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Ankita Moss April 14, 2020

Assessing the perceived value of neuroethics questions and policy to neuro-entrepreneurs

by

Ankita Moss

Karen Rommelfanger

Adviser

Neuroscience and Behavioral Biology

Karen Rommelfanger

Adviser

Gillian Hue

Committee Member

Benn Konsynski

Committee Member

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Ankita Moss

Karen Rommelfanger, PhD

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Abstract

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By Ankita Moss

"Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives" delineates guiding questions for global neuroscience research. These questions tackle issues such as identity, morality, cross-cultural differences, privacy, and potential stakeholder involvement in ethical decision-making. This project aims to extend the work outlined in "Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives" by assessing the perceived value of these ethical questions and categories to neuro-entrepreneurs, neuro-industry, and neuro-innovation.

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1. Background and Significance of Project:

Like genomic data, which sparked the robust expansion of bioethics, neural information can feel deeply personal (1). Neuroethics (the discipline that analyzes the "the social, legal, ethical and policy implications of advances in neuroscience") has developed at the heels of increasing neuroscience research and advancement (2). Issues of cognitive enhancement, loss of privacy, and identity are all present and future concerns of the field of neuroethics. Such drastic changes have the possibility to alter societal definitions and boundaries regarding what it means to have merit and quite possibly what it means to thrive within a society (3). Governmental bodies such as the NIH BRAIN Initiative's Neuroethics Working Group serve to navigate unique ethical issues and future implications in neuroscience research, such as challenges to autonomy and privacy unique to gathering and utilizing brain data (4). Such efforts have sparked an attempt to properly mitigate and combat possible negative implications; however, robust neuroscience research and advancement has not only expanded internationally, but has also recently merged with entrepreneurship (5). An influx of neuroscience companies and "neuro-entrepreneurs" will allow neuroscience advancement to permeate on not only an international scale but also at the level of individual autonomy, as it is likely that those operating in the private sector can scale and make neurotechnology available and accessible for individual members of society.

In order to further discuss this matter, one must first understand the context in which the term "neuro-entrepreneur" is applicable. While some management and entrepreneurship studies define "neuroentrepreneurship" or "neuropreneurship" as the application of cognitive science and neuroscience to the practice of entrepreneurship itself, we refer to "neuro-entrepreneur" in our study, as any individual who creates, deploys, or works on a neuroscience product within the

private sector (6). “Neuro-entrepreneurship,” for the purpose of our study, is the application of entrepreneurship to translational neuroscience research and the deployment of neurotechnology, or neuro-innovation, in the private sector. Neuroscience products can range from brain-machine interfaces to neuro-marketing tools and personality assessments utilized in the workplace. Such spheres can be broadly categorized under the umbrella term “neuro-industry,” an interdisciplinary sector that creates or deploys commercialized “neuro-innovation” or “neurotechnology” (broad, and in the context of this paper, interchangeable terms, encompassing novelty from machines to pharmaceuticals). As “neuro-industry” grows, its implications for society must be considered. The goal of this paper is to advance and accelerate science by anticipating and mitigating obstacles that might prevent otherwise good innovation from coming to fruition.

Currently, due to neuro-industry’s relatively nascent stage, it is unclear as to whether the values and goals of most neuro-entrepreneurs resonate with neuroethics. Recent papers such as “Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives” (NeQN, for short) outline essential questions to guide neuroethical vetting in neuroscience research (7). Increasing investment in the seven active or existing international brain initiatives prompted the creation of the NeQN in order to provide a guide for ethical neuroscience research and the consideration of implications. Such literature prompts the research question of whether or not neuroethical guidelines would be seen as useful to neuro-entrepreneurs and neuro-industry. The development of the seven existing or active Brain initiatives (by Canada, EU, Japan, United States, Australia, China, Korea) and the emergence of literature calling for neuroethical frameworks and guiding questions (such as “Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives”) have occurred on a landscape of increasing neuroscience

research and neuro-company formation (5). The Australian Brain Alliance is one example of a national endeavor that is in the planning phases of advocating for positive benefits and mitigating the ethical consequences of neuro-innovation and neuro-entrepreneurship in Australia (8). Existing and expanding international efforts highlight how neuro-innovation has become an ethical priority that will only increase in importance. These efforts point to the "shifting international landscape in which the discipline of neuroscience recognizes neuroethics as integral to the neuroscientific enterprise" (9, pg 363). "Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives" considers global innovation and diverse stakeholders into its guiding questions, setting a precedent for cross-cultural considerations to be incorporated into future neuroethical guidelines for neuro-entrepreneurs.

As neuro-industry grows on the heels of increasing investment into international-level neuroscience research, the next step is to understand how one could create an ethical framework for neuro-entrepreneurs as well, possibly by using the NeQN as a model.

In order to consider whether guidelines on neuro-innovation will be useful to neuro-entrepreneurs, one must first take into consideration the contexts and processes of innovation itself. Cultural Swirl, developed by anthropologist Ulf Hannerz, provides a socio-anthropological theory to understand the process of innovation (10). It does so by accounting for both anthropological and modern theories of innovation. Cultural Swirl Theory recognizes that innovation arises from a mix of skilled, diverse individuals in close proximity. Neuroethics, similarly, is a field that is applicable to humanity at large, not just one culture; therefore, it calls for a framework of understanding that involves a host of global and experiential perspectives. The NeQN were designed to meet the challenge of being adaptable for interpretation across

cultures and more inclusive of a plurality of perspectives. Understanding the Cultural Swirl recipe for innovation is integral in assessing the value of multiple stakeholders in the processes of neuroethics, as delineated by the authors of "Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives."

