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REGULATING SCIENTIFIC RESEARCH: A CONSTITUTIONAL MOMENT?

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AUTHOR's VERSION BEFORE PUBLICATION

ABSTRACT: This article discusses how and to what extent a transnational societal constitution for science is emerging. It outlines how specific norms and rules secure the autonomy of science (the 'constitutive function') as well as define the limits of the operations of science with respect to other social systems and the individuals in their environments (the 'limitative function'). It also discusses to what extent complex trends and dynamics in the current science system can be understood in terms of a constitutional recalibration, in which the unleashed dynamism of scientific and technological innovation is counteracted by a varied array of norm-producing initiatives, such as the increasing importance of ethics bodies in research, public engagement strategies, and initiatives aimed at 'open science' and 'responsible research and innovation'.

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INTRODUCTION

The emergence of modern science is tied up with an extension of the social space of the pursuit of knowledge for its own sake. This means disputes and questions for knowledge are resolved by reference to observation and theory and without resorting to arguments about the desirability of particular outcomes from a political, religious, or any other extra-scientific point of view. The early demarcation between science and other societal spheres, was drawn in the seventeenth-century scientific academies like the Florentine *Accademia dei Lincei* (1603) or the London *Royal Society* (1662)). Although the seventeenth century was also a period of frequent disputes between science, politics and religion (e.g. the appearance of Galileo's *Dialogo* (1632)), the academies provided a first blueprint for scientific communication, operating relatively disengaged from religious and political preoccupations. By mobilizing themselves around a conception of distinctive methods for scientific activity (primarily experimentation) and focusing on the production of new knowledge ('innovation') - instead of guarding and commenting on the old one -, academic scholars were able to generate a convincing organizational alternative for the hierarchical universities, and could present themselves to the rest of society as a distinct community.[1] In the centuries that followed, the idea of scientific research focusing on the production of new, yet socially corroborated knowledge, slowly but surely, became the province of the professional figure and social role of the 'scientist' (a term first used by William Whevell in 1833 to describe the participants at a meeting of the British Association for the Advancement of Science).[2] With the institutionalization of the modern 'research' university (itself dependent upon government patronage, or, alternatively, funding by the private sector), universities provided the main organizational form in which the practice of science could become a full-time career - by providing wages, fusing research with teaching, and allowing (ironically) the historic prestige of universities as centers of scholasticism to valorize the new science.

The autonomy science acquired in the nineteenth century, soon led to the insistence on 'academic freedom', or the professional autonomy of the 'academic scholar' to freely define the objectives and approach of his or her research.[3] It is to be noted that, as a fundamental right, academic freedom guards the individual autonomy of the scholar, but also facilitates functional differentiation of societal systems, in this case, protecting science against unwanted intrusions from politics, economics or religion.[4] Characteristically, individual academic rights became balanced by academic duties and got embedded in the 'ethos' of the academic community, which had the potential to regulate, restrict or sanction academic behavior, thereby interfering with individual academic freedom. The professional autonomy of academics was in turn buttressed by the autonomy of the university, its freedom from political or other interference and its autonomy to hire whomever fits its professional criteria.[5] In a limited number of countries, such as Germany, academic freedom became undergirded by written, constitutional law. The modern German constitution, for example, includes

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[1] S. Shapin, *The Scientific Revolution* (1996) 131-135.

[2] M. Bucchi, *Science in Society. An introduction to social studies of science* (2004) 12.

[3] J. Ben-David, *The Scientist's Role in Society. A Comparative Study* (1971).

[4] N. Luhmann, *Grundrechte als Institution. Ein Beitrag zur politischen Soziologie* (1965); G. Verschraegen, 'Human Rights and Modern Society: A Sociological Analysis from the Perspective of Systems Theory' (2002) 29, *Journal of Law and Society* 258.

[5] M. Tight, 'So what is academic freedom?' In *Academic freedom and responsibility*, ed. M. Tight (1988); E. Shils, Academic Freedom and Permanent Tenure, (2004) 33, *Minerva* 5.

an important paragraph on "freedom of research"[6], which is mostly interpreted as a reaction against the subordination of science under the Nazi regime.[7] Although different historical experiences led to various normative configurations (constitutive rules, laws and codes shaping how scientists work), early modern science mostly functioned according to the model of Polanyi's self-governing 'Republic of Science'.[8]

It is only in the second half of the twentieth century that regulation of scientific research and innovation becomes increasingly formalized and caught up in a real frenzy of normative regulation. Especially in the last decennia, several initiatives aiming at formalising a set of research-related rights, codes and principles have emerged, deriving both from professional associations, states, intergovernmental or regional organisations like the EU, epistemic communities or NGO's. Different reasons can account for this. As scientific research and innovation becomes more strongly intertwined with economic production and innovation, medical diagnosis and treatment, or even, political accountability, there is an increasing recognition and negotiation of the responsibilities of scientists beyond those associated with their academic professional roles. Faced with new lines of scientific and technological research such as nanotechnology, synthetic biology or human genomics, the power of science and technology to produce both immense benefit and catastrophic harm is recognized. Regulators and policy-makers are confronted with scientific and technological promises as well as their attended risks and face the paradox of enabling the dynamics of scientific innovation as well as protecting ourselves against it.[9] At the same time, several threats are posed to the academic freedom and the professional autonomy of researchers. In fact, several constitutional concerns have been raised with regard to traditional academic freedom : from the freedom of expression and association to the right to access data, from harassment and censorship to indirect political influencing, from the pressure to commercialize data to biasing research in order to reciprocate financial sponsors.[10]

This whole set of challenges, and their increasing scale, is urging new and varied forms of constitutional responses. In this article, I aim to explore the contours of what can be called 'a societal constitution' for science. I will outline how specific norms and rules secure the autonomy of science (the socalled 'constitutive function') as well as define the limits of the operations of science with respect to other social systems and the individuals in their environments (the 'limitative function').[11] I will also discuss to what extent complex trends and dynamics in the current science system can be understood in terms of a constitutional recalibration, meaning that the unleashed dynamism of scientific and technological innovation is exposed to and counteracted by a varied array of norm-producing initiatives, such as the increasing importance of ethics bodies in research, public engagement strategies, and initiatives aimed at 'open science' and 'responsible research and innovation'. Although this group of initiatives remains inchoate, they seem to attest to the

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[6] Art. 5 German Basic Law

[7] See P.G. Altbach, 'Academic freedom: International realities and challenges' (2001) 41, *Higher Education*; J. Vrielink, et.al., 'Academic Freedom as a Fundamental Right' (2011) 13, *Procedia Social and Behavioral Sciences* 117–141.

