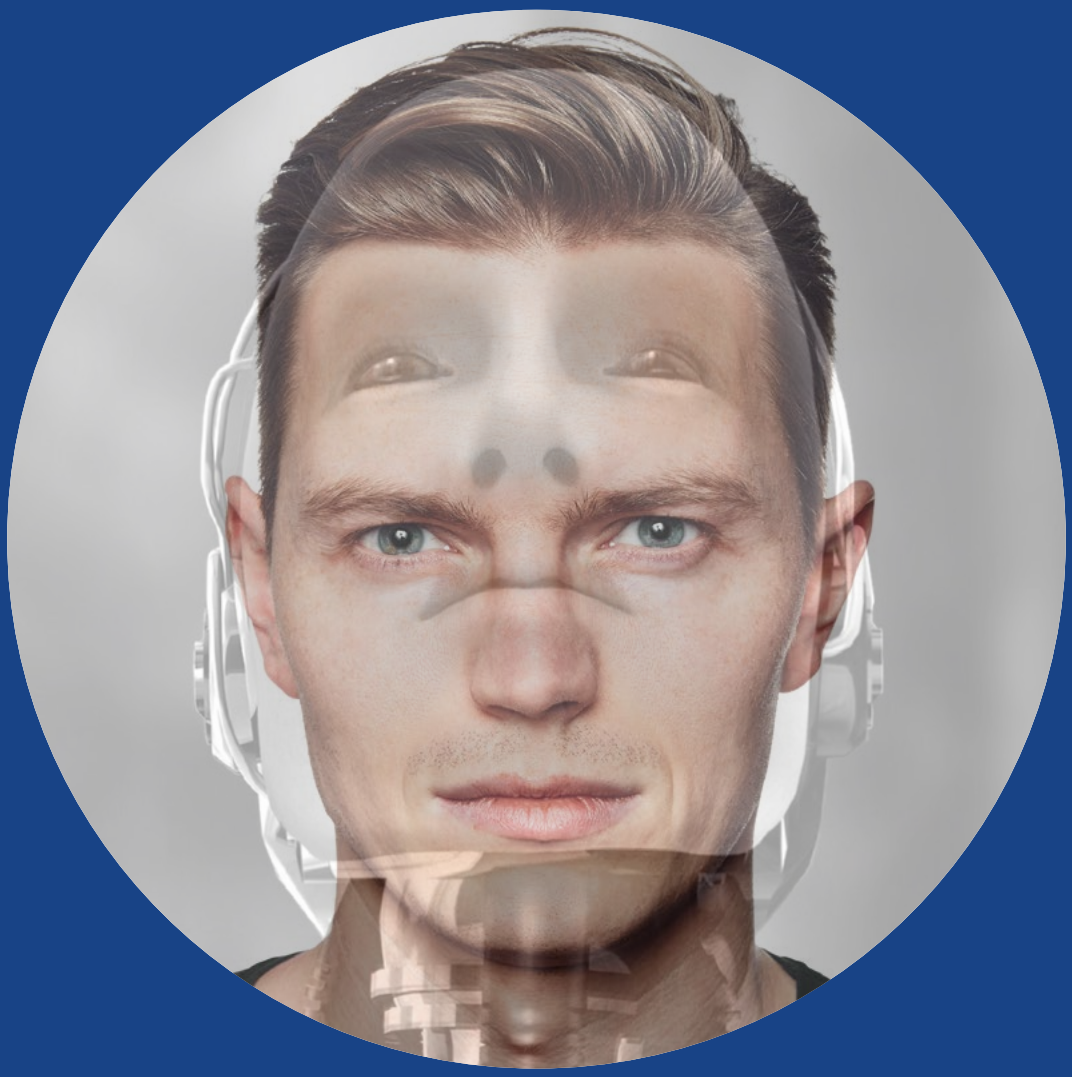