Although the theory of Cultural Swirl describes how bringing together diverse stakeholders can collectively bring about cultural and/or technological innovation and change, it is also important to consider the individual players themselves. In order for an innovation to be beneficial to humanity, it must be ethical while also delivering some form of progress (for example, solving a niche or widespread public health issue). Entrepreneurs and innovators might struggle with the tensions of fast-paced innovation and the slowness that ethical regulation might cause; however, studies have demonstrated that creativity and ethics are complementary and equally important to the entrepreneur or innovator (11). Through data and discussions, Bierly, Kolodinsky, and Charette demonstrate how ethics does not in fact hinder the creative process. The researchers found that creatives are "situationists," a term derived from the work of psychologist Dr. Donelson Forysth, meaning they tend to act cautiously, in terms of moral-decision-making, while being pragmatic and demonstrating the understanding that they cannot slow innovation (12). Using this definition, one might also call entrepreneurs consequentialists, as they focus on end goals and understand that the way to achieve the end goal depends on the situation itself. Successful creatives may in fact just use ethics as a heuristic for fast-paced decisions. Buchholz and Rosenthal further discuss how the spirit of entrepreneurship aligns with ethics, demonstrating how, in order to thrive as an entrepreneur, one needs a strong moral decision-making toolkit that can be easily utilized for fast-paced decision-making (13). The authors argue that entrepreneurship, in this way, integrates speed and reflexivity within the

framework of ethics. Entrepreneurs are essentially examples of those who act quickly based on their decision-making toolkit, and are thus individuals or exemplars who must master both ethics and innovation in order to benefit society in the most efficient way possible. Such literature demonstrates how creative situationists like entrepreneurs can be key players in the creation and drafting of ethical guidelines. These creative situationists who use ethics as a toolkit could be considered key players in the Cultural Swirl Theory.

Figure 1: Cultural Swirl Theory

Anthropologist Ulf Hannerz, who generated Cultural Swirl Theory, sews these ingredients together in his work, proposing that using one's individual experiences, unique ideas, and culture(s) are analogous to utilizing a toolset to spark innovation. In his work "Transnational Connection," Hannerz paints arguments for diversity with increasing globalization, comparing diversity of culture and thought to ecological diversity and niches (14). He states that cultural diversity in itself is a form of a niche experience that contributes to innovation. *Although each culture thrives on its own resources for its own very specific goals, integrating this plurality of views for a common purpose that resonates with all of humanity can be beneficial in the long-run.* Here we note that one of the key features of an ethics and neuroethics toolkit is being able to examine a problem from multiple perspectives and engage in perspective-taking.

Hannerz explains how innovators from diverse backgrounds and niche cultural knowledge can come together to tackle a potentially divisive issue, like neuro-innovation, that will affect not just one culture but all of humanity. Through Cultural Swirl Theory, multiple

stakeholders bring diverse perspectives together to spark innovation toward a common goal. Using the concept of utility brought about by multiple stakeholders, one can see how neuroethics tools such as the NeQN, which are designed to incorporate diverse cultural perspectives, along with neuro-entrepreneurs skilled at ethical heuristics within their craft, can be complementary and enriching to neuro-innovation.

This project explores the value of neuroethics to neuro-entrepreneurs and neuro-industry leaders by testing the hypothesis that neuroethics is valuable to neuro-entrepreneurs and neuro-industry. Information on the sociology of innovators, and particularly neuro-entrepreneurs, is integral to determining whether neuroethical guidelines could serve neuro-entrepreneurs whose work may have implications for a global stage, and thus, society at large. In order to assess the value of neuroethics to neuro-entrepreneurs, the relationship between ethics and innovation generally for entrepreneurs and innovators must be dissected and analyzed - investigating whether or not ethics and innovation are viewed as mutually exclusive, and perhaps, operate separately. This sociological investigation was conducted through a series of one-on-one interviews conducted with neuro-entrepreneurs.

This project and the interview guide are informed by the concept of Cultural Swirl, the socio-anthropological idea that the selection of diverse stakeholders or a heterogeneous group of actors will contribute to innovation. The project is also based on “Neuroethical Questions to Guide Ethical Research in the International Brain Initiatives,” as the questions heavily consider the effects of a culturally diverse group of stakeholders on neuro-innovation. The goal of this study is to expand upon “Neuroethical Questions to Guide Ethical Research in the International Brain Initiatives” to include neuro-entrepreneurs as a key stakeholder group, specifically exploring perceptions and experience with ethics and the creative process in innovation.

2. Hypothesis Stated

Hypothesis: **Neuroethics is not contrary to, but can enrich neuro-innovation.** Guiding neuroethics principles are in alignment with the process of neuro-innovation not only within academia, but also in the private sector.

3. Methodology to Test Hypothesis

a. Mechanism and Logistics of Data Collection

To test the hypothesis of this study and explore possibilities for new directions, qualitative data collection via comprehensive interviews was conducted with ten neuro-entrepreneurs (15). Each neuro-entrepreneur had unique experiences and various backgrounds. The cohort of these ten neuro-entrepreneurs was conducive to the theory of Cultural Swirl, as participants represent entrepreneurs from around the globe.

After obtaining verbal consent from the participants, one-on-one semi-structured interviews (the interview questions guided the conversation, which honed in on specific topics relevant to the biography of the neuro-entrepreneur for depth), lasting from 30-45 minutes were conducted. These interviews helped gauge attitudes toward neuroethics within neuro-industry as well as the purpose and process of innovation itself. Interview conversations were recorded and transcribed in order to preserve the true syntax and meaning of the content. All neuro-entrepreneurs involved in the study were made aware of this recording and verbally consented to participate in the interview and data collection process. All recordings and identifying information were stored on password-protected devices. All interviews were recorded on the interviewer's password-protected Zoom account. The recordings were deleted after they were

transcribed and coded. Throughout the process of data collection and data integration into this final work, all digital files were given pseudonyms and codes to protect the identity of the participant. Interviewees (participant neuro-entrepreneurs) were made aware of the protection measures and agreed to continue with the data collection process with the knowledge of a possible breach in confidentiality.