[8] M. Polanyi, 'The Republic of Science: its political and economic theory' (1962) 1, *Minerva*.

[9] See, for instance, S. Jasanoff, *The Ethics of Invention. Technology and the Human Future* (2016).

[10] See, for instance, Altbach, op. cit., nr.8.; Vrielink, et.al, op. cit, nr.8; J. Lexchin, 'Those who have the gold make the evidence: how the pharmaceutical industry biases the outcomes of clinical trials of medications' (2012) 18, *Sci Eng Ethics*.

[11] G. Teubner, *Constitutional Fragments. Societal Constitutionalism and Globalization* (2012) 75-88.

recalibration of old agreements concerning the autonomy of science and its relations with its societal environment, in particular politics, law and the economy. In this sense, these initiatives can be seen to perform some of the fundamental functions of constitutionalism in the science system, by producing acts directed to the establishment and protection of the freedom of research, keeping check of the harming effects of scientific research on individuals' body and mind as well limiting the effects of money, power and other media on the proper functioning of science.

The remainder of this article is structured as follows. I start by briefly reviewing the main structures of the modern science system as it emerged in the nineteenth century, highlighting how science's autonomy was realized without much legal support. I then provide an overview of the 'normative infrastructure' of the global science system and discuss the contours of an emergent, though fragmented transnational constitution for science.

SCIENTIFIC COMMUNICATION AND PROFESSIONAL SELF-REGULATION

As historians and sociologists of science have noted, the modern system of science gets its most important features in the course of the nineteenth century, during which it emerges as one of the global function systems of society.[12] A number of interrelated structural evolutions and innovations are important to mention here. Already in the previous centuries scientific communication started to differentiate and self-organize as 'cognitive criteria' increasingly began to operate as a selector of possible meanings, irrespective of normative considerations (just think about Enlightenment imperatives such as skepticism and critical spirit). This provided scientists with the possibility to come up with provisional interpretations or hypotheses that they may wish to change after learning or 'falsification'.

Yet, it took inventions such as the scientific journal and the modern citation before science could turn into a self-referential system of scientific communication, oriented to the self-proclaimed 'accumulation of scientific knowledge'. By accepting or rejecting the specific knowledge claims in each paper under review knowledge claims can be sorted under the specific code of science, taking into account the current state of knowledge.[13] Truth claims can be evaluated by academic colleagues through formal peer review, and then be circulated within the academic community in the form of publications. On the basis of these publications, the internal scientific communication differentiates between 'old' and 'new' knowledge.[14] In other words, science becomes oriented to the practice of 'research'; ever since the late 18th century and the invention of the 'research university', scientific researchers are normatively expected to 'do research', that is, contribute to the production of novelties. Hence, the open-ended notion of the future becomes a hallmark of science and broader scientific culture, with its problem oriented, skeptical and critical character.

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[12] For a good overview, see R. Stichweh, *Wissenschaft, Universität, Professionen* (1994); for a good case-study, see R. Stichweh, *Zur Entstehung des modernen Systems wissenschaftlicher Disziplinen: Physik in Deutschland 1740–1890* (1984).

[13] See Y. Fujigaki, 'Filling the Gap between Discussions on Science and Scientists' Everyday Activities: Applying the Autopoiesis System Theory to Scientific Knowledge.' (1998) 37, *Social Science Information*, 5.

[14] N. Luhmann, *Die Wissenschaft der Gesellschaft* (1990) 220.

The notion of research is also connected to methods, which allow first-order observations of empirical reality to become oriented towards the binary true/false code; only first-order observations that have been gathered in a 'methodologically correct' way can be retained for future scientific communication.[15] In order to cope with external complexities, the system of science increases its internal complexity, mainly by differentiating itself into the form of 'disciplines' (and 'subdisciplines'), which can be considered the most basic unit of the internal social differentiation of science.[16] Over time, scientific subdisciplines become increasingly numerous and specialized by absorbing knowledge from the outside through highly specific frames and knowledge procedures, used to sort, categorize and reconstruct its knowledge in ever smaller fields. While early scientific communities and specialist disciplines were organized on a national basis and mainly communicated through national journals, from the second half of the 19th century national communities of specialists are step by step transformed into global research communities.[17]

What is striking, when one compares this piecemeal differentiation process of the global science system with that of other function systems, is the important role of professional self-regulation and the relatively small importance of law. Partly because specialized science is hardly understandable to outsiders, it is the professional or academic community that structures the largely informal communication serving to develop research designs, organise processes of research, or evaluate other research results and truth claims. The importance of informal communication between insiders has led Luhmann to conceive of 'scientific reputation' as a secondary code next to truth/untruth.[18] This means that publications are not only evaluated by academic peers as a contribution to a disciplinary stock of knowledge, they are also considered in the social dimension as an achievement of the respective author(s), which, in turn, adds to his/her/their reputation. "The attribution of reputation takes place in the informal communication system, where it can be found in face-to-face situations in the form of appreciation towards renowned colleagues, as well as in the formal communication system in the form of citations."[19] Both institutionalised forms of recognition serve to steer attention in the sense that "it guides members of a discipline towards relevant topics as well as towards the most competent colleagues in that discipline. It acts as a 'symptom for truth' and pre-determines the flow of information insofar as it increases the chances of being noticed and thus being recognized by members of the discipline. Trust in the reliability of the internal scientific evaluation and the recognition of the reputational hierarchy depend on and strengthen each other".[20]

It is thus primarily the scientific community that has the potential to regulate, restrict or sanction academic behavior. To get published one needs to follow the methodological rules or theoretical presuppositions that are commonly accepted by academic peers. To get a job in academia, or to get resources for research projects, one is judged and 'certified' by peers based on professional academic criteria. Once in an academic position, one can start observing and judging others, whether in academic recruitment or in publishing. So, one can argue that this system primarily functions by

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[15] Luhmann, op.cit, nr.16, 413-415.

[16] Stichweh, op.cit, ch.3.

[17] R. Stichweh, Science in the System of World Society, (1996) 35 *Social Science Information*.