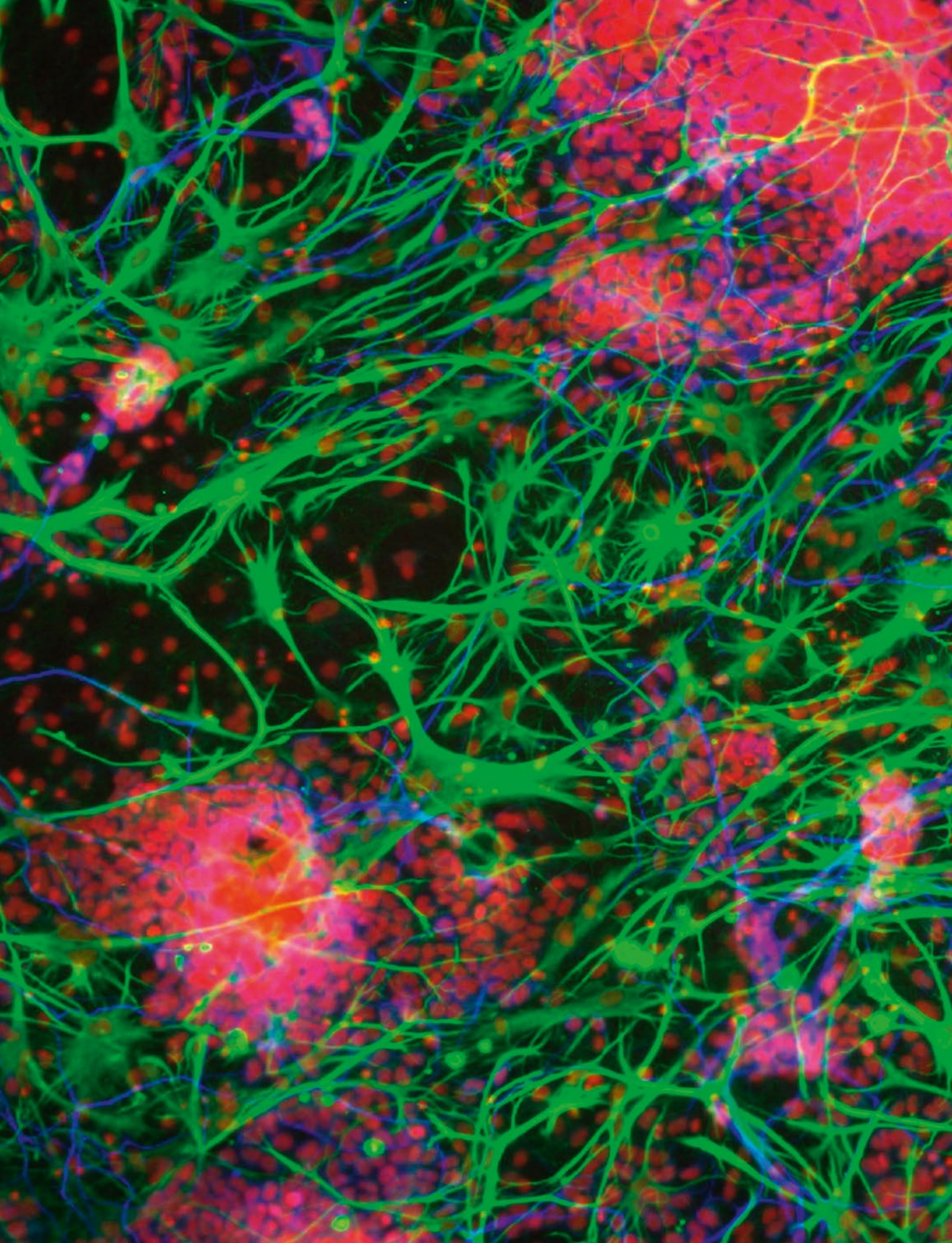