After the recording process, the interviews were transcribed through a vetted transcription service. Once the interview had been transcribed, the interviewer deleted the interview recording from the password-protected device and stored the typed/written information within a password protected account on Emory Box before finally deleting the file. All identifying information was stored on the mentioned password-protected devices only and therefore is not included in this paper.

As recruitment was initially via email, the research team was aware of the names and email addresses of the participants; however, the researcher's email is, and was, password-protected. Only the research team had access to the password-protected email and subsequent documents that included identifiers linking codes to participants. At the end of the interviews, the researcher asked the participants if she could contact them in the future should the study need clarification of information collected during the interview.

Interview times were mutually agreed upon for audio privacy. At the end of the tenth interview, the end of the data collection process, the research team noted that all interviews were performed remotely and that all data collection occurred on Emory University's campus.

b. Grounded Sociological Theory: Creation of the Interview Guide and Conceptual Map

Before the creation of the interview guide, the research team formulated a preliminary conceptual map that integrated the concepts of innovation and ethics. Innovation (concept A) and

ethics (concept B) gradually grew to the questions “What is Neuro-Innovation?” (innovating within the sphere of neuroscience) and “Is neuroethics / ethics part of this creative process?” respectively. Under each preliminary concept were key words that could possibly represent a certain identified theme during the interview data collection process. Concepts A and B come together in the resolution of our hypothesis, “How does neuroethics / ethics help the neuro-innovation process?,” component of the conceptual map. In this way, concepts A and B merge together within the hypothesis of this study to guide the process of testing our hypothesis.

Grounded Sociological Theory (the development of a sociological theory based off of collected data and integration of that data) allowed for reiterations and reintegrations of concepts A and B after each interview (16). The diverse perspectives of the recruited neuro-entrepreneur sample informed the conceptual map, which informed the interview guide.

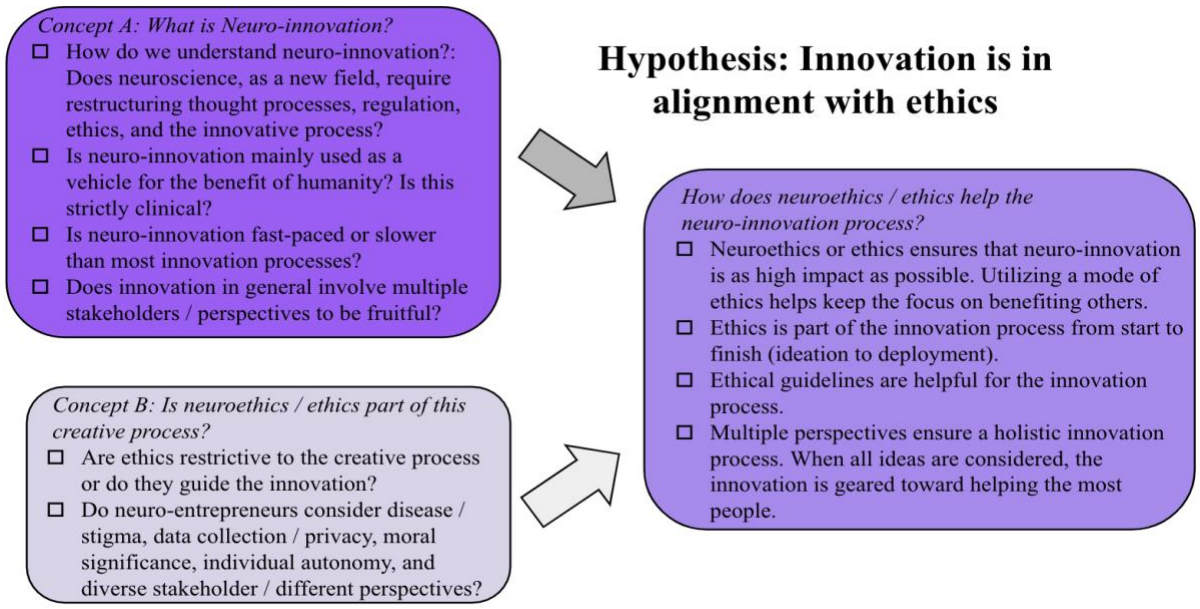


Figure 2: Final Concept Map

Like the concept map, a preliminary interview guide was also created (however, the development of the guide was informed by the preliminary conceptual map). The interview guide

was also informed by "Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives," which contains five question subsets or themes (7).

These are, briefly:

1. The impact of brain disease models and stigma
2. The ethical standards of biological / neural data collection and privacy
3. The moral significance of neural systems (which proved to be *currently* less relevant to neuro-industry)
4. The impact on or challenges to individual autonomy
5. Appropriate contexts for neuro-innovation usage and deployment and diverse stakeholder involvement

The conceptual map and NeQN together provided the framework for the initial iteration of the interview guide. Interviews were used to collect data regarding attitudes toward neuroethics. This data and categorization of receptiveness toward neuroethics and perceived value of an expanded neuroethics to neuro-entrepreneurs continuously informed the hypothesis and conceptual map as well. Several iterations of the conceptual map were created as greater understanding of the collective responses of the neuro-entrepreneurs unfolded throughout the analysis (as is protocol in grounded theory). Grounded Sociological Theory was used to ensure that the experiences of subsequent interviewees aligned with the goal of the study and the NeQN question subsets (16).

c. Methodology for Identifying Themes

Questions from the interview guide formulated for this study were asked in order to identify themes articulated by each participant/neuro-entrepreneur. After each interview was conducted and each respective transcription file was received, the research team annotated each file based on the current iteration of the concept map. In order to ensure that annotations matched the attitudes of the neuro-entrepreneur at the time and that tone was preserved, the research team created a password-protected document with reflections that were written immediately after each interview.

