Bioelectronic Medicine—Ethical Concerns

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Bioelectronic medicine (BEM) offers exciting opportunities to treat diseases such as movement disorders and refractory inflammatory disease. The many variations of BEM allow for noninvasive aspects of treatment that might eliminate or reduce the need for pharmaceuticals; therefore, the term “electroceuticals” may be suitable. BEM has been effective for movement disorders and improvement of prosthetic devices. Based on this implication, there is an allowance to impact many focus areas that include but are not limited to autoimmune disease, sensory motor conditions, and neurological conditions. There are a wide array of ethical issues that relate to BEM, which include informed consent, research ethics, innovation, academic–industry relationships, intellectual property, and the conundrum that needs to be addressed when altering the brain such as the issues of autonomy and free beneficence and social justice. The major goal is to heighten awareness of ethical issues and facilitate a proactive ethical approach regarding BEM research.

The ethical issues that relate to medical research will form the basis for this paper. The history of ethical transgressions in medical research led to changes in the law as well as changes in the expected norms of medical research. The ethical principles that underlie these changes are expected to be embedded in the process of medical research. However, there are many relevant ethical issues that do not involve the law, such as character, trust, professional promise, and agency. As new technologies emerge, society must address the ethical concerns so as to preclude nonethical occurrences. A goal of this paper is to increase the awareness of ethical issues that occur in research that can potentially lead to discernment and correct behavior. This paper will address the ethical theories and concerns that are found within bioelec-

tronic medicine (BEM). Additionally, the topics of innovation, academic–industry relationships, and intellectual property will be addressed pertaining to research ethics.

BACKGROUND

Ethical Theories

Is BEM research different than any other medical research and does it therefore require a new look by medical ethics? The answer is yes. A major difference is the ethical concerns that relate to research that alter the brain and impact the mind. It may be worthwhile to start with the consideration of ethical theories. Why theories? Theories provide clarity, coherence, comprehensiveness, simplicity, explanatory power, jus-

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tificatory power, and practicality (Beauchamp and Childress 2013). Which theory would best address the ethical concerns surrounding BEM? Utilitarian theory (consequentialist) is best used to address BEM and public policy issues. Diametrically opposed to Utilitarianism is Kantian theory (nonconsequentialist), which states that people are not to be used as a means to an end and that there are mandatory rights and obligations. Virtue ethics require traits of character such as compassion, kindness, and empathy. The use of principlism (Beauchamp and Childress 2013) focuses on autonomy, beneficence, nonmaleficence, and justice. Other theories of ethics such as pragmatism, phenomenology, ethics of care/feminist ethics, communitarianism, contract theory, and casuistry also deserve consideration. Each of these theories have principles that are *prima facie*. In other words, they may need balancing, determination of proportionality, with other principles for assessment and decision making. After addressing an ethical analysis of BEM research from the view of principlism, we will need to account for the progress that has been made with informed consent and research. Human research implies that an investigation will be done with subjects in which we do not know the results or outcome. The ethical bedrock of research ethics involving human subjects is informed consent. The underpinning of research ethics (or ethics in general) is character. Good character enables empathy and the ability to not use subjects/patients as means to an end. In the arena where this plays out, the requisite skill is the ability to communicate.

Jonsen and Toulmin favor a casuistic approach for medical ethics that applies to research ethics when they address the “tyranny of principles,” noting the following: “...Why is the zealot’s concentration on universal and invariable principles so damaging?” “In the actual business of dealing with particular real-life cases and situations, such rules and principles can never take us more than part of the way. The real-life application of moral, legal, and administrative rules calls always for the exercise of human perceptiveness and discernment...the more problematic the situation becomes, the greater the need for discernment.” “Surely this issue is rath-

er one of the exercises of wisdom, discretion, and discernment in enforcing the rules we already have” (Jonsen and Toulmin 1988). Pellegrino (2004) approaches ethical issues with a phenomenological approach. “An ethics based in the clinical encounter promises to be more closely related to the concrete experiences of doctor and patient than the application of pre-existing theories.” The phenomenological approach that relates to research is critical as it relates to the nature of the relationship between researcher and subject.