The Next Step

EXPONENTIAL LIFE

Neurotechnological Progress: The Need for Neuroethics

JAMES GIORDANO



Opening image:
Fluorescence light micrograph of neural (nerve) stem cells that have been derived from human embryonic stem cells (HESC).

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MORE ABOUT THE AUTHOR [+]

The use of increasingly sophisticated techniques and technologies has enabled rapid discoveries and developments in brain research that are being translated into varied applications in medicine, public life, and national security. Such developments foster a host of questions and problems generated both by the novelty of neuroscientific tools and techniques, and by social effects that neuroscientific information and capabilities incur. These issues are the focus of the field of neuroethics. This chapter describes these new developments, addresses neuroethical issues, questions and tasks, and posits directions for neuroethical engagement and guidance of neuroscientific knowledge and capabilities.

DEVELOPMENTS IN—AND INFLUENCE OF—NEUROSCIENCE AND TECHNOLOGY (NEUROS/T)

Brain science is developing at a rapid pace, fostered by ever more convergent, multidisciplinary methods (Giordano, 2012a) that afford a systems-based, integrative approach to the development and translational use of neuroscientific technologies and techniques, that is, neuroS/T (Giordano, 2012a, 2012b). Research and applications of neuroS/T are aimed at evaluating and treating a number of neuropsychiatric disorders and conditions, and are also being increasingly viewed as a means of affecting neural substrates of cognition, emotion, and behavior to modify aspects of human performance (if not personality).

In general, neuroS/T can be defined as those methods and devices that are utilized to access, assess, and/or affect neural systems. As depicted in Table I, these approaches can be categorized as:

1. Assessment neuroS/T, including genetic, genomic, and proteomic methods, various forms of neuroimaging (e.g., tomographic and magnetic imaging; quantitative and magneto-encephalography); and biomarker assays for particular neurological functions and neuropsychiatric conditions;
2. Interventional neuroS/T, to include neuro/psychotropic drugs and novel pharmaceutical methods; neuromodulatory devices (e.g., transcranial magnetic and/or electrical stimulation—TMS and tES, respectively; deep brain stimulation—DBS, and cranial and peripheral nerve stimulators); neural tissue and genetic implants and transplants; and neural- and brain-machine interfaced neuroprosthetic systems.

CATEGORIES OF NEUROSCIENCE AND NEUROTECHNOLOGY (NEUROS/T)	
	Assessement NeuroS/T
	(Neuro) Genetic and Genomic Probes
	Biomarker Assays
	Neuroimaging
	Computerized Tomography (CT)
	Single Photon Emission Computerized Tomography (SPECT)
	Positron Emission Tomography (PET)
	Magnetic Resonance Imaging (MRI)
	Functional Magnetic Resonance Imaging (fMRI)
	Diffusion Tensor and Kurtosis Imaging (DTI/DKI)
	Neurophysiological Methods
	Electroencephalography (EEG)
	Quantitative Electroencephalography (qEEG)
	Magneto-encephalography (MEG)
	Interventional NeuroS/T
	Neuro- and Psychotropic Drugs
	Neural Tissue Implants/Transplants
	Neurogenetic Implants/Transplants
	Cranial and Peripheral Nerve Stimulation Devices
	Transcranial Neuromodulatory Devices
	Transcranial Electrical Stimulation (tES)
	Transcranial Direct Current Stimulation (tDCS)
	Transcranial Alternating Current Stimulation (tACS)
	In-dwelling Neuromodulatory Devices
TABLE I	Deep Brain Stimulation (DBS)

To be sure, the field—and its domains of application and use—is fast paced, engaged by multiple entries that are vying for defined outcomes (and "prizes" of innovation, discovery, recognition, and economic gain), and as such can be seen as a "neuroS/T speedway." Reflective of the racing comparison, it is a highly competitive environment, which, while offering definable benefits (to both stake and shareholders), is not without risk, if not frankly dangerous as neuroS/T is ever more broadly engaged in the social milieu (Giordano, 2016a).

Ongoing governmental and commercial support, such as that provided via the *Brain Research through Advancing Innovative Neurotechnologies (BRAIN)* initiative in the United States, and the European Union's *Human Brain Project*, has sustained rapid development of new ideas, concepts, methods, devices, and abilities, which are being quickly and broadly translated for use in medicine, public life, international relations, and global security. Such

growth and varied applications are reflected by an ever-increasing number of reports in the international peer-reviewed literature (Giordano, 2012a), and patents for neurotechnologies (Lynch and McCann, 2010; NeuroInsights, 2015).