After four interviews were annotated, the research team developed multiple themes that matched the information presented and were consistent with the information provided within each interview. Next, these four interviews were re-annotated and coded to match the theme guide created. Interview transcription file coding involved matching the information provided by the neuro-entrepreneur to the key words in the concept map and the written theme document (the research team constructed a number and letter system for each theme).

The research team then modified the concept map based on the new themes. After four more annotations of new interview transcription files, the research team further elaborated on the current theme guide and added new themes when consistent information matching a new idea was presented by the neuro-entrepreneur cohort. These four subsequent interviews were coded according to the preliminary theme guide created. New themes and elaborations on existing themes identified were then integrated into the subsequent re-coding of these next four transcription files. The new themes were then added to the first four interview files, which were also, again, first coded with the preliminary theme guide. The last two interviews were transcribed and coded using the final theme guide.

4. Results: Themes Identified During the Data Collection Process

Although many of the themes proved mostly consistent within the neuro-entrepreneur cohort, the qualitative findings of this research project are not intended to be generalizable. The following are the final themes identified at the end of the data collection process (at the end of the ten interviews). The theme categorization is derived from the final version of the conceptual map. “What is the purpose of neuro-innovation(s)?” and “What are the key (neuro)ethical tensions of neuro-entrepreneurs?” stem from concept A “What is neuro-innovation?” and concept B “Is neuroethics / ethics part of this creative process?” respectively. “How would ethics fit with the neuro-innovation/creative process?” is derived from the “How does neuroethics / ethics help the neuro-innovation process?” conceptual map component that integrates concepts A and B.

a. Table of Themes:

How would ethics fit with the neuro-innovation/creative process?
1. Ensuring/Maximizing impact: Ethics is desired for preventing harm to the end-user and ensuring impact; bringing end-users/patients in is important along with other diverse stakeholders. In order to maximize impact, ethics also needs to be as nimble as the tech, keeping up with the science.
2. Restrictive vs Guiding: Ethics enforcement is viewed as restrictive and slowing, primarily through the lens of regulation; however, ethical guidelines are helpful tools throughout the innovation process.
3. Lacking incentives: Incentivization of ethical behavior is missing and desired.
4. ROI, ethics, and scale: Neuro-entrepreneurs should be focusing on maximizing the use of their products while also mitigating negative uses. This responsibility to both ROI and ethics results in tension.
What are the key (neuro)ethical tensions of neuro-entrepreneurs?
1. Data Ownership: Users should own their data, but the business model doesn't allow for it (Small companies are more incentivized to sell data for growth).
2. Access and Justice: Neuro-innovation will alter societal norms and statuses. Innovations can empower society, but the tech and insights are not always shared with everyone in society who might benefit.
3. Neurodata and Misuse: Current data regulations suffice, but may not be sufficient for future implications and possible uses of brain data. Misuse of neurodata is lack of transparency to the user or patient.
4. Societal Norms: Unintended uses or access to data may lead to stigma, discrimination, power imbalances, and other uses, but the implications are not apparent to users (or the entrepreneurs who sold the data).
5. Autonomy: Neurotechnology / neuro-innovation can enhance or diminish autonomy.
What is the purpose of neuro-innovation(s)?
1. Reducing suffering and increasing happiness: from disease and injury to lack of access. Ethics is seen as facilitating this alleviation.
2. Clinical: Neurotechnology can be used to meet unmet clinical needs, improve treatment, and provide extra diagnostic accuracy/prediction, impacting how diseases

are labeled and defined.
3. Non-clinical: Off-label use or diagnostic neurotechnology that moves into or is created for the commercial domain raises ethical concerns.
4. Empowerment: Neurotechnology / neuro-innovation should aim to help people and enhance "autonomy" of the public, empowering them to have greater bandwidth of knowledge, choices, and behaviors.

Figure 3: Final Categorical Themes

b. Evidence of Themes:

I. How would ethics fit with the neuro-innovation/creative process?

1. Ensuring/Maximizing impact: Ethics is desired for preventing harm to the end-user and ensuring impact; bringing end-users/patients in is important along with other diverse stakeholders. In order to maximize impact, ethics also needs to be as nimble as the tech, keeping up with the science.

Participants reported that, in order to keep up with the pace of technology and increasing globalization, ethics needs to be an ongoing conversation amongst intellectually and experientially (socially, culturally, etc) diverse stakeholders.

> "It's important for us **to reassess the pace of technology.**" (J1)

Specifically, one participant noted that legal regulations might not be keeping up.

> "**The technology changes faster than the laws can keep up with**…."The two challenges are, one: how do any set of laws or guidelines keep up with the pace of technology? And then secondly, how do you define it so that it's of any practical use? Neurotechnology is a very broad definition" (M6)

Most importantly, the stakeholders involved should represent different parts of the innovation process. End-users and patients who utilize the technology are vital to a stakeholder cohort for a thorough consideration of ethics. In order to maximize impact within the current pace of

technology, those who are impacted must be involved in the conversation.

> "**I would like to see all those big groups representing users and patients** working with the neuro-entrepreneurs to help shape that innovation in a way that is as useful as possible." (A2)

> "I would say definitely intended users,...so the general public or people who would be using the product would be stakeholders." (M6)

> "**I think that ethics should be an ongoing conversation between all the stakeholders**… so, the scientists, policy makers, government, investors who support those entrepreneurs, investors and advisors who help make companies grow, and in some cases I would say, the subset of the investor community that's also philanthropic." (D4)

In the above quotes, the participants (neuro-entrepreneurs) mention that patients and end-users should be included in the conglomerate of diverse stakeholders who contribute intellectually to an idea or innovation. The participants also mention how the ethics of innovation must be an ongoing conversation amongst all diverse stakeholders to ensure holistic considerations and maximal impact. Technology outpaces legislation and ethics; therefore, many perspectives must be considered to ensure that ethics does not fall short in any category.