Ethical Concerns

The introduction of any new medical technology raises ethical concerns about their use and abuse in both the clinical and research settings (Cabrera et al. 2014). While these concerns are not unique to BEM, careful consideration of these concerns can help shed light on how clinicians and researchers can address them. This section will address only some of the ethical concerns that relate to informed consent and they include the following: (1) autonomy (free will), (2) beneficence versus nonmaleficence (harm versus benefits), and (3) social justice (access to care). In addition, there are concerns raised beyond the ethical theory of principlism (Beauchamp and Childress 2013). These include fairness (Rawls 1971), intellectual property (Drozdzoff and Fairbain 2015), and agency. In addition, when applying these principles to the informed consent process, one must be aware of difficulties such as the potential for coercion, persuasion, or manipulation (Joffe and Truog 2010).

The basic elements of informed consent are (1) voluntariness, (2) patient competency, (3) adequate disclosure of risks and benefits, (4) patient/subject understanding, and (5) authorization. Informed consent requires considerable time and communication skills and should not just be viewed as a process whereby a form is signed. There is still a need for more research to improve the understanding of and processes for informed consent (Candilis and Lidz 2010).

Patients often misunderstand much of the information they are provided. For example, in research, the nuances of therapeutic misconcep-

tion highlight one of the major difficulties within the informed consent process. However, “with careful planning, the therapeutic misconception can be dispelled, leaving the subject with a much clearer picture of the relative risks and benefits of participation in research” (Appelbaum et al. 1987). The need for informed consent within BEM research is to ensure that “adequate protections are in place for research subjects and patients, the probable benefit of research into and the therapeutic applications of neuroprosthetics outweigh the risk and therefore can be ethically justified” (Glannon 2016). Glannon’s view of therapeutic misconceptions may be overly optimistic. In addition, one must consider the challenges faced by patients with psychiatric disorders and their ability to provide informed consent. Do they have the capacity to understand? Are they able to understand the information provided? Do they understand the consequences? And are they able to reason? (Appelbaum and Grisso 1988). “The question is whether they (patients with treatment-resistant neurological and psychiatric disorders) have the cognitive capacity to give informed consent and effective capacity to understand how the technique might alter their brain and a voluntary decision to undergo or forgo...” (Fins and Schiff 2010). As Fins and Schiff note, “In proven and unproven applications of deep brain stimulation (DBS), the disease itself would not necessarily preclude the capacity to rationally and freely decide whether or not to have a stimulating system implanted in one’s brain” (Fins and Schiff 2010). Another ethical concern is the potential for conflicts of interest. Does the investigator have a financial interest? Does the institution have a conflict of interest? Are there adequate policies in place to address these concerns? Should there be an independent person who obtains consent? Ideally, this would have to be someone who is not involved with the research but does have adequate knowledge and understanding of the research project to obtain informed consent.

In order to properly understand the research ethics set forth, it is important for institutional review boards (IRBs) to address the concerns stated above as they may play a major role in

the way that research will be conducted as time progresses. As a whole, it is beneficial for IRBs to facilitate proper educational standards so they can be prepared for critical oversight. If there are ethical constraints, this can be addressed as well so that they can ensure both scientific and ethical parameters that surround BEM.

The difficulties encountered regarding conflicts of interest are present in many of the references for this paper. Fins et al. (2011) note that “investigators who conduct sponsored research should not have, or assume corporate fiduciary roles, as board members entrusted with potential oversight responsibility of their own research and conduct.” Lo and colleagues (2000) looked into conflicts of interest policies at 10 major research universities and found that they “...receive the largest amount of research funding from the National Institutes of Health. Their standard regarding conflicts of interest was that...university-based investigators and research staff be prohibited from holding stock, stock options, or decision-making positions in a company that may reasonably appear to be affected by the results of their clinical research.”