[18] Luhmann, op.cit, nr.16, 245-251.

[19] N. Taubert & P. Weingart, Changes in Scientific Publishing. A Heuristic for Analysis, In: *The Future of Scholarly Publishing: Open Access and the Economics of Digitisation*. Weingart P, Taubert N (Eds), 3.

[20] Taubert & Weingart, op. cit., nr.22, 3.

relying on professional self-organisation. It is true that this self-governance has been enabled and buttressed by law, but, as Gunther Teubner argues, until now, science has had little need for law.

> "Methodology, the philosophy of science, and epistemology are themselves capable of hammering in the boundary stakes that mark out the realm of science. Despite all the worrying phenomena of corruption in the academic world, its superfluous to attach a legally binding self-description to science as a collective qua scientific community, or even for the scientific community to be incorporated in parallel to the formal organization of the state in order to secure the scientific credentials of knowledge. The law plays thus a relatively small role in the scientific constitution. Although law is needed to guarantee the freedom of science and to secure the formal organization of universities, science basically has arrived at its autonomy without legal support"[21]

THE NORMATIVE AND LEGAL INFRASTRUCTURE OF THE SCIENCE SYSTEM

Science may not have required law for realizing its own autonomy, it has, like all function systems, a need for constitutive norms, rules and procedures stabilizing expectations and clearly distinguishing between permissible and impermissible practices. Although the modern system of science has specialized in building and testing cognitive expectations, it is built on an infrastructure of rules and norms. This infrastructure contains both methodological and procedural rules circumscribing how everyday research should be conducted, more formalized, juridical rules pertaining to the organization of science and universities, as well as a more general normative system, which one might call the institutional 'ethos' of science.

One of the best and most influential descriptions of the latter was sociologist Robert Merton's 1942 paper on 'the normative structure of science'. [22] What values and norms of behaviour, enquired Merton, ensure the proper functioning of science? Written under the shadow of Nazism, Merton argued that the success of scientists in producing and extending socially certified knowledge depends, at once, on a functionally differentiated context (namely democracy, which allows science a measure of autonomy from political intrusions) and on an internal institutionalized ethos of values held to be binding upon the behavior of scientists. This 'ethos' or normative culture of the professional academic community comprised the famous four 'institutional imperatives' or main values of science:

1. *Universalism*. Scientific claims and results are to be judged regardless of the characteristics, such as class, race or religion, of their proponents. Scientists are to be rewarded solely on the basis of their results.

2. *Communism*. Results and discoveries are not the property of the individual researcher. Science is a collective endeavour, and the state of knowledge in a respective subject or field of research is the result of collective work. There is hence a need for a free public sharing and easy circulation of research results. Individual creativity must be recognised in the form of authorship, not ownership.

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[21] Teubner, op.cit, n.11, 108.

[22] Ch. 13 in T.K. Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (1973), 267.

3. *Disinterestedness*. Every researcher pursues the primary goal of the advancement of knowledge, indirectly gaining personal recognition.

4. *Organized scepticism*. Scientific claims should be exposed to critical scrutiny before being accepted. Researchers must be willing to subject all findings, including their own, to theoretical and methodological critique, suspending definitive judgement until the necessary proof has been obtained.

In enunciating these principles, Merton repeatedly emphasized the fact that they should be considered valid from a social structural-functional point of view, not from that of the scientist's individual motivations.[23] After all, if all scientists would usually conform to these norms, the latter would not be necessary. Behavior consonant with these mostly informal expectations is functional for the growth of scientific knowledge. For that reason young scientists are socialized into these norms through textbooks, precept and example; conformity will be rewarded, and transgressions met with moral denunciation. Although subsequent research suggested that these institutional norms were frequently violated and better conceptualized as 'ideological-rhetorical' professional repertoires [24], Merton's analysis did have the advantage of pointing to the highly specific normative infrastructure of modern scientific culture.

As Merton already suggested ("The norms are expressed in the form of prescriptions, proscriptions, preferences, and permissions"[25]), the institutionalization of science and the normative codification of the scientist's role takes place not only through informal communication. In the course of the twentieth century, an array of formalized or 'deontological' codes-of-conduct for the professional scientist sees the light. Especially in the field of bio-medical research, different national and international codes and guidelines were developed, often in response to public outrage and severe violations of the scientific ethos (as we now understand it). At the close of World War II, the 1947 Nuremberg Code was drafted as a response to the medical experiments performed under national-socialism. Interestingly, this Code implicitly hints at the earlier 'Nuremberg Laws' of 1935, which invoked hereditary principles elaborated in biological discourse, and constituted the broader legal framework enabling the state to categorize and treat citizens on the basis of the *racial* identity of their ancestors[26]. At the time, race science was "considered to be rigorous and authentic scientific research conducted by highly respected professional scientists"[27]. Yet, it was especially the eagerness of race scientists to put their insights into political action and the concomitant politico-legal adoption of race science by the Nazi regime which created a de-differentiation of science and made it into a deadly tool of ethnic cleansing.[28] The Nazi Regime eventually established thirty-three university research institutions and eighteen university professorships dedicated to 'racial hygiëne'.[29] Although

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[23] M. Bucchi, "Norms, competition and visibility in contemporary science: The legacy of Robert K. Merton", (2015) 15, *Journal of Classical Sociology*, 233–252.

[24] M. Mulkay, *Science and the Sociology of Knowledge* (1976)

[25] Merton, op. cit, nr. 24, 267.

[26] The Nuremberg Laws were issued in several installments, including the "Law for the Alteration of the Law for the Prevention of Hereditarily Diseased Progeny of June 26, 1935.; the "Law for the Protection of the Hereditary Health of the German People" of October 18, 1935; and the "Law for the Protection of German Blood and Honor" of November 26, 1935. See R. Grundmann, N. Stehr, *The Power of Scientific Knowledge. From Research to Public Policy* (2012) 71; GJ Annas

[27] Grundmann and Stehr, op.cit., nr.27, 70.

[28] Id.