2. Restrictive vs Guiding: Ethics enforcement is viewed as restrictive and slowing, primarily through the lens of regulation; however, ethical guidelines are helpful tools throughout the innovation process.

Participants viewed that ethics as a guide is a helpful tool for neuro-entrepreneurs throughout the innovation process, even at the grassroots stage;

> "I would say that, again, the relationship lies where both creativity and innovation are applied. That's where ethics really comes in…But, you know, on the other end of things, I think where it comes into play in a practical sense, beyond just informing your every, waking decision, is where, for example, a scientist is going to determine which among the probably tens to hundreds of ideas that they have, which ones that they pursue and seek grant money for." (D4)

However, ethics, if seen as stringent regulation, enforcement, or law, was perceived as hindering

the innovation process and ROI (return on investment).

> "I think that ethics guides creating new things and creativity in a lot of ways…. I think ethics is important. **I also think that we can't slow our pace of innovation.** There's so much to know, to discover. I think it's a compromise." (J1)

> "**Ethics should not be compromised in any way** and to innovate, you have got to think out of the box. So they're connected" (V8)

> "We should always have balance and not stop innovation because of an extremely regulated space." (V8)

Overall, the entrepreneurs describe how ethics within the innovation process is helpful. They also detail how the pace of innovation is important, and that ethics, in order to be cohesive and conducive to innovation, must not hinder innovation. Ethics must therefore be guiding but not restrictive in order to be helpful for neuro-entrepreneurs. During the interviews, entrepreneurs specifically stated and suggested that ethical guidelines would be beneficial for the innovation process. However, when asked about laws/regulation, the entrepreneurs stated that this level of strict ethical enforcement, which they interpreted as legal/compliance regulations, might hinder the innovation process and ROI.

3. Lacking incentives: Incentivization of ethical behavior is missing and desired.

Interviewed entrepreneurs are motivated by economic opportunities and the current state of the market. Opportunities are motivating factors for entrepreneurs, with ROI as positive reinforcement. Some participants suggested that shifting this model to incentivizing ethics could motivate entrepreneurs to innovate ethically.

> "**I think clearer incentives to do the right thing**... and these can come in different ways….They can come from more favorable regulation. It can come from those user groups, I mentioned them earlier. Maybe rewarding good behavior. For example, nothing prevents AARP or any of these big groups representing millions of patients from saying, we're willing to review all the new neurotech in the field and whoever is the best one or two applications that really help people and that care about our privacy and that care

> about ethics, we're going to help promote them among our users and help drive adoption. It could be positive media coverage to reward the people who take care of these things. So, those are the things that I think would be beneficial in this field, as in any other emerging field." (A2)

This entrepreneur details how incentives can motivate ethical behavior, and specifically how, for example, current positive reinforcers like mass media, press, and economic opportunities can be integrated into the model for how ethical innovation practices can be maximized by neuro-entrepreneurs.

4. ROI, ethics, and scale: Neuro-entrepreneurs should be focusing on maximizing the use of their products while also mitigating negative uses. This responsibility to both ROI and ethics results in tension.

In order to both maximize impact and ROI, while combating possible negative uses of neurotechnology, neuro-entrepreneurs must find a balance. However, ethics and innovation at their core can pull entrepreneurs in opposite directions at first, resulting in tension and conflict regarding innovation strategy.

> "You never know whether there's going to be some application that could be potentially profitable or something that could be dangerous." (G3)

> "Often when you're an entrepreneur, **you need to also maximize the value for all the shareholders, which means that you need to make more and more revenue.** So, often it will make sense to go in different directions." (V8)

> "**I don't think you're doing a very good job of being an entrepreneur if you're not thinking about it [(multiple uses)]** that way. Because, A, if you're not thinking about it that way, you're not thinking about your exit opportunity and you're not thinking about the externalities, just like, 'Here's all the ways that my product could have an effect.'" (W9)

The entrepreneurs discuss how ROI is a central facet of business and how this impacts the direction of product innovation. In order to maximize profit, entrepreneurs need to maximize uses for their technology. However, it is important to determine whether or not deployed

technology can be used negatively and or lead to adverse consequences.

II. What are the key (neuro)ethical tensions of neuro-entrepreneurs?

1. Data Ownership: Users should own their data, but the business model doesn't allow for it (Small companies are more incentivized to sell data for growth).

Many of the participants reported that in order to mitigate harm to the end-user or patient, the end-user or patient should own their data and consent to all usage of that data. However, small companies must focus on growth, which incentivizes leaders and entrepreneurs of these small companies to sell data and utilize end-user or patient data for profit.

> "I**t's easier to sell data than it is to preserve it and not sell data**. And I think increasingly we're seeing pressure to sell data, that's what pharma wants to buy, that's what everyone wants to buy. At least for tech companies, the more, the larger the data set, the more well annotated it is, the more valuable it is. Data is the new oil…. in a small start up company you have a lot more constrained resources. I think that you have to think intelligently and you're less able to make mistakes." (J1)

The entrepreneurs detail how it is easier to sell data than ensure that the privacy of the end-user is protected. In order to mitigate possible violations of end-user or patient data privacy consent, ethical guidelines to protect the identity of the user should be formulated.

In addition, participants consistently noted that the consumer should own their data and had strong values toward transparency.

> "I guess it [(misuse)] would be something that goes against the expressed consent of the end user. So, let's imagine the end user is assuming whatever data is getting captured through a device or through a lab is going to be private and confidential and then somehow, the developer, or someone else accesses that data and serves that in a way that is inappropriate." (A2)

> "Patients should have the option as to who gets to see it [(the data)] or gets alerted." (S5)

The entrepreneurs are suggesting that end-users should control the fate of their own data and that

this should be an implemented ethical practice.

2. Access and Justice: Neuro-innovation will alter societal norms and statuses, leading to questions of access and justice. Innovations can empower society, but the tech and insights are not always shared with everyone in society who might benefit.