It is important to recognize the differences in the ethical concerns with the different forms of BEM. DBS, brain-computer interface, brain-to-brain interfaces, and hippocampus devices are of more concern than transcranial magnetic stimulation (TMS), or transcranial direct current stimulation (tDCS). The latter two devices are considerably less invasive (no intracranial procedure is needed). Also, these devices are available commercially. A tDCS device can be purchased online for \$379 (cesultra.com). The website outlines its benefits for anxiety, stress, and stress-related disorders. And for an additional \$20, they will provide a physician’s prescription.

However, these devices alter brain function and, similar to psychiatric pharmaceuticals, they are likely to have side effects. “The potential issue of unintended consequences due to brain stimulation finds clear parallels with the unintended effects of medication” (Glannon 2016). For example, the drug Ritalin changes behavior for the good, but has side effects. As with pharmaceuticals, there are concerns that these de-

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vices will be used for enhancement and not for treatment of medical diseases. This brings up ethical issues that relate to access for pharmaceuticals, electroceuticals, and related medical devices.

Clausen (2010) identifies five areas of ethical concerns that relate to DBS for Parkinson's disease (PD). They are (1) weighing risks and benefits, (2) equitable patient selection, (3) protecting the health of children, (4) patient autonomy, and (5) normative impact on quality of life. Clausen cites several sources for complication rates. These include complication rates of 6.8% (Voges et al. 2007) and the 4.5% required hardware removal as a result of infection (Sillay et al. 2008). A summary of the side effects includes cognitive, behavioral, psychiatric, and psychosocial (Alegret et al. 2001).

The vulnerability of those with PD or other brain diseases mandates concern regarding therapeutic misconception. The assessment of capacity is made more difficult with patients whose mental status might interfere with aspects of informed consent. The medical conditions that patients may have may also be a concern when obtaining informed consent. For example, a psychiatric diagnosis should not preclude the obtaining of informed consent (Appelbaum and Grisso 1988). These issues also exist with patients who have movement disorders (Pavlov and Tracey 2015). What will their quality of life be and who determines what is acceptable?

When research involves the brain/mind, the issues of free will and determination needs to be addressed. Moreno (2003) notes "...our growing knowledge about the origins and physical basis of mental states, let alone the possibility of controlling them with some specificity, threaten the liberal ideals of freedom and personal responsibility." Neuroscience is on the road to showing once and for all that mental states reduce brain states, and even brain states that could be subject to direct manipulation. This brings up the possibility that there is no free will or that it can be manipulated or controlled with devices. One could analogize the use of pharmaceuticals or extant devices such as cochlear implants, cardiac pacemakers, or genetic editing.

The need to address the ethical concerns noted above should begin before the research is initiated and they should continue during the progression of the research. They should also be part of the ongoing assessment after the research is completed.

RESEARCH ETHICS

The Belmont Report (1979) clearly states that research should contribute to generalizable knowledge that is relevant to the discussion of ethical concerns. This may preclude practices such as acquiring robust patent banks that include research by others and has the purpose of protecting a company's patents for the purpose of maximizing profits by restricting access to information. The report addresses some "basic ethical principles," which include (1) respect for persons, (2) beneficence, and (3) justice. Respect for persons means that individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to protection. Additionally, there are inclusion elements regarding informed consent and that participation is voluntary. As research is to discover information that is not known, the "informed patient" model may not apply. The concept of a "reasonable volunteer" may be more appropriate. In the usual informed consent process for a procedure, the expected outcomes and related statistics are to be made available (www.hhs.gov/ohrp/humansubjects/guidance/belmont.html).