The tools of neuroscience have become ever more prominent as a means to access, evaluate, and manipulate brain structure and function, and such information and capacity, while nascent and contingent, incurs far-reaching potential to affect medical, ethical, legal, and cultural norms, ontological status, and social action. Clearly, there is much that *can* be done with neuroscience and its tools, but in each and every case, it is important to consider what *should* be done, given the boundaries of neuroscientific knowledge and technology, sociocultural realities, extant moral constructs, and the potential to use any scientific and technological tool to evoke good or harm.

At the fore is the need to appreciate neuroscience as a human endeavor, and to assume responsibility for the relative rightness and/or wrongness of the ways that neuroscientific knowledge and interventions are employed. Brain research prompts new vistas of understanding, and may alter the ways that humans and nonhuman beings (e.g., animals, artificially intelligent machines, etc.) are regarded and treated. Moreover, neuroscience provides means to control cognition, emotion, and behavior. While beneficent motives may drive the use of such capabilities, neuroscience is not enacted in a social vacuum, and thus neuroS/T interventions and manipulations are subject to the influences of the market and political direction. Therefore, it is vital to ask how these goods and resources will be utilized and distributed, and what effect(s) use and allocation would incur on individuals, groups, and society.

Imperatives for innovation, the novelty of approaches, current limitations of knowledge, and resultant uncertainties of the relative benefit, burdens, and harms of neuroS/T can each and all evoke a variety of neuroethico-legal and social issues (NELSI). As shown in Table II, these can be generally categorized as:

> 1. Those that are focal to characteristic qualities, parameters, ambiguities, and problems inherent to the complex and sophisticated techniques and devices being developed;
> 2. Those arising from the widening applications of neuroS/T, misuse of neuroscientific knowledge and/or capabilities, and/or distribution of neuroS/T in light of the increasingly diverse nature of twenty-first-century world culture, international commercial entities, and political support for neuroS/T research, development, and use (Giordano and Benedikter, 2012a, 2012b; Hughes, 2006; Lanzilao, Shook, Benedikter, and Giordano, 2013; Lynch and McCann, 2010; NeuroInsights, 2015). These issues are not mutually exclusive, but rather are interactive and can often be reciprocal in effect, and therefore require an interfluent approach to their address and resolution (Giordano, 2010; Giordano and Olds, 2010).

I posit that three primary, and three derivative questions are fundamental to querying the ways that neuroS/T can and should be engaged in various spheres of use (Giordano, 2011; 2014; 2016a).

A patient undergoing a CAT (Computerized Axial Tomography). This form of radiological exploration allows organs—especially the brain—to be studied from different angles.

CATEGORIES OF NEUROETHICAL ISSUES	
	Technology Inherent
	Novel, "Frontier" Science and Technology
	Unknown Mechanisms
	Unanticipated Effects
	Runaway Effects
	Societally-Derived/Focal
	Misperception/Misinterpretation of Capabilities, Limits and/or Meaning/Value
	Inapt Use/Misuse
	Economic Manipulation
	Provision/Distribution of Resources
TABLE II	Cultural Variability in Needs, Values, Use and/or Access

PRIMARY NEUROETHICAL QUESTIONS

Taking these in turn, it is first essential to ask: *what are the actual capabilities of specific types of (assessment and interventional) neuroS/T*? The capabilities and limitations of a particular technology and/or technique define if, how, and to what extent such tools can be validly and reliably employed to depict, define, and affect brain structure and function(s) relative and relevant to neuropsychiatric state, conditions, and capacities. Simply put, what can the tools of brain science *really* do? A complete analysis of the capabilities and limitations of various forms of neuroS/T is beyond the scope of the present chapter; for an overview, and discussion of NELSI fostered, see Giordano (2016a, 2016b, 2012b).