Neuro-entrepreneurs should be aware of the implications of neurotechnology / neuro-innovation on macro and micro scales, especially regarding access.

> "The fact that there's so many people suffering from brain diseases and over one billion people diagnosed… in let's say, the developed world. In many reports they say one out of three will develop a brain disease, I think that the impact is also pretty high. So I've been very lucky to have that set of skills and knowledge to be able to work in this field…. It's very important how we are going to regulate this and how are we going to use it in a way that we don't cause huge problems in the future where we have kind of like 'the super elite' and 'the normal people'... and that's kind of abuse. And this is just one example." (V8)

This neuro-entrepreneur distinguishes between access in technologically connected and economically prosperous individuals and/or societies and individuals and/or societies without such benefits. The entrepreneur delineates this future issue further, stating that neuro-innovation that is capable of human enhancement, particularly through neurotechnology, for example, can lead to discrimination that is even deeper than that which we have in society today. Many participants noted that neuro-innovation has the potential to divide society and create prejudice and bias. It is important to innovate consciously, keeping in mind all those who can be affected and all the divides that can be made.

3. Neurodata and Misuse: Current data privacy regulations suffice, but may not be sufficient for future implications and possible uses of brain data. Misuse of neurodata is lack of transparency to the user or patient.

Most interviewees reported that current privacy and data regulations suffice due to the current

lack of knowledge about the power or future implications of brain data. In the future, however, neuro-entrepreneurs predict that it will be increasingly important to reassess the implications of brain data and monitor regulation and protection of user privacy.

> "I think in the future, it's much more of a risk than now. With that being said, I do think that it's important for us to set a limit on privacy for brain data just so that people's confidentiality is protected….We should not limit brain data to just be data from the brain collected from an MRI, but we should also include any manifestation of behavior of the brain that could relate to a brain circuit and define underlying functionality." (J1)

This entrepreneur discusses how the current limits of what constitutes brain data are currently undefined and unknown. Due to this unknown categorization and these unknown implications, entrepreneurs currently believe that brain data requires no extra enforcement than other types of biological data. However, the entrepreneurs also discuss how it is important to monitor brain data as technology progresses in order to prevent possible negative and harmful brain data usage in the future.

4. Societal Norms: Unintended uses or access to data may lead to stigma, discrimination, power imbalances, and other uses, but the implications are not apparent to users (or the entrepreneurs who sold the data).

Many participants noted that neuro-innovation currently has and will continue to have the potential to change societal norms. As a vehicle for data creation and categorization, neuro-innovation will reshape society in some way, either major or minor. Current implications are minor, but future implications are currently unknown and have the potential to have a major impact on the way society categorizes and/or stigmatizes individuals.

> "I think that this could impact insurance companies…. how to handle that data is I think really unclear at this point….interaction with your brain with technology will 100% redefine and change societal norms because we'll have to ask ourselves how we live with that technology and how our brain relates to technology, how we want to move forward as a society with that." (Y7)

This neuro-entrepreneur explains how brain data will reshape societal norms and redefine standards. Neuro-innovation will permeate different aspects of daily life on a global scale, whether through direct usage or even lack of access. Entrepreneurs and the general public do not currently know how exactly neuro-innovation will impact society; however, it is clear across the board from interviews in this neuro-entrepreneur cohort that neuro-innovation will change society in some way.

5. Autonomy: Neurotechnology / neuro-innovation can enhance or diminish autonomy.

Consistently, participants noted how neurotechnology and neuro-innovation has the potential to influence how an individual operates in the world. Such potential can be used for enhancement and for limiting interaction and autonomy. Some examples neuro-entrepreneurs provided are generalizable to innovation, not just neurotechnology.

> "So [(with neurotech)] you make things more and more efficient and you, as you expand somebody's ability to multitask and take on more complicated things, that causes personal stress, right? And it increases the level of **competitiveness and speed** at which things are done." (G3)

> "I do think, in the future, that trend will continue. Meaning, brain tech will e**mpower the autonomy and the decision making of peopl**e. However, there will also be instances where there is abuse and when there are ways in which brain tech is used to reduce the autonomy of individuals. So, we have to anticipate those risks and know how to mitigate them." (A2)

> "People that are in a certain coma or something...with EEG devices, you can already kind of capture certain brain patterns and you can already establish communication….of course, it depends if it can also pose the opposite, a huge restriction if... like science fiction movies type of thing like Black Mirror and reading minds and then, passing this information to those big corporations or governments….**so it can go both ways I think it can be very empowering, but also it can be limiting.**" (V8)

The entrepreneurs explain how neurotechnology can, for example, enhance the autonomy of patients whose life experiences have been limited due to disease or disability. However, the entrepreneurs also explain how technology can be used for the opposite purpose, limiting an

individual's autonomy. Entrepreneurs are currently unclear as to which neuro-innovation could specifically be used to hinder autonomy but mention that any technology that is meant to enhance the experiences of the user can also be abused to hinder the ability of an individual.

III. What is the purpose of neuro-innovation(s)?

1. Reducing suffering and increasing happiness: from disease and injury to lack of access. Ethics is seen as facilitating this alleviation.

Neuro-entrepreneurs are motivated to innovate in the neuroscience space to increase happiness and alleviate suffering.

> "**For me, it's a very personal tie**. My brother suffered a psychotic episode halfway through college,... it's translated into this company." (J1)
>
> "I think that we've evolved a lot and **there's no need for suffering**. And that being said, we have to find ways to do this kind of innovation in a responsible way, in an ethical way." (V8)

The neuro-entrepreneur explains how motivation to innovate in the neuroscience space stems from a desire to better the human experience and reduce levels of suffering. The motivation to alleviate suffering and increase happiness is compatible and complementary to ethics. This type of intrinsic motivation is conducive to ethics and innovation existing together within the innovation process.