Beneficence is operationalized when we minimize harm and maximize benefits. The thorny issue of research is that there may be occurrences in which there are no benefits to the subject. Also addressed by the Belmont Report is the task of balancing individual needs and societal needs. Justice issues relate to fair distribution and what criteria should be applied. These issues require constant attention because of evolving improvements in health care such as organ donation and transplantation. The report notes several implications regarding fair distribution and they are as follows: (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to societal contribution, and (4) to each person

according to merit. “The fairness of research would be that those who participate in a research project are likely to benefit. This requires awareness of the potential for biases such as race, gender, social, and cultural factors” (www.hhs.gov/ohrp/humansubjects/guidance/belmont.html).

The foundational ethical element that relates to medical research is informed consent. Informed consent should not be viewed solely as a signed form. Rather it should be viewed as a document in which a patient grants permission to the applicable physicians and/or researchers regarding acknowledgment of treatment protocols and possible consequences. There are seven requirements for ethical clinical research. They are (1) social or scientific value “...value enhancements of health or knowledge...”; (2) scientific validity, methodologically rigorous; (3) fair distribution selection, scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits; (4) favorable risk–benefit ratio...the potential benefits to individuals and knowledge gained by society must outweigh the risks; (5) independent review; (6) informed consent; and (7) respect for enrolled subjects, “subjects should have their privacy protected, the opportunity to withdraw and their well being monitored” (see Table 1; Emanuel et al. 2000).

Therapeutic misconception “...occurs when subjects in research fail to distinguish between clinical care and research and fail to understand the purpose and aim of research, misconceiving their participation as therapeutic in nature” (Miller and Brody 2003). Persuasion is “influence that is not controlling and also warranted...coercion (is the use of) credible and severe threat of harm or force to control another...ma-

nipulation...most likely forms of manipulation are informational manipulation and withholding information....” To adequately address this issue, they suggest a neutral professional who is not associated with the research to discuss the technical and the ethical issues that relate to the research and to be aware of the therapeutic misconception as it relates to informed consent.

Due to the potential for conflicts of interest with researchers involved with “dual use” in neuroscience research, there should be added responsibilities. These may include the “...moral responsibilities of neuroscientists that includes the aims and implications of their work with particular attention to the agenda of various funding sources” (Moreno 2003).

The ethical issues that have been discussed thus far require ongoing vigilance. The Nuffield Council on Bioethics Report outlines procedures for brain research in the United Kingdom (see Table 2). They have ethics councils that are actively involved as part of the research team. They note the uniqueness of research involving the brain: “The brain has a special status in human life that distinguishes it from other organs. Its healthy functioning plays a central role in the operation of our bodies, our capacities for autonomous agency, our conception of ourselves, and our relationships with others... and thus in our abilities to lead fulfilling lives. This means that novel neurotechnologies raise ethical and social concerns that are not raised to the same extent by other novel biomedical technologies” (Nuffield Council on Bioethics 2013).

INNOVATION

The creation of new knowledge through innovation is at the core of our discussion regarding BEM. Innovation is “...a significant modification of a standard technique, a new application of or a new indication for an established technique, or an alternate combination of established research that occurs when the information is acquired and will be disseminated and or published...for the first time” (Reitsma and Moreno 2002). Innovative research occurs in many

Table 1. Ethical requirements for clinical research

Social or scientific value
Scientific validity
Fair subject selection
Favorable risk–benefit ratio
Independent review
Informed consent
Respect for potential and enrolled subjects

Data adapted from Emanuel et al. (2000).