[29] Id., 77.

later treatments of Merton's work have largely ignored the peculiar historical (and ideological) context of its formulation of science, his descriptions of the 'scientific ethos' formulated during the late 1930s and early 1940s were clearly written in response to the direct political interventions in science in National Socialist Germany.[30] The Nuremberg Code of 1947, in its turn, was drafted specifically in relation to the abuse of human experimental subjects by physicians during the Nazi regime. It is generally considered the first international framework regulating research conduct. Subsequent international codes were written to improve, specify and interpret this work[31]: in 1964 the World Medical Association's (WMA) drafted the Declaration of Helsinki[32], in 1993 the International Ethical Guidelines for Biomedical Research involving Human Subjects was drafted in cooperation by the Council of Medical Organizations of Medical Science (CIOMS) and the World Health Organization (WHO)[33], in 1997 the Council of Europe came up with the convention on human rights and biomedicine.[34] All declarations were designed to provide guidance for conducting research involving human subjects and have been regularly amended to take into account various evolutions within biomedical research. Because most of them are drafted by international organizations they have an explicit global reach. As much biomedical research involving humans is carried out in poorer or developing countries (to lower costs and take advantage of less demanding regulatory systems), they also aim to tackle the lack of legal protection for experimental subjects in countries with limited statehood, for instance by installing special obligations for the sponsors of research (e.g., they must engage in capacity-building in the host country to enable it to conduct independent ethical and scientific review).[35]

The most important and influential issue in the global codes for biomedical research is undoubtedly the principle of informed consent. The first principle of Nuremberg set forth the definition of informed consent that, with minor variations, has been incorporated in all subsequent codes and regulations.

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and

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[30] E. Mendelsohn, 'Robert K. Merton: The celebration and defense of science' (1989) 3, *Science in Context* 269.

[31] See R.J. Levine, Ethics and Regulation of Clinical Research, 2nd edn. (1988); B.A. Brody, *The Ethics of Biomedical Research. An International Perspective* (1998); U. Schuklenk, R. Ashcroft, 'International research ethics' (2000) 14, *Bioethics*, 158–72;

[32] World Medical Association, *Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects*. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

[33] Council for International Organizations of Medical Sciences, *International ethical guidelines for health-related research involving humans,* <https://cioms.ch/wpcontent/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf>

[34] Council of Europe, *Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, <https://rm.coe.int/168007cf98>.

[35] See R.J. Levine, 'Global issues in clinical trials'. In *Global Dimensions of Domestic Health Issues*. Eds. M. Osterweis, D.E. Holmes (2000) 119; E.J. Emanuel, et. al. 'What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research' 2004 (189) *The Journal of Infectious Diseases*, 930. For a broader discussion of societal constitutionalism in contexts of limited statehood, see G. Verschraegen, Hybrid Constitutionalism, Fundamental Rights and the State, (2011) 40 *Netherlands Journal of Legal Philosophy*, 216.

> comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.[36]

Soliciting informed consent has by now become a standard prerequisite to carry out research involving human subjects. In the course of the last decennia, the institutionalization of informed consent has been consolidated by a growing patients' rights movement, and a greater awareness of possible risks caused by medical research[37], which is partly caused by the proliferation of genetic information that has reshaped the assessment of risk and dangers.[38] As a consequence, numerous research and health care institutions now routinely demand informed consent for patient–biomedicine encounters, and many journals publishing biomedical research demand formal ethical clearance, which is mostly linked to informed consent procedures.

Another important evolution concerns the diffusion of 'ethics committees', 'institutional review boards', or 'research ethics boards', all with the task to assess the complementarity of research projects with human rights. Ethics committees were initiated in clinical and pharmaceutical research, but are increasingly present in other fields of research as well (where they are often known as 'institutional review boards').[39] Obviously, all research including interventions on a person, entailing the use of cells or tissues of human origin, or making use of personal data, can impact with the fundamental rights of a person participating in a scientific project. In order to protect these fundamental rights the Declaration of Helsinki recommended that an 'experimental protocol' should be 'transmitted for consideration, comment, and guidance to a specially appointed committee.' Since the eighties, 'ethics committees' have been established by a broad variety of organizations, including university hospitals, general hospitals, medical associations, or pharmaceutical companies. They are based on a variety of regulations, from professional deontological codes to formal public laws, with private law-making often preceding activities of parliaments or administrations, who have tried to respect and to overtake existing regulations.

From the point of view of societal constitutionalism, these written codes and procedures seem to form the building blocks of a sectorial constitution, if not for scientific research as a whole, then at least for biomedical research. One can observe an emergent transnational regime here, that produces legal norms performing 'constitutive functions' defining how scientific research should be conducted, as well as 'limiting functions' with regard to the integrity of individuals' minds and bodies. Research ethics committees, for instance, not only protect the rights of individuals participating in

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[36] Nuremberg Code, Principle 1. <https://history.nih.gov/research/downloads/nuremberg.pdf>

[37] R.R. Faden, T.L. Beauchamp, *A History and Theory of Informed Consent* (1986).

[38] R. Chadwick, K. Berg, Solidarity and equity: new ethical frameworks for genetic databases. (2001) 4, *Nat Rev Genet.* 318.

[39] On the diffusion of ethics research committees to the social sciences, see for instance, C.K. Gunsalus et.al., The Illinois White Paper. Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep" (2007) 13, *Qualitative Inquiry*, 617.

research, they also serve as effective ‘boarder guards’ protecting scientific institutions from wider public scrutiny by being, or at least, appearing responsive to broader public concerns.[40]

This emerging transnational space of law is a complex ‘assemblage’ of levels, structures and organisations, in which private norm-making is increasingly coupled to public law-making, allowing for mutually reinforcing co-evolutionary processes.[41] The Declaration of Helsinki, for instance, was issued by a professional organization, the World Medical Association, and originally seen as an ‘ethical code’ binding only for the members of the WMA. Although not uncontested, the Declaration has, over time, gained a status comparable to Human rights Declarations, to the extent that also nonmembers of the World Medical Association will face significant protest when trying to depart from the rules of action it lays down.[42] The declaration is regularly referred to in jurisprudence, [43] and has been codified in, or influenced, national or regional legislations and regulations, such as the EU Clinical Trials Directive published in 2001[44] or the American Belmont Report (1978)[45], subsequently encapsulated in a federal regulation known as ‘the Common Rule’.[46] All together these different legislative initiatives display significant coordination dynamics, they increasingly refer to and connect with each other, and together produce a generally accepted symbolic reference to human rights. It remains a question, however, to what extent this emergent regime in the biomedical research will mature into a genuine global ‘constitution’ for the science system as a whole. For this not only entails questions about the fundamental differences between research disciplines, it also implies a more thorough and mutual coupling of science and the law than can currently be observed.[47]

THE STRUCTURAL COUPLINGS OF SCIENCE: TOWARDS A CONSTITUTIONAL RECALIBRATION?