Presumed validity of given neuroS/T incurs relative value of using certain techniques and technologies in practice. Therefore a second fundamental question is: *whether, and in what ways could interventional neuroS/T (e.g., drugs, neuromodulatory devices, etc.) be used or misused to treat neuropsychiatric disorders and/or affect fundamental aspects of personality or "the self"?* Discerning the technical capacities of neuroS/T establishes those ways that given tools and techniques act at particular substrates to alter mechanisms and processes of cognition, emotion, and/or behavior. Here, the border between issues and questions inherent to a neuroS/T approach (e.g., capabilities, limitations, effects, etc.) merges with those derived from its possible applications (to define, evaluate, and treat neurological and psychiatric disorders, and to alter neurocognitive functions and performance). At the crux is a heuristic reliance, which we have referred to as "builders' bias": namely, that the tools employed to establish (theoretical) bases of/for what is regarded as functional or dysfunctional, and normal or abnormal, create—if not prompt and sustain—the impetus and justification to utilize such (classes and types of) tools to affect the structures and functions that are axiomatic to such definitions (Giordano, 2010).

We have posed that working—and socially recognized—distinctions of function, dysfunction, and norms instantiate a threshold for whether some neurological intervention

would be considered to be a “treatment” (i.e., to prevent, mitigate, or reverse a circumscribed dysfunction, disorder, or “disease”), or an “enhancement” (i.e., to change cognition, emotion, or behavior in ways that represent some recognized optimization of particular aspects of performance: Gini, Rossi, and Giordano, 2010; Gini and Giordano, 2010; Shook and Giordano, 2016). Indeed, there is abundant and rich discourse addressing if and how the use of neuroS/T constitutes treatment or enhancement, and the NELSI generated by such use (for complete bibliography, see: Martin et al., 2016), and the core question of what constitutes treatment or enhancement spawns further inquiry about the provision (and availability) of various interventions to individuals, groups (i.e., professions, inclusive of possible direct and dual use for military purposes), and (developed, developing, or nondeveloped) nations.

Extending discussion to account for the use (misuse, or nonuse) of neuroS/T on international scales prompts the third fundamental question; to wit, *how will markets for neuroS/T influence—and be engaged to affect—the commercialization and global economics of neuroscientific and technological resources and services?* Brain science represents a significant market that has shown an excess of $150 billion in annual revenues, which exhibits approximately 5% in net growth. The globalizing trend in neuroS/T is reflected by recent estimates of a greater than 60% increase in neuroS/T research and its translation (into medical, public use, and military markets) occurring by 2025, with significant gains being achieved by Asian and South American enterprises (Lynch and McCann, 2010; NeuroInsights 2015). That such efforts may equal or exceed Western endeavors only serves to fortify both the economic capability—and power—that could be leveraged through neuroS/T, and the need to recognize and acknowledge multicultural philosophies, values, and practices when addressing (and attempting to resolve) NELSI, and the ways that neuroethical discourse informs national and international guidelines, policies, and laws (Anderson, Fitz and Howlader, 2012; Lanzilao, Shook, Benedikter, and Giordano, 2013; Shook and Giordano, 2014).

DERIVATIVE NEUROETHICAL QUESTIONS

From these primary questions, three further queries arise that are focal to if and how neuroS/T might be employed within various societal domains. First among these is: will (and how might) necessary insight be levied when evaluating neuroS/T so as to acknowledge the actual strengths and limitations of these approaches? Second is: will (and how will) sufficient prudence be exercised when determining if, when, and how neuroS/T outcomes and tools are to be employed in specific ways within the medical, social, legal, and even political milieu? Third, yet certainly not last nor least is: if and what ethical system(s), and methods might be best suited to engage deliberations about—and provide direction for—the viability and value of employing neuroS/T in the aforementioned ways and settings on local to the global scales? (Giordano, 2014).

A PARADIGMATIC APPROACH TO NEUROETHICAL ADDRESS

In addressing these questions—and in developing possible solutions—I have argued that a simple precautionary posture, while certainly seeking to maximize benefit and reduce risk and harms, would be inadequate, as it tends to be overly proscriptive if and when accounting for the reality of burdens and risks that often occur as science and technology become iteratively more vulnerable to unanticipated effects and/or misuse. On the other hand, a solely permissive orientation, while being less restrictive, could encourage a *laissez-faire* attitude and foster something of a "wait and see" approach, that could fail to engage deliberations necessary to gain timely insight and guidance for neuroS/T developments that emerge upon the world stage (Giordano, Forsythe and Olds, 2010; Sarewitz and Karras, 2012). Thus, I believe that some balance of precautionism and assertivism is better suited, if not required, to enable effective neuroethical address (Giordano, 2012a; 2014; 2016a). To obtain such balance, I have advocated a preparatory stance that is built upon responsibility for remaining apace with—and realistically appraising—developments in neuroS/T innovation and translation (i.e., the "6-R" construct, as depicted in Table III).