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Table 2. Broad ethical concerns related to brain research

Ethics of research with invasive technologies	Validity of informed consent and competency determinations Obligations regarding long-term upkeep of implanted devices, and follow-up with research participants Participants' physical and perceived nonphysical harm and how to manage such issues
Altering, enhancing, and/or manipulation of self/agency	Technologies that do or could involve brain stimulation; brain-computer interfaces; brain prosthetics; enhancers of memory, attention, reasoning; manipulation of memories, etc. Perceived violations of autonomy, authenticity related to altering experience, personal narratives, personal identity
Privacy/discrimination concerns, and the need for privacy protection	Generation of information about individual traits/conditions that are of medical/social/legal relevance Questions of cybersecurity Neural signatures could be found that predict traits, personalities, cognitive abilities, etc. Protecting the privacy of information when using wireless technologies in the brain Lack of a neuroscientific analog of the Genetic Information Nondiscrimination Act
Translation to context beyond the clinic/bench	Ethics of commercialization, public-private partnerships, and wider application of imaging technologies for commercial purposes Privacy safeguards Managing potential conflicts of interest

For more information, see BRAIN initiative (braininitiative.nih.gov/pdf/02092016_meeting_Summary_508C.pdf).

venues, for example, universities, medical centers, research institutes, industry, and national laboratories. Some of the basic needs for innovation to occur are freedom, knowledge, and truth. Additionally, the sharing of information is essential to research and innovation and this may include factors such as cooperation and collaboration. Interference with these characteristics of research is not in the best interest of industry. Corporations are the fiduciaries of their stockholders, whereas physicians and researchers are, by virtue, the fiduciaries of patients/subjects.

There are also conflating relationships between industry and research concerning patents. Patents may create a protective, exclusive barrier to sharing information and the practice of collecting patents that are kept in "corporate patent banks." These tend to protect a company's existing patents until the current patent is expired. This may be beneficial for a long period of time, but it may not be very fruitful for society. A major effect of patent banks is to protect profit by eliminating competitors' ability to create ge-

neric equivalents and allow patients to have choices and potentially save money. "It is precisely the obsession with the bottom line that has led to a slowdown in the drug pipeline..." (Goozner 2004). "In 1950, per 1 billion dollars invested, 70 new drugs were approved by the FDA and in 2010, there are .70 drugs approved per 1 billion dollars" (Scannell et al. 2012).

The travails experienced with DBS at Weill Cornell Medical Center have been clearly discussed. The factors relate to intellectual property as well as basic ethical issues regarding patients/subjects and research. For example, companies may decide that the profitability does not exist and ends their relationship with the research. Subjects are then left without devices essential to their care. This is especially true when there are few researchers and only a few companies who can provide the needed devices (Fins et al. 2011).

The ability to improve the performance of soldiers and to be able to better protect the nation is obvious, but it tends to raise some ethical issues. The United States Military does have the

responsibility to protect the country and assist its warriors in ways that might improve performance. Thus, devices being used for medical research may be useful in war. For example, the term “dual use” can be applied to many of the devices being discussed within the realm of BEM. The extension of intracranial devices into other parts of the brain is advancing and because of its successes has been of interest to the military (Moreno 2012). However, “the brain is not like other organs; whenever we talk about modifying the brain, we enter special territory that calls into question whether we are stepping over some natural line and jeopardizing our essential nature or personhood.” Undoubtedly, we are “stepping over” with some of the more recent research that addresses psychiatric disorders such as depression, movement disorders, and with the military, efforts to make the “perfect warrior.”

We need to recognize that electronic devices have been part of medicine for quite some time and examples may include cochlear implants as well as cardiac pacemakers. Cochlear implants were not welcomed by the deaf community and were viewed as a form of eugenics (Solomon 2012). In addition, performance improvement drugs such as Ritalin and steroids have been abused for decades. The conundrum tends to revolve around a nonresolvable ethical concern that indicates that the devices will be able to control the brain/mind. Moreover, DBS for movement disorders have become part of mainstream medicine, albeit with risks (Sillay et al. 2008).