Merton’s concern was to show how the institutionalization of science as it emerged from the scientific revolution and subsequently took the form of ‘academic science’, presupposed not only a series of distinct methods and activities but also a underlying normative framework. The Mertonian description of science was geared to the rather small, disciplinary communities which dominated science during the late 1930s and early 1940s. Before the second World War, science was a relatively small scale affair (artisan or ‘little science’). University education in most countries included no more than 2-4 % of the relevant age group (recruiting predominantly in the male population), yet from the fifties onwards the inclusion of the population (now male and female) into higher education

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[40] See S.E. Kelly, ‘Public Bioethics and Publics: Consensus, Boundaries, and Participation in Biomedical Science Policy’(2003) 28, *Science, Technology & Human Values*, 339.

[41] See also, P.F. Kjaer, *Constitutionalism in the Global Realm. A sociological approach*, 2014, Ch 4.

[42] See, for instance, “Trials on trial: The Food and Drug Administration should rethink its rejection of the Declaration of Helsinki"453 (7194) *Nature*, 427.

[43] JF Merz, “The Nuremberg Code and Informed Consent for Research” 2018 (319) *JAMA*, 85.

[44] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001. See <https://ec.europa.eu/health/human-use/clinical-trials/>

[45] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research* <https://videocast.nih.gov/pdf/ohrp_belmont_report.pdf>

[46] Office for Human Research Protections, *Code of Federal Regulation, Title 45*, retrieved at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

[47] See Teubner, op.cit, nr.11, 102-113.

increased dramatically.[48] Hand in hand with the worldwide expansion of the university as an institution, scientific communication saw a tremendous growth in size and velocity. Already in the sixties, the historian of science Derek de Solla Price, showed that the growth rate of scientific research during the past two centuries has been higher than that of any other human activity. Price demonstrated how the total number of researchers had risen from 50,000 at the end of the nineteenth century to more than one million at the beginning of the sixties, and the number of scientific journals burgeoned from around 100 in 1830 to several tens of thousands after World War two.[49] At the same time, science had become "a collaborative, as opposed to individual, enterprise: between the 1920s and 1950s, the percentage of scientific papers written by a single researcher published in American specialist journals diminished by half, while the ratio of papers signed by at least four researchers increased concomitantly. In short, by the 1960s, artisan or 'little science' had become a huge enterprise in both social and economic terms. Physicist Alvin Weinberg termed this 'big science' in analogy with 'big business' – the great conglomerates of capitalist industry which grow exponentially and double in size approximately every 15 year."[50]

The simultaneous process of growing inclusion, globalization and scale-expansion of science[51] quickly made science into a very different beast as the one that could be observed in the thirties or fourties.[52] Although there is quite some disagreement on the specifics, most scholars regard contemporary science as differing significantly from the science of the nineteenth and early twentieth century, that is, 'academic' science. Indeed, they speak of a 'postacademic science', or a 'mode-2 science', thereby contrasting it with 'mode-1' academic science.[53] This transformation of science made Merton's view of the primary regulative role of academic group norms less useful, because the latter "was profoundly embedded in theoretical presuppositions that had a much stronger currency at the time compared to contemporary analytical frameworks and research landscape".[54]

One of the most salient changes is that most branches of science has long ceased to be an affair of individual scientists; in by far the largest subsectors of scientific activity, in the natural sciences, in biomedical and technological research, it has actually become impossible for individuals to carry out scientific research on their own (and get published). Ever since the emergence of 'big science', research is organized as work of teams or distributed over (international) consortia and networks. It is also highly dependent on technical apparatuses, infrastructure and databases, that should be neatly managed to produce new research insights. What the individual can do as a researcher, even down to the specific topics he or she can choose to research, hence depends fundamentally on

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[48] See E. Schofer, J.W. Meyer "The Worldwide Expansion of Higher Education in the Twentieth Century" (2005)70, *American Sociological Review*, 898.

[49] D.J. de Solla, Price, *Little Science, Big Science*, (1963); Bucchi, op.cit, nr.2, at 7.

[50] Bucchi, Id.

[51] For more sociological background, see R. Stichweh, *Die Weltgesellschaft. Soziologische Analysen* (2000).

[52] For a nuanced discussion of continuity as well as discontinuity in the 20th-century Science system see G. Metlay "Reconsidering Renormalization: Stability and Change in 20th-century Views on University Patents" (2006) 36, *Social Studies of Science*, 565.

[53] See, for instance, M. Gibbons et al. *The New Production of Knowledge: Dynamics of Science and Research in Contemporary Societies* (1994); H. Etzkowitz, A. Webster "Science as intellectual property". In*: Handbook of Science and Technology Studies*, Eds. S. Jasanoff, et al. (1994); H. Nowotny et al., *Re-Thinking Science: Knowledge and the Public in an Age of Uncertainty* (2001).

[54] See Bucchi, op. cit, nr.24., at 246.

broader organizational and technical preconditions. Regulative norms which solely focus on individual behavior are hence increasingly less useful.

The dependence of science on technology (in most fields of scientific knowledge production) also had the effect of eroding the boundaries that had previously separated scientific, or philosophical-theoretical knowledge—what the Greek philosopher Aristotle characterized as *episteme*—from engineering, or practical-technical knowledge (Aristotle's *techné*). As the 'objects' for research are becoming increasingly produced and modified by high-tech research equipment, the distinction between research and engineering is blurred. In "technosciences" as microelectronics, genetic engineering, and, more recently, artificial intelligence, nanotechnology and synthetic biology, there is no longer a clear line of demarcation between scientific theory and engineering practice—or, for that matter, between the academic world and the world of business. Many authors also see an erosion of the traditional disciplinary system. In an influential account of the evolution of science since the seventies, Michael Gibbons and his co-authors highlighted how scientific research and technological development have come to be increasingly carried out in a "transdisciplinary" manner in so-called "contexts of application"[55]. Mode II knowledge is increasingly produced in settings that are "externally" constructed by hybrid constellations of government funding agencies and business firms. In these 'mode II' settings, disciplinary boundaries, distinctions between pure and applied research and institutional differences between, say, universities and industry, seem to be less and less relevant.[56] University-based academics work ever more often together with corporate employees and government officials in temporary groups or networks on particular projects in what has been called a "triple helix" linking the state, the market and the academy in web-like relationships.[57] Above all, this change is characterised by stronger "societal contextualisation of research and its outcomes". Research thus should be understood as "part of a larger process in which discovery, application and use are closely integrated", as no longer strictly confined to disciplinary and institutional territories, and as bringing about experimental processes which are "increasingly guided by the principles of design, originally developed in the industrial context."[58]