2. Clinical: Neurotechnology can be used to meet unmet clinical needs, improve treatment, and provide extra diagnostic accuracy/prediction, impacting how diseases are labeled and defined.

Participants noted that neuro-innovation is helpful for clinicians and medicine at large; it

complements the diagnostic process and increases efficiency. Integrating neurotechnology into the clinical setting impacts the way diseases are labeled and defined. Anything that impacts diagnosis (like neurotechnology) will impact how diseases are diagnosed and perceived in society.

> "I think technology does play a role in what is disease and what is normal. I do think it does constitute a treatment….it can be used for selecting the right treatment." (J1)

The neuro-entrepreneur states that neurotechnology itself can be a treatment and can also complement the diagnostic process. The mechanism by which neurotechnology influences the clinical space depends on the purpose of the particular innovation and its usage within that space.

3. Non-clinical: Off-label use or categorizing neurotechnology that moves into or is created for the commercial domain raises ethical concerns.

Participants also noted that neurotechnology that is deployed for commercial use is susceptible to exploitation upon its arrival to the market. This susceptibility to misuse and misinformation for the purpose of increased ROI via commercial deployment raises ethical concerns.

> "So, what we have to think about is, something as benign as a fitness tracker could have unintended consequences." (S5)

Neurotechnology has the potential to create categories and place individuals into boxes through collected user data. This neuro-entrepreneur, in the quote above, states that labeling and categories that stem from neurotechnology can have negative consequences for the individual and society.

4. Empowerment: Neurotechnology / neuro-innovation should aim to help people and enhance "autonomy" of the public, empowering them to have greater bandwidth of knowledge, choices, and behaviors.

Neuro-entrepreneurs should aim to create innovations that empower individuals.

> "So, without any brain tech, I think right now, many people feel they have very little autonomy because we are at the mercy of ignorance about the brain, of ignoring the brain until it becomes a big clinical problem and then we are at the mercy of technicians, the psychologies, the physiatrists and neurologists. So, I think, right now brain technology, both when you it is used by consumers directly or by professionals, many people are seeing that it promotes autonomy because it empowers people to start to make decisions and to be aware about something that, until now, they have had zero inside info." (A2).

This entrepreneur explains how neurotechnology opens a new avenue of choices and knowledge for the individual to access. Neuroscience and the workings of the brain itself have been historical unknowns to society, innovators, and researchers. Increased development and deployment of neurotechnology for the enhanced autonomy of the user will deliver answers about the breadth and depth of neuroscience, while enhancing the human experience. The participants note that neurotechnology should be created to enhance the human experience and widen the breadth of individual capabilities in a positive way; all neurotechnology should benefit humanity and enhance autonomy in some way.

5. Discussion and Conclusion

The qualitative data collected from these neuro-entrepreneurs is a preliminary exploration of neuro-entrepreneurs' attitudes and needs for ethics. The findings most specifically highlight the innovation processes of these neuro-entrepreneurs and how ethics can be used as a toolset to create a future that benefits humanity and creates minimal harm. One neuro-entrepreneur pointed to the reasoning for this study as timely: that "in innovation and the consumer space, the genetic stuff is already widespread, but the neuro stuff is not quite there yet" (M6). Genomics as a field has sparked widespread ethical discussion and bioethics working groups, and neuroscience, on the heels of the genomic ethical dilemma, is relatively new with the field of neuroethics being only about 10-15 years old. The results of the qualitative interviews from this study suggest that neuro-entrepreneurs are beginning to understand that ethical issues will persist at the end of the innovation process and with the continued widespread use of neurotechnology. All neuro-entrepreneurs who participated in this study indicated that ethics is also beginning to be a vital component of the innovation process, even at the ideation stage. Integrating ethics within the beginning (ideation, prototyping, testing) stages of the innovation process and at the deployment stage ensures end-user and patient safety and assists the entrepreneur in deciding which projects are viable and beneficial for humanity.

As described in the results, one neuro-entrepreneur posed two questions toward the end of an interview: "The two challenges are, one: how do any set of laws or guidelines keep up with the pace of technology? And then secondly, how do you define it so that it's of any practical use? Neurotechnology is a very broad definition" (M6). Keeping these two questions in mind, weaving ethics into the innovation process is a potential solution for the neuro-entrepreneur's

dilemma - it sparks conversation amongst diverse stakeholders to ensure that the neurotechnology created is beneficial for individuals with various backgrounds and perspectives, as well as humanity at large. Ethics as a component of innovation also sets a precedent for the entrepreneurs who operate within the space of neuro-innovation, as a relatively new and potentially dangerous field, to develop neurotechnology with the betterment of the end-user in mind.

In order to accomplish this integration of ethics into the process of innovation from start to finish, a guide must be created for neuro-entrepreneurs. Throughout the interviews and data collection process, the neuro-entrepreneurs articulated that restrictive laws or enforcement would hinder innovation and project goals. However, the entrepreneurs who participated in the study all stated that guidelines, or similarly guiding questions, would be helpful for facilitating the innovation process. The idea gleaned from the interviews and data collection process regarding the value of guiding questions is similar to the framework of guiding questions provided within "Neuroethical Questions to Guide Ethical Research in the International Brain Initiatives." This insight demonstrates that both academic and government-based neuroscience research and neuro-industry would benefit from ethical guidelines. Neuro-industry, in particular, as discussed by the neuro-entrepreneurs of the study, would benefit from guiding questions but would be hindered by restrictive guidelines. The results of this study provide future directions as to the work ahead in integrating ethics with neuro-innovation: drafting neuroethics guidelines for neuro-entrepreneurs and neuro-industry.