6-R GROUNDWORK CONSTRUCT	Responsibility for...
	Realistic Assessment: of the neurotechnology and NELSI
	Research: for ongoing evaluation of use/effects-in-practice
	Responsiveness: to benefits, burdens and deleterious effects
	Revisions: in technology, marketing and directions for use
	Regulation: that remains flexible to iterative change in neuroS/T

TABLE III

This orientation directs queries about the dimensions and extent of using particular neuroS/T in practice (i.e., "6-W questions"); and frames such use within specific contexts and contingencies as relative and relevant to maximizing benefits, and mitigating burdens and risks that may be incurred by patients, publics, and so on (i.e., the "6-C concept"; Giordano, 2016a, 2015a, 2015b; Giordano, Casebeer, and Sanchez, 2014).

The "6-W questions" define patterns of employment, depict targeted benefits, and discern burdens and harms that are likely to be incurred by the use of neuroS/T. These questions are:

> **What** neuroS/T approaches are being considered and/or advocated for use; and what are the identified benefits, and potential burdens, risks, and/or harms?
> **Why** are specific neuroS/T approaches being considered (e.g., in light of their actual capabilities to affect pathology, cognition, emotion, and/or behavior; inadequacy/ineffectiveness of other approaches, etc.)?
> **Who** will receive such neuroS/T (e.g., specific individuals, groups, etc.)?
> **When** will particular types of neuroS/T be considered and/or advocated for use (e.g., within a medical treatment protocol; under certain occupational conditions and contingencies)?
> **Where** will neuroS/T be utilized/provided (e.g., clinical, para-clinical/occupational, or other settings)?
> **Which** programs of subsidy will be used and/or developed to support both provision of neuroS/T as well as continuity of research and care necessary for sound translation of brain science in practice?

These questions should be framed by/within a 6-C concept that builds upon the work of Casebeer (2013) to characterize and examine the development and use of neuroS/T with reference and as relevant to:

> **Capacities**—of the science and technology in question;
> **Consequences**—of research and/or use of neuroscientific knowledge and/or tools in practice;
> **Character**—of both the research, and how use(s) of neuroS/T might affect individual and/or community identity and ontology;
> **Continuity of Clinical Care and Research**—as necessary to address and manage any/all effects incurred by using certain neuroscientific techniques and technologies;
> **Consent**—with regard to the nature, extent, and provision of available information as required to assure voluntary participation in research trials or use of neuroS/T;
> **Contexts**—in which specific types of neuroS/T might be used within various situations, institutions, and sociocultural contingencies that may affect the aforementioned variables.

“As long as our brain is a mystery, the universe, the reflection of the structure of the brain will also be a mystery.”

SANTIAGO RAMÓN Y CAJAL (1852–1934)
Spanish physician and neuroscience pioneer, recipient of the Noble Prize for Medicine in 1906.
Chácaras de café (1920).

Semi-schematic cross-section of a mammal’s cerebral gyrus. Drawing by Santiago Ramón y Cajal, c. 1888.


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ASSESSING CURRENT AND FUTURE NELSI

Extant evidence from the international peer-reviewed literature, public media and forums, and commercial trends can be employed both to map key NELSI domains generated by neuroS/T in global contexts, and to identify those foci that are of primary concern and importance (Nuffield Council on Bioethics, 2013; Schnabel et al., 2014). Such investigations can reveal the extent and interactions of various domains of effect and influence, and can be employed to 1) model NELSI (domains) incurred by various uses of neuroS/T, and 2) develop patterns of interactions and interconnection(s) between emerging scientific and technological developments and various domains of a society in which ethico-legal issues may arise and exert influence.