From a systems theoretical point of view these different evolutions do not simply cancel the autonomy of science acquired in its differentiation processes in the 18th and 19th century, but rather point to an increased interdependency of science with other societal systems. Rudolf Stichweh, for instance, points to "an increasing number of structural couplings of science with the other function systems of society"[59] . The expansive literature on the knowledge society also reflects this "transformation of science from a relatively minor institution encapsulated from social influence to a major institution that influences and is influenced by other social spheres"[60]. Yet, to the extent that different societal systems become dependent on scientific knowledge, and science's linkages with other sectors intensify, there is also a need for specific norms and rules securing the autonomy of science as well as defining the limits of the operations of science with respect to individual minds and

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[55] Gibbons et al., op.cit., nr. 49.

[56] Id. at 27, 30.

[57] H. Etzkowitz, L. Leydesdorff, The Triple Helix -- University-Industry-Government Relations: A Laboratory for Knowledge Based Economic Development, (2015) 14 *EASST Review* 14.

[58] Id., at 46.

[59] R. Stichweh*, System/Environment Relations of the Modern System of Science, 1750– 2017*, unpublished paper, 2017.

[60] Etzkowitz, Webster, op.cit. nr.49, at 488.

bodies and the natural environment. I have already pointed out how a transnational, hybrid space of law, including new regulations and new bodies such as ethics committees, emerged in response to the scale-expansion of science. Below, I shortly discuss how the intensification in the interdependencies between science and other societal systems goes hand in hand with a varied array of other norm-producing initiatives.

The most prominent changes with regard to the "societal contextualisation of research and its outcomes"[61] can probably be observed in the couplings between science and the economy. As we've already argued, in the largest subsectors of scientific activity (biomedical and technological research) the boundary between public and private research has become increasingly confuse. Additionally, established disciplines get caught up in new 'contexts of application', for instance, "linguistics, for a long time a purely curiosity-oriented basic research field, suddenly became part of the emerging transdisciplinary area of cognitive sciences which has strong links to computer and software industry."[62] Obviously, opportunities for commercial utilization of scientific research were also available

> "to scientists in the past, such as the Curies, Marie and Pierre, and Pasteur, who did not believe in crossing the boundary between science and business themselves, even though they evinced a strong interest in the practical implications of their findings. What is new in the present situation is that many academic scientists no longer believe in the necessity of an isolated 'ivory tower' to the working out of the logic of scientific discovery (…) academic scientists are often eager and willing to marry the two activities, nominally carrying out one in their academic laboratory and the other in a firm to which they maintain a close relationship. A typical initial reaction of a molecular biologist to the possibility of doing science for financial gain as well as the production of knowledge was, ''I never realised I had a trade,'' later followed by, ''I can do good science and make money''.

In this new research setting, the classical Mertonian norms are seen to be under increased pressure. Many scholars have been describing how the creation of national competitiveness policies in the early to mid-1970s has led to a situation in which the norm of communism – publicly sharing research results - is being or has been replaced by the norms of competition and private intellectual property.[63] Much research in these fields is hence carried out with a view to its potential of commercialization and the ability of getting a patent granted. Massimiano Bucchi argues that "the spread of patenting, even in such areas as the life sciences, is interwoven with the need for research secrecy. The miniaturization of certain laboratory technologies and the simultaneous diffusion of digital technologies have offered an increasingly large number of 'final consumers' access to products (such as genetic tests for potential pathologies, parentage or even potential talents) in ways that elude the traditional regulatory 'filters', and even validation by the scientific community."[64] In contrast with academic science, this new form of 'entrepreneurial science' produces knowledge that is not necessarily made public and assessed on its scientific potential by academic peers, but rather knowledge that is more centred on commercial potential and controlled by managerial authority. Henry Etzkowitz notes that while

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[61] Gibbons, et.al, id., at 4

[62] H. Etzkowitz, "The norms of entrepreneurial science: cognitive effects of the new university–industry linkages" (1998) 27, *Research Policy*, at 826.

[63] See, for instance, H Etzkowitz, op.cit., nr. 54; Metlay, op. cit, nr. 48; Bucchi, op. cit. nr. 28.

[64] Bucchi, id., at 238.

> "*older forms of university–industry connections involved payment for services rendered, whether it was received directly in the form of consultation fees or indirectly as endowment gifts" the new university–industry relationships involve "the multiplication of resources through the university's and faculty members participation in capital formation projects such as real estate development and formation of firms (…) the capitalization of knowledge, its transformation into equity capital by academics involving sectors of the university such as basic science departments heretofore relatively uninvolved with industry, and the university's emergence as a leading participant in the economic development of its region*"[65].

At the same time, technoscientific research has become increasingly expansive and hence dependent on increased funding. As the range of research institutions and universities has expanded, and public research funding has not grown as fast as the number of researchers seeking support, the competition among researchers and universities for funds, both public and private, increases.

There is now increasing evidence that this growing interdependency between science and capital is significantly impacting the autonomy of scientific research. The intrusion of economic rationality not only creates pressures for the privatization and commercialization of research results, it also affects the research process and results itself. A growing body of evidence supports the hypothesis that financial relationships are statistically associated with research outcomes, finding, for instance, that industry-funded research is four times more likely to yield results favorable to industry than independently funded research.[66] This can be partly explained by the fact that private funders have the financial resources to conduct trials and studies with large sample sizes and hence are more likely to obtain positive results than government-funded researchers.[67] Yet, there are also strong indications that the strong dependency on capital can affect the credibility of the research process itself, be it in the phase of problem selection (only funding research projects that are likely to reflect positively on a company's products), study design (under-powering a study to show no statistically significant evidence of an adverse effect), data collection (fabricating or falsifying data), data analysis (choosing a method of data analysis most likely to support one's hypothesis), data interpretation (overstating the significance of data) or publication (not publishing data or studies that undermine one's hypothesis).[68] Furthermore, "because many important decisions that affect the research will have been made prior to publication and are not stated in print or available to readers and reviewers"[69] the influence of financial relationships on research will often not be evident in a published paper.

