44/48), regards as possible the access to samples and data from both not for profit (73%) and for profit organisations (71%). A preference for national (100%) or EU researchers (97%) over non-EU researchers (90%) was expressed by the 38 ECs that provided an answer to this question. The access/transfer of biological materials and related data is subject to conditions for both not for profit and for profit organisations; these conditions are primarily regarding referencing the biobank in publications, co-authorship, privacy protection and returning results to the biobank (Table 6).

Subjects' IPRs, remuneration and benefit sharing

Regarding the economic aspects of participating in collections of biological materials, we took into consideration subjects' remuneration, subjects' IPRs and benefit sharing between research sponsor and donors/community (in this case, the benefit is intended as a good that contributes to the well being of an individual and/or given community that is not identical with profit in a monetary or economic sense). Subjects' remuneration is allowed by 27% of IRCCS ECs and 18% of the other ECs, which consider remuneration exclusively as a flat refund and refund for documented expenses. Regarding IPR, the majority of ECs that discussed the matter (18 out of 26 IRCCS ECs and 15 out of 22 other ECs) regards the renouncing of the donors' IPR as acceptable (73%); the donors' reservation of IPR is regarded as acceptable by a minority of ECs (30%). One EC asks for a form of benefit sharing, specified as the possibility to access innovative treatments (Table 7).

DISCUSSION

The constitution and management of biobanks gives rise to ethical issues that deserve to be discussed, both theoretically and involving interested parts, as it is testified also by studies carried out through interviews with investigators and participants.¹⁰

The Italian Data Protection Authority's General Authorisation for the Processing of Genetic Data is in Italy the only legal document with specific relevance to biobank research. Other legal provisions¹¹ related to clinical trials, informed consent and research ECs, largely resulting from European directives implementation, focus on trials with medical products and can only partially be adapted to cover genetic research and biobanking. Given the lack in the country of biobank regulation on one hand and the increasing number of biobanks and genetic research on the other, it is worth understanding how the matter is regulated in actual research situations. This knowledge can also be useful when considering writing guidelines grounded both in values and in practice, which can contribute to the creation of a consistent and coherent ethical and legal framework for biobanks, within the country and in the European context, able to increase opportunities of research both of high scientific quality and promoting participants' fundamental rights.²

ECs, tasked with evaluating research protocols, can contribute to the understanding of the present situation. For this reason, we conducted a survey among local Italian ECs to document their attitudes and policies, even if unwritten, on the ethical-legal aspects of biobanks and research on biological materials.

EC survey participation

The global number of ECs that answered the questionnaire (52) was not high. This can be interpreted as lack of interest in the matter because of either the fact that not all ECs are involved in evaluation of research protocols on biological materials or an underestimation of the ethical issues related to biobanks. Difficulties experienced by ECs in developing clear policies for research on biological materials, given

the lack of strict regulation in the country, cannot be excluded as a deterrent for responding to the survey. The ECs that responded to the questionnaire can be regarded as only partially representative of the Italian ECs; this was a limitation of the study. Nevertheless, we consider the survey results significant, in that they most likely reflect the status of thinking of the Italian ECs on the matter, because of the distribution of answers, both in terms of rate of IRCCS ECs and other hospitals' EC participation and in terms of geographical location. Italian IRCCSs which are dedicated to research for institutional mission, and consequently their ECs, are in fact expected to be in the forefront of biomedical research and reflections on that. As attended, these ECs exhibited a greater interest and sensibility for the ethical aspects of biomedical research, that increase in private institutes, maybe also for the religious characterisation of part of them. Moreover, the higher rate of participation of ECs in northern Italy compared with central and southern Italy is not unusual and seems to reflect a general attitude of the country.

Areas under investigation

Information and informed consent procedures. In the health research context, informed consent is a fundamental ethical requirement to guarantee subjects' right to autonomy and self-determination in all kinds of research, be it medical, biological or genetic. The donor's consent request (subject to the prior supply of adequate information) is not a mere formality, as it has a legal value; but, more, it does testify to a respect for others, even in the biological and genetic research fields, implying that the enrolled subjects are considered to be persons who are thereby not reduced to being solely an 'experimental tool'.¹²

Nevertheless, a difference exists in the literature on the importance attributed to informed consent in research using biological materials compared with research carried out directly on human subjects. The reason for this is related to three major factors: the low risk of direct physical harm involved in biological research; the possibility for using the materials in an anonymous way; and the opinions and attitudes of donors themselves, who occasionally do not perceive informed consent as an important issue and do not read information provided to them.¹³

However, in a certain sense, informed consent in genetic research can be regarded as more important than in other fields of research in humans. In fact, genetic research poses only a minimal physical risk for the subject, but it can lead to obtain a greater number of private information than other types of clinical experiments. This is a matter of great importance, even apart from the use that can be done of that information.¹²

Informed consent is a complex issue, as it involves understanding of information, appreciation, reasoning and ability to express a choice.¹⁴ IC is even more problematic in the context of genetic research and research using biobanks in which full information becomes difficult because of the rapid evolution of research methods and opportunities.