In some cases, however, patterns of neuroS/T use(s) and effect(s) will be entirely new. In such situations, a more casuistic approach may be required to provide prior exemplars that may serve as comparitors from which plots of near- to mid-term future trajectories can be developed. Toward such ends, we have proposed a method referred to by the acronym *HISTORY*—that addresses *h*istoricity and *i*mplications of *S/T*, and engages *o*mbudsmanship, and *r*esponsible *y*eomanry in the pragmatic elucidation, and address of ethical-legal and social issues and problems generated by S/T in specific contexts (Giordano and Benedikter, 2013; Tractenberg, FitzGerald, and Giordano, 2014). Historical analysis of the influence and implications of S/T is an important step toward ombudsmanship: revealing and depicting ethico-legal and social issues and problems evoked by S/T and its various applications in a given social setting. From this arises responsible yeomanry: the identification and analysis of actual capabilities and limitations of neuroS/T, and the needs, values, and mores of individuals and communities that will utilize and be affected by such tools and techniques.

Whether assessed by depiction of extant progress, or via casuistic evaluation of previous relevant trends, the modelling of social effects of neuroS/T characteristically entails extrapolations of concept-to-construct articulation. However, we have shown that modelling neuroS/T progress and influence beyond a ten- to fifteen-year future horizon becomes difficult due to fractal growth of S/T, reciprocal interaction(s) of S/T and social forces, and resulting diversity of potential (known and unknown) effects (Schnabel et al., 2014). This is particularly true of NELSI generated in and by dual use of neuroS/T, given world stage economic and political scenarios that affect national security agenda and the employment of biotechnology in military operations (Abney, Lin, and Mehlman, 2014; Dando, 2015; Giordano, 2016a; 2014; Giordano, Forsythe, and Olds, 2010; Tabery, 2014).

Force-planning techniques may be useful—if not essential—for enabling preparation for circumstances and effects incurred by neuroS/T development and articulation at the upper limit of these ten-to-fifteen-year timespans. Force planning employs a multidisciplinary and multifaceted approach to appraise strategic needs set forth in strategy, establishes requirements to meet these needs, and selects capabilities that will optimally suit operational requirements as projected over a defined time frame (ten to fifteen years). This process entails analyzing resource constraints, changing environments, and risks (e.g., uncertainty and negative outcomes associated with mismatches among essential factors) to discern key variables so as to optimize modelling and planning for NELSI and their effects in and upon given sociocultural settings (Giordano, 2016a).

If and when used within an integrative approach to neuroS/T assessment, the engagement and adaptation of extant force-planning methods could provide a valid and valuable approach to neuroS/T and NELSI modelling. Such methods can: 1) enable a more flexible and responsive orientation to predicting and describing likely public health, socio-economic, political, and military scenarios that can shape if, why, what, and how neuroS/T may progress within international ecologies; 2) define key NELSI arising in and from these trajectories and scenarios, and in these ways 3) inform proximate and mid-term future guidance and governance of neuroS/T. At present, we are developing modelling and gaming-simulation protocols that identify domains and plot trajectories of effect generated by uses and applications of neuroS/T at varying timepoints of extrapolation, and under multivariate conditions (Schnabel et al., 2014).

ENGAGING NEUROETHICS IN PRACTICE

Recent recommendations, such as those offered by the Presidential Commission for the Study of Bioethical Issues (2015) and federal guidelines and regulations (e.g., ICH E-6, ISO 14155; 2011; and 21 CFR 812.43) provide important parameters for research and use of neuroS/T. However, a number of neuroethical challenges remain, as the breadth, pace, and distribution of neuroS/T, and the demand for such techniques and technologies expand (Giordano and Shook, 2015). Indubitably, neuroS/T can and will affect and be affected by sociocultural needs, values, and views. Although some needs and values may be common to many if not all cultures, others will differ.