While there are clear indications of the intrusion of economic and financial rationality in science, important counter-movements are also apparent. In response to the problem of financial conflicts of

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[65] Etzkowitz, op.cit., nr. 58, at 825.

[66] M. Friedberg et al., 'Evaluation of conflict of interest in new drugs use in oncology' *JAMA* (1999) 282; J. Lexchin et al., 'Pharmaceutical industry sponsorship and research outcome and quality: Systematic review' 2003 (326) *BMJ.* 1167; P.M. Ridker, J. Torres, 'Reported outcomes in major cardiovascular clinical trials funded by for-profit and not-for-profit organizations: 2000–2005' (2006) 295 *JAMA* 2270; S. Sismondo, 'Pharmaceutical company funding and its consequences: A qualitative systematic review' (2008) 29 *Contemporary Clinical Trials*, 109.

[67] D.B. Resnik, K.C. Elliott, 'Taking Financial Relationships into Account When Assessing Research' (2013) 20 *Account Res*. 184.

[68] Id., 187-189.

[69] Id., at 191.

interests, many scientific journals, government agencies, and universities require disclosure of sources of funding and financial interests related to research (e.g. stock ownership, patents).[70] In response to the privatization and patenting of research results, different initiatives have been taken to incite researchers to share results widely and rapidly through 'open science' and 'open publishing' schemes'. While intellectual property rights such as copyright, patents and trademarks grant owners exclusive rights to immaterial assets such as new knowledge, inventions and designs, the last couple of decades have seen the emergence of new forms of intellectual property protection that allow widespread sharing and reuse.[71] The general term 'open source', for instance, refers to methodologies that promote the free redistribution and access to an end product's design and implementation details; in the sphere of biomedical research it refers "to the use of legal licenses and technological platforms that allow access, sharing, reuse, recombination and modification of biomedical data such as genomic sequences."[72] In reaction to the growing cost of scientific publications, groups of scientists have also started and maintained significant 'open publishing' schemes by creating archives and digital journals for the circulation of research findings free from the limitations and economic constraints imposed by large publishers. More generally, the idea that researchers should enjoy access to an open-by-default research data environment is gaining foothold. While open access and open science initiatives primarily originate in private law-making, public parliaments and administrations, have tried to overtake and stimulate the creation of open research environments.[73]

New norm-constituting initiatives are not only directed against the stronger privatization and financialization of research, however. As 'post-academic 'or 'mode II' science is increasingly carried out in so-called "contexts of application", where the line of demarcation between disciplines, and between science and application is blurred, there is also a need to rethink and recalibrate how science deals with the effects and unforeseen impacts – potentially harmful - that are triggered by research. While the early Mertonian, professional codes of conduct mainly treated this problem by pointing to the role responsibilities of individual scientists, there has been an increasing sense that risks and dangers of scientific and technological innovation are far beyond the framework of individual role responsibility.[74] Although scientists may not individually be irresponsible people, it is the often complex interplay of science and society, of high-risk technology and the social, which creates what Ulrich Beck has called 'organised irresponsibility'.[75] Technological risks, as Charles Perrow has argued, mostly follow from a interaction of loosely coupled systems, many of which may

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[70] See M.K. Cho et.al. 'Policies on faculty conflicts of interest at US universities' (2000) 284 *JAMA*, 2203; R.J. Cooper et.al 'Conflict of interest disclosure policies and practices in peer-reviewed biomedical journals'(2006) 21 *Journal of General Internal Medicine*, 1248; S. Krimsky, L.S. Rothenberg. 'Conflict of interest policies in science and medical journals: editorial practices and author disclosures' (2001) 7, *Science and Engineering Ethics* 205.

[71] See also M Schiltz, G Verschraegen, S Magnolo 'Open Access to Knowledge in World Society?' (2005) 11, *Soziale Systeme*, 346.

[72] See A Delfanti, *Biohackers. The Politics of Open Science* (2013) 4.

[73] See in particular the different initiatives of the European Commission with regard to Open Science. <https://ec.europa.eu/research/openscience/index.cfm>

[74] Think, for instance, the dilemmas faced by several groups of physicists who studied uranium fission in 1939 and 1940. See S.R. Weart 'Scientists with a secret' (1976) 29*Physics Today*, 23.

[75] U. Beck, 'Risk Society revisisted: theory, politics and programmes. In *The Risk Society and Beyond: Critical Issues for Social Theory*, eds. B. Adam et.al. 2000.

themselves be in part so complex as to be outside direct control.[76] This problem of unpredictability intensifies in the case of new and emerging technologies, with which little experience exists and whose effects may not be directly visible or materialise for many years. Niklas Luhmann hence emphasized how the uncertainty, which is already inherent in autonomous scientific research, "escalates" in the fields of ecology and technological consequences:

> "*Science finds itself driven into territory it would never (or only in exceptionally rare cases) have entered for theory-controlled research reasons of its own. Problems occur here that do not arise within the framework of the research itself, so that it remains unclear exactly how such problems are to be formulated; which discipline they should be assigned to; what efforts, what time should be earmarked for the research; and whether it will be possible to gain useful knowledge within the meaning of its own vehicle; it is carried in the lateral shadows.*"[77]

Over the last decennia, the dilemmas of control for emerging technologies, and the question of how to proceed with regulation under conditions of uncertainty and ignorance[78], has catalysed an increasing reflection on the classic Mertonian self-regulation or the so-called 'social contract for science' (in which scientific freedom is exchanged for the expectation of socially-beneficial impacts) and risk-based regulation as a predominant science and innovation governance paradigm[79]. Although many still plea for reinforcing the traditional academic 'ethos', the increasing frequency of 'scandals' concerning academic misconduct (data manipulation, bogus peer review, ghost writing, etc.) seems to indicate that professional deontological rules are no longer capable of mastering the enormous expansion and dynamisation of contemporary global science. In a world of large-scale research consortia, bibliometrics, big data, automation and the intensification of interactions between academic and industrial research, the traditional codes of conduct for individual researchers are in need of a sociological update. They should be generalized and respecified to the fit the specific demands of the contemporary science system; they should enter the 'capillaries' and 'arteries' of current techno-science and alter the 'internal constitution' of this global system, possibly in close interaction with the scientists who are active within these fields, as well as with outsiders affected by scientific research and innovation.[80]

As science and technology are 'overflowing' the boundaries of existing regulatory frameworks, an array of new initiatives to regulate research and innovation has seen the light. Heterogeneous forums (e.g. citizen panels, public consultations) in which non-expert stakeholders and citizens play a significant part alongside scientists have attracted a lot of interest.[81] Deliberative technology assessment procedures such as 'Constructive Technology Assessment' have been developed to allow users, stakeholders and citizens to exert an influence on the research and design process.[82] Different approaches to anticipate the longer-term implications of emerging technologies (e.g. forecasting,

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[76] C Perrow, *Normal Accidents. Living with High-Risk Technologies*, 1984.