An ethical concern when altering brain function and thus controlling the mind is the issue of free will and personhood. There is not consensus either with a pharmaceutical approach or a device approach as to whether mind control is beneficial. The history of medical research should leave us with ethical concerns and humility as we approach this new field of BEM. It should be recognized that “hacking” the brain (neurosecurity) is an issue that has been addressed (Moreno 2012) and has continued to be a concern. “This debate should involve the collaboration of ethicist, neuroscientists, engineers, computer scientists, cybersecurity experts, lawyers, and

other significant stakeholders, informed regulators, and policy makers” (Ienca and Haselager 2016). The need for ethical guidelines is clear as indicated above (Goering and Yuste 2016).

Along with the alteration of brain function, there is an additional ethical concern surrounding BEM that includes health care information in real time. Through the use of real-time visualization, there is an allowance to use data points to potentially find correlations between factors such as health problems, demographics, and even specific regions throughout the globe. Data sets are typically developed through an immense sense of collaboration, but there are concerns regarding privacy. When data is shared, there is need to comply with specific standards even if there are innovative approaches. While the use of real-time health information is progressively developing, there are many clinicians who will be able to draw actionable insight as time progresses. Moreover, they will be able to view and assess applicable metrics to discover new ways to explore health care outcomes (Ola and Sedig 2016).

ACADEMIC–INDUSTRY RELATIONSHIPS

Research in academia may allow for more open access than that within the military. The latter does not tend to fall under the same regulations related to disclosure. Hopefully, researchers from both academia and the military will be able to work together. A major concern includes the economic “capture” of academic researchers through Defense Advanced Research Projects Agency (DARPA) grants that have the great possibility of offering “dual uses” from the results of research. The “capture” of Universities was elaborated upon in *Universities in the Marketplace* (Bok 2003). He felt that there were three factors necessary for a university to prosper. They included highly trained specialists, expert knowledge, and scientific advances that could be used. There can be an argument made that research does not know a priori whether the results will be of use. And therein lies the economic problem of creating new knowledge. Why would an industry that is the fiduciary of its stockholders support basic, exploratory research where the re-

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sults are not known? It has been suggested that industry should not get involved until phase 3 of clinical trials research (Fins et al. 2011). The obvious conflict relates to the different roles that the Universities have versus those of industry. Of course, the Bayh–Dole Act (1980) seeks to foster university involvement with industry through acquisition of intellectual property (Bok 2003). The “perfect storm” for pushing this relationship was the decreased funding of basic research by the National Institutes of Health. “Individual investigators, medical schools seem unwilling to admit that their financial interests could possibly affect the results of research performed within their walls” (Bok 2003). One of the many effects has been that the “...efforts by universities to patent scientific discoveries have become well established, the financial results are reminiscent of intercollegiate athletics...” The concern is that research universities will become entrepreneurial universities and that may undermine academic standards, damage the academic community, risk reputation, and undermine the conscientiousness of the faculty (see Table 3; Bok 2003).

Markel points out distortions in science and discovery that have resulted from the Bayh–Dole Act and suggest that “...conflict of interest be identified and contained in order to protect patients. How can scientific discovery proceed if all innovations and research tools are patented and the discoverers control access to them” (Markel 2013). The Common Rule may suggest ways we can “recalibrate the Bayh–Dole Act” (Menikoff et al. 2017). These new regulations were made public in September 2015 and will go into effect in 2018. Included in this work are suggested changes that relate to informed consent by using the “reasonable person” standard and the sug-

gestion that information should then be “concise and focused.” The Common Rule does not require informed consent for the use of biospecimens, such as leftover blood samples. In general, the new Common Rule improves the informed consent process and the patient will then be able to facilitate beneficial factors. When this takes place, the efficiency of research is improved.