Thus, existing ethical precepts and principles, while viable—and valuable—in some cases, will likely not be sufficient or adequate to address and guide the specific situations and contingencies posed by the varied (sociocultural) contexts in which neuroS/T is being developed and/or employed (Levy, 2010; Giordano, 2010; Giordano and Benedikter, 2012a, 2012b; Shook and Giordano, 2014). We have opined that the internationalization of neuroS/T necessitates a move away from older, exclusively Western philosophy and ethics. A contemporary neuroethics can only be meaningful and applicable upon the twenty-first-century world stage if the sociocultural contingencies and exigencies of various stake- and shareholders in neuroS/T are taken into accord. To account for this, we have endorsed a cosmopolitan approach that can be articulated within particular communitarian contexts

through adapting certain existing principles and the development of others. While hypothetical and tentative, we maintain that this construct, while not without problems (such as potential tensions arising from inter-communitarian engagement), affords promise as a methodological paradigm for a "globalizable" neuroethics (Lanzilao et al., 2013).

Neuroethical address and guidance of neuroS/T research and use will require dedicated efforts toward the formation of working groups, ongoing discourse, formulation of methods and protocols, and establishment of national and internationally relevant and viable standards and guidelines. We have proposed that a defined percentage of the total budgets of national initiatives dedicated to brain research be allocated to addressing key NELSI arising in and from funded neuroscientific projects (Giordano and Shook, 2015). Specifically, we advocate a nonagnostic approach, in which there is targeted address of the NELSI that could likely be generated by the science that would be conducted under particular requests for proposals (RFPs). As well, equivalent investment by the private and commercial sectors would be instrumental to establishing well-conceived and NELSI projects that reflect and are aligned with the direction, scope, and activities of these groups' respective endeavors in neurotechnological research and its translation (Avram and Giordano, 2014; Lanzilao et al., 2013).

Working in concert, efforts of federal and private (i.e., commercial and philanthropic) entities could aggregate funding to support the formation of a network of neuroethics centers (both in and outside of academia) that would serve as interactive (and in some cases, governmentally independent) resources to conjoin multidisciplinary scholars and practitioners to focus upon key NELSI that are germane to major areas of neuroS/T investment, development, and articulation affecting various spheres of society (e.g., medicine, public life, the military, etc.). As well, it will be vitally important to educate professionals (in a variety of fields, including the sciences, humanities, law, and politics) as well as the general public about what neuroS/T can and cannot do, given the current level and planned courses of research, development, and use, and the NELSI likely to be spawned by the realistic employment of neuroS/T. Indeed, learning must precede positive change, and absent this learning, change can evoke false hopes or fear, and give rise to misdirected action—often with dire consequences.

CONCLUSION

I have stated that it would be unwise, if not wholly irresponsible to: "...ignore the gravitas of neuroscientific information, its impact upon society, the resultant ethical (and legal) situations that will arise, and necessity to make moral decisions about the ways neuroscience and its tools are employed" (Giordano, 2011), and hence have repeatedly called for "no new neuroS/T without neuroethics" (Giordano, 2015c). But equally, I appeal for any and all neuroethico-legal deliberation to be soundly based upon the realities of brain science and its actual capabilities, limitations, and uses (i.e., "no neuroethics without neuroscience").

Moreover, while ethical deliberation and explications may be vociferous, such discourses can be vacuous unless there is directed effort to inform the development of guidelines and policies (Giordano, 2015c; Giordano and Shook, 2015). However, the pace of scientific and technological development often outstrips that of policy formulation. While on one the hand, this could be viewed as enabling deep and equivocal discourse about science and technology, and its societal implications and effects, on the other, it can rightly be seen as rendering policy to be post-facto and reactive, rather than reflexive and proactive. So, by the time policies are enacted, they may in fact be implementing governance of dated effects and "old" science and technology (Swetnam et al., 2013).

Thus, guidelines and policy must be informed in a timely manner, and must remain relatively flexible to meet contingencies fostered by iterative developments in neuroS/T and the social domains in which such science is articulated. It is inevitable that neuroS/T is, and will become, an ever more salient reality—and powerful force. How this force and power will be manifested in the future is dependent upon—and subject to—current and ongoing neuroethical address, deliberation, and prudent engagement toward guidelines and policies that shape and direct the use of neuroS/T in twenty-first-century society.

> "That we would do / We should do when we would"
> Shakespeare (*Hamlet*, 4.7: 118–119)

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