[77] N. Luhmann, *Risk: A Sociological Theory* (1993) 205.

[78] See M. Gross, *Ignorance and Surprise. Science, Society and Ecological Design*, 2010.

[79] R. Owen, et. al, 'Responsible research and innovation: From science in society to science for society, with society' (2012) 39 *Science and Public Policy* 751.

[80] See Teubner, op. cit., nr.11, Ch 4.

[81] See, for instance, M Callon et.al, *Acting in an uncertain world*, 2010.

[82] J. Schot, A. Rip 'The Past and Future of Constructive Technology Assessment' (1997) 54 *Technological Forecasting and Social Change*, 251.

scenario development, anticipatory governance) have seen the light.[83] The epistemic rationale behind these different initiatives is that “the traditional sources of expert knowledge are too narrowly focused to capture all the issues that need to be debated.”[84] By providing an interface between science and politics, the general public debate can be complemented with scientific advice while science can take into account extra-scientific concerns.

In the biomedical sciences and notably, genomics, various research and public interaction activities aiming to anticipate and address ethical, legal and social implications (ELSI) or aspects (ELSA) of emerging innovations took a more institutionalized shape. These research assessment became integral part of the European Commission’s Research Framework programs from 1994 onwards as well as in many national funding programs in the field of the life sciences.[85] Over the last few years, these programs have been, slowly but surely, replaced by the concept of responsible research and innovation (RRI). The latter has gained quite some visibility and traction in an EU, and specifically European Commission (EC) policy context; it became an integral part of European research funding within the most recent research framework program, HORIZON 2020, which started in 2014.[86] Although it remains unclear how RRI is to be ‘implemented’ in concrete research practices, it aims to allow for both the avoidance of unintended consequences of an innovation, and the movement of governance away from ‘reactive forms’ to prospective and proactive forms.[87]

CONCLUSION

This article has discussed to what extent a transnational societal constitution for science is emerging. It has first focused on the classic approach of professional scientists’ self-regulation. By way of peer evaluation and ‘codes-of-conduct’ type of regulation, professional science has long, and rather successfully, guarded the boundaries between research and its societal environments. Although the functional differentiation of science was legally buttressed by fundamental rights and ‘academic freedom’, it has predominantly arrived at its autonomy without much legal support. After World War II, however, the regulation of scientific research and innovation became increasingly legally codified and shifted away from mere professional self-regulation. In response to severe historical examples of

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[83] See, for instance, D Barben et.al, ‘Anticipatory Governance of Nanotechnology: Foresight, Engagement, and Integration’ in *The Handbook of Science and Technology Studies, Third Edition*, eds. EJ Hackett et.al.(2008) 979.

[84] H. Collins, R. Evans, *Why Democracies need Science*, 2017, at 133.

[85] H Zwart, A Nelis, 'What is ELSA genomics?', *EMBO Reports* (2009) 10, 540.

[86] Responsible Research and Innovation is an increasingly common keyword in research policy and regulation, especially in the EU, but increasingly also worldwide. Many countries as well as the European Union have formed initiatives and funding streams to stimulate research on, and adoption of, RRI principles. Among other developments, a Journal of Responsible Innovation began publishing peer-reviewed articles in 2014. For more information, see, R. Owen, op.cit, nr. 80; J. Stilgoe et.al. ‘Developing a framework for responsible innovation’ (2013) 40 *Res. Policy*, 1568.

[87] B.E. Ribeiro et al., 'A Mobilising Concept? Unpacking Academic Representations of Responsible Research and Innovation' (2017) 23 *Science and Engineering Ethics*, at 89; see also M. Van Oudheusden, Where are the politics in responsible innovation? European governance, technology assessments, and beyond. (2014) 1 *Journal of Responsible Innovation*, 67-86; L. Landeweerd, et.al. ‘Reflections on different governance styles in regulating science: a contribution to ‘Responsible Research and Innovation’ (2015) 11 *Life Sciences, Society and Policy*.

the ‘dedifferentiation’ of science (e.g. Nazi human experimentation) and faced with new lines of scientific and technological research, several attempts were undertaken to define how scientific research should be conducted (constitutive function) as well as legally limit the catastrophic harm research can have on the integrity of individuals’ minds and bodies (limiting function). As these fragmented legislative initiatives, deriving both from private and public sources, started to refer and connect with each other, they can be seen as the building blocks of a sectorial constitution, if not for scientific research as a whole, then at least for biomedical research. In the last decennia, an new array of research-related initiatives, codes and principles (e.g. ‘responsible research and innovation’) have emerged, reacting primarily at the increased structural couplings of the scientific system and aiming to recalibrate techno-scientific research with it’s different environments (industry, politics, environmental protection, etc.). Although this second group of norm-producing initiatives has various and changing labels, and remains inchoate and uncodified, it attests to the erosion of old agreements concerning the autonomy of science and its relations with politics, law and the economy. By setting up new forms and forums of norm-making, it has challenged scientists’ professional autonomy over the definition of standards of evidence and proof. By highlighting the linkages of science with the broader ‘knowledge society’, and by stressing the fundamental uncertainty as well as potentially far-reaching societal implications of research, it has raised questions over the certification and reliability of knowledge and over how scientific knowledge-making should be calibrated with broader societal concerns. Although these recent initiatives definitely acknowledge the complexities and uncertainties linked to research and innovation in contemporary societies, it remains to be seen whether and how they can be built in the emergent, though fragmented, transnational constitution for science.