We asked the ECs what informed consent model they regard as suitable for research on biological materials among the four models of informed consent for biobank-based research characterised in international ethical and legal documents⁹ with the addition of presumed consent. The question focused on biological materials collected for research purposes, while the secondary use for research of samples collected for health safeguard is under the Italian Data Protection Authority's General Authorisation for the Processing of Genetic Data that requires subjects' informed consent or, in case IC is impossible, the use of non-identifiable samples or the EC's favourable opinion on

Table 7 Remuneration, benefit sharing and IPR

	IRCCS ECs	Other ECs	Total
Remuneration	7/26 (27%)	4/22 (18%)	11/48 (23%)
Benefit sharing	0/26 (0%)	1/22 (5%)	1/48 (2%)
Donors renouncing IPR	14/18 (78%)	10/15 (67%)	24/33 (73%)
Donors reserving IPR	5/18 (28%)	5/15 (33%)	10/33 (30%)

the research protocol along with the Data Protection Authority's authorisation.

Italian ECs placed great importance on the issue of informed consent, with both broad consent and presumed consent having very low support. In contrast, specific consent and partially restricted consent were chosen as suitable forms of informed consent by 52% and 38% of the ECs, respectively. Interestingly, partially restricted consent was the first option for IRCCS ECs, whereas specific consent was the first option for the other ECs. These attitudes are maybe because of the different quantity of research and different level of research specialisation occurring in national institutes of excellence compared with other hospitals. IRCCS research presumably requires a type of consent that provides the opportunity for the use of samples in future research that may not be fully declared at the moment of collection but that may arise following the rapid discovery and evolution of methodologies.

Protection of confidentiality, communication of research results and access to samples. Protection of confidentiality is a very notable point in the managements of biobanks. It is recognised that the degree of data protection is closely linked to questions of withdrawal from a research project, dissemination of results to participants (generally or individually), follow-up with participants and third-party access to research data.¹⁵ Disorganised management of these elements can lead to contradictions or practical impossibilities. On the contrary, a good planning can promote, from the one hand, subjects' autonomy and well being through the respect for private life, subject's control on her/his samples and the possible benefits coming from knowing individual research results, and, from the other hand, social justice through the maximisation of opportunities of research and therefore of possible benefits for the society at large.

ECs primarily prefer the use of single or double code to sample anonymisation, mainly when samples are used within the centre that collected them. This can be because of the questionable value of samples coming from non-identifiable donors,¹⁶ but also the choice of guaranteeing the subjects' option to withdraw from research (required by almost all ECs) and be informed of research results (required by half of the ECs). Withdrawal results in the destruction of the samples for the large majority of ECs, while anonymisation is an option but never the exclusive one. This is in line with the European Rec 2006,¹⁷ which states that the subject who withdraws consent has the right to have the materials either destroyed or rendered unlinked anonymized; however, this solution is questioned by authors who argue that the stability of biobanks is not compatible with the destruction of biological materials but only with their anonymisation.¹⁸

It is worth noting that the access/transfer of biological materials was regarded as possible by the large majority of ECs. This is in line with European guidelines that recognise the need to maximise the possible research benefit coming from the use of biological materials through maximising collaborative high-quality research¹⁹ while avoiding the problem of having biological materials donated in a spirit of solidarity being monopolised by small groups of researchers.¹⁷

Commercial exploitation and benefit sharing. In the European regulation on biological materials, an evident asymmetry can be traced between the fact that on one hand, human subjects should provide biological materials in a spirit of altruism and solidarity, and on the other hand, individuals and bodies that use the subjects' biological materials can have a legitimate gain resulting from the use

of those materials. As a general rule, the European legal and ethical framework stresses the principle of prohibition to commercialise the human body and its constituent parts. Nevertheless, this general rule does not prevent the possibility of payment for legitimate scientific or technical services rendered in connection with the use of biological materials;²⁰ applications for patents resulting from the use of biological materials;^{21,22} a logic of voluntary and unpaid donation for individual and of economic reward for industry;²³ and marketing authorisation for human tissue-engineered products.²⁴

Regarding the economic aspects of taking part in biological material collections, the general attitude of ECs is to regard the participation in research on biological materials as a voluntary enterprise characterised by a spirit of donation: ECs prefer for subjects to renounce IPR, and remuneration, if any, is accepted only in form of refunds for expenses. Finally, survey results demonstrated that ECs did not elaborate on the issue of benefit sharing. This is a point deserving more attention by ECs: benefit sharing could be a good solution for maintaining the subjects' spirit of altruism and free donation on one hand, whereas solving the asymmetry mentioned above between subjects' unpaid donations and third parties' legitimate gain on the other. The elaboration of a plan for benefit sharing can contribute to foster justice in biomedical research.

CONCLUSIONS

We presented the results of a survey conducted among Italian ECs to document their policies on the ethical aspects of biobanks and research using biological materials. The results are intended to contribute to the understanding of the present situation in Italy; they may also be useful in view of writing guidelines grounded both in values and in practice.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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