To date there have been some ethical guidelines and principles for innovators. For example, in 2014, the UNICEF Innovation Unit set out four ethical guidelines for its framework

in global innovation, as well as principles for innovation:

> "Innovation is humanistic: solving big problems through human ingenuity, imagination and entrepreneurialism that can come from anywhere."
>
> "Innovation in non-hierarchical: drawing ideas from many different sources and incubating small, agile teams to test and iterate on them with user feedback."
>
> "Innovation is participatory: designing with (not for) real people."
>
> "Innovation is sustainable: building skills even if most individual endeavors will ultimately fail in their societal goals."
>
> (17).

While many of these points would likely resonate with our participants, they do not address the specific *neuroethical* themes we were exploring such as privacy, autonomy, stakeholder involvement, and identity. Notably, the Organization for Economic Cooperation and Development, a transnational policy and governance institute, identified neurotechnology as a singular technology that calls for a set of Neuroethics Principles (18).

While there are promising data from this study, there are some significant limitations. First, the neuro-entrepreneurs were recruited from one of the team member's personal networks (Dr. Karen Rommelfanger). Not all participants were aware of what neuroethics was or had read neuroethics literature. Some participants had already implemented neuroethics working groups within their efforts and some asked for clarification about the definition of neuroethics and its scope and impact on neuroscience thus far. Given the limitations of this study, future directions for this research include interviewing a higher number of participants until there is a full breadth of themes and no other themes come to fruition throughout the data collection process. In addition, these participants would be recruited through a snowball method, wherein each

participant recommended others in their networks to be interviewed until those networks were exhausted. This process has already begun. Once all data provided by participants can consistently fit under any formulated theme and no new themes emerge, we can move onto using these identified themes for quantitative research. These themes can be integrated in a survey which can be administered more broadly. Through this process, a neuroethics guide can be created for neuro-industry, fulfilling the next step of "Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives."

For data collection in the future, multi-stakeholder involvement should be a focal point within the interview guide. Some neuro-entrepreneurs from this first cohort were familiar with the phrase "multi-stakeholder involvement" and "stakeholder," while some asked for a clarifying definition. The future interview will include more questions about the breadth and variety of key stakeholder involvement in the innovation process, specifically discovering which players can bolster innovation according to neuro-entrepreneurs. Addressing the involvement of diverse stakeholders and more details about the creative process and perfunctory details of the innovation pipeline will help us understand how this might or might not fit Cultural Swirl Theory, or help us ground our finding in other innovation theories. Similarly, the revised interview guide will also dive deeper into the types of guiding ethical questions and specific ethically tense scenarios that neuro-entrepreneurs experience in order to best learn how neuroethics guidelines could assist neuro-entrepreneurs in the innovation process. Honing in on these questions specifically, within the interview guide, will be a helpful future direction to accelerate the formation of guiding neuroethical questions for neuro-industry and neuro-entrepreneurs.

Conclusion

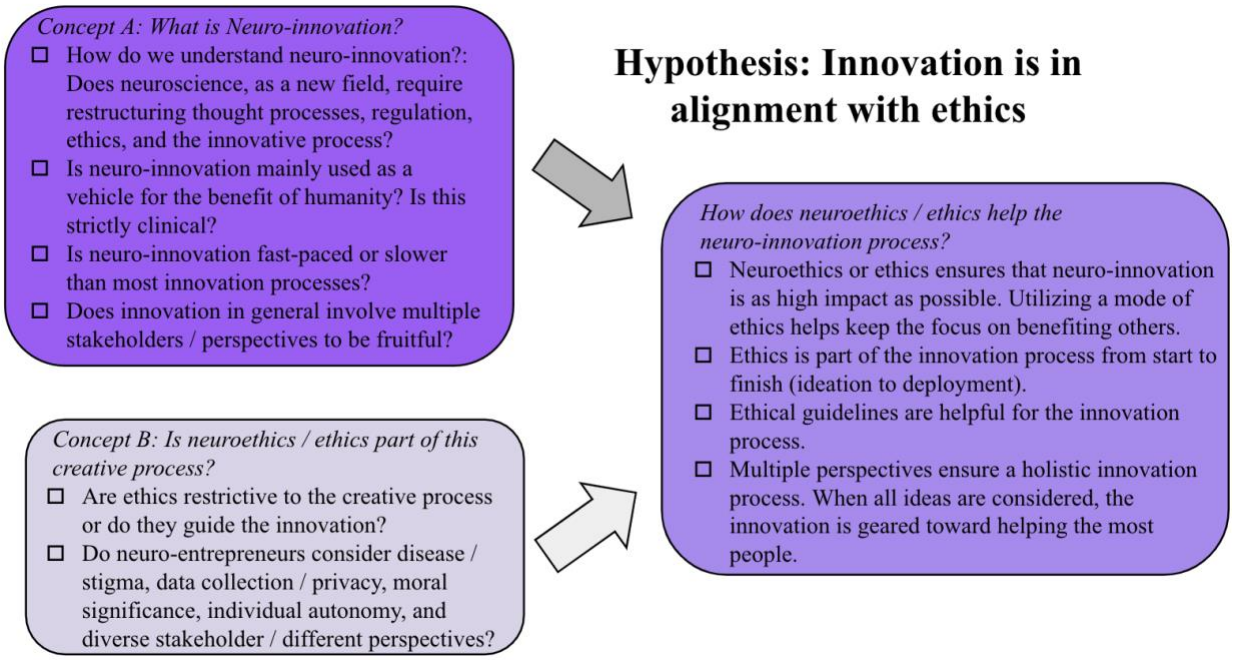
In conclusion, preliminarily we found supporting evidence of our hypothesis in that the neuro-entrepreneurs of our cohort have articulated that neuroethics is important throughout the innovation phase, but more work will be needed to understand which type of ethical guideline or framework is most beneficial for neuro-entrepreneurs. The next phase of this research will more closely examine how diverse stakeholders come into play within the neuro-innovation process. This phase will also hone in on the exact type of neuroethical guide