Relationships with industry can have positive and negative effects. For instance, the financial support from industry may accelerate research and publications. In contrast, industry support may result in delayed publication and secrecy to protect industry profits. Industry is the fiduciary for their investors/stockholders. Physicians and researchers have fiduciary responsibilities to patients/subjects. The prevalence of industry delaying publication and maintaining secrecy has been well documented (Czarnitzki et al. 2014). The concerns that relate to delayed publications, secrecy, and patents include the fact that there are social costs. Czarnitzki and colleagues note the increasing financial support for research in Germany and its effects on delayed publications and secrecy that may correlate with the financial support from industry. Blumenthal and colleagues had similar concerns. They found delayed publications, secrecy, decreased participation in university activities, and other conflicts. And “dazzling as those benefits may seem (profits to universities and industry), ...the risks created by academic–industry relationships have proved to be just as eye-catching.” The authors indicated that they are “threats to human subjects of research,” which could then impact the entirety of the research process (Blumenthal et al. 1986). The risks tend to arise from conflicts of interest and based on the concerns, the factors mirror the findings of Czarnitzki. These conflicts may be addressed contractually (Mamajiwalla and Seide 2015).

Though theoretically different, there are “common” aspects of research for the organizational cultures of universities and industry (see Table 4). Collaborations that are likely to avoid conflict and have long-term relationships will have found ways to facilitate the common orga-

Table 3. Types of universities in the marketplace

Universities
Academic universities
Research universities
Academic research universities
Industry universities
Industry research universities

Data adapted from Bok (2003).

Table 4. Comparing and contrasting organizational cultures

University	Common	Industry
Public mission	Creating societal value	Shareholder value
Publication	Brand reputation	Revenue
Basic research	Research	Applied research
Curiosity-driven	Science-driven	Results-driven
Creating knowledge	Sharing knowledge	Utilizing knowledge
Open source	Collaborative innovation	Protected innovation
Investigator needs	Patient needs, find cures	Market needs
Education	Exchange know-how	Retain know-how
Academic freedom	Tackling big questions	Measureable objectives

Data based on Ehrismann and Patel (2015).

nizational cultures that benefit their best interest and still adhere to their fiduciary roles (Ehrismann and Patel 2015). Universities have three promises that form the basis of their social responsibilities: to teach, create new information, and be a repository of information. These “other” responsibilities/relationships tend to create “research universities” (Bok 2003).

INTELLECTUAL PROPERTY

Drozdo and Fairbairn (2015) delve into the legal complexities of intellectual property rights in contracts between universities and industry. The character of the players involved is critical as the myriad of conflicts of interest that occur during the years, or decades, that research will take place may have issues that require trust, goodwill, and legal counsel. Ethics will be at the core of some of these issues. This concern has been noted in the Nuffield Council Bioethics Report where they addressed not only interests such as safety, privacy, confidentiality, and equity, but also virtues such as inventiveness, humility, responsibility, and awareness of the vagaries of the communication of research with the media (Nuffield Council on Bioethics 2013). The report cautions us to “...resist the temptation to over-claim or engage in unjustified extrapolation beyond that which is supported by research evidence.” It is worth noting that only two countries allow pharmaceutical advertising on television: the United States and Australia. In addition, they ask that “...businesses and universities developing and promoting

commercial products from neurotechnological research should also reflect on their own responsibilities when seeking to publicize this research, attract funding for development, and market their products.”

The research activities at the Feinstein Institute for Medical Research have been facilitated by collaborating with other research institutions and industries to foster sharing of information while protecting intellectual rights. However, the history of patents and their present use by industry may not always be in the best interest of patients/subjects. There are issues pertaining to risk factors and trust. Moreover, there are also problematic occurrences with informed consent that may play a role.

CONCLUDING REMARKS

This article attempts to heighten the awareness of the ethical issues regarding BEM and will hopefully lead to earlier involvement of ethics (committees) and a more proactive approach to addressing the ethical concerns. The experiences with DBS offer significant insight and should allow for fewer difficulties when dealing with the ethical issues that relate to BEM. Moreover, with the use of the ethical theories discussed, this provides a strong infrastructure that can provide guidance for the progression of the field. Although there are still many ethical complexities to take into consideration, professionals have a strong capability to address the issues accordingly and create standard parameters for proper progression in the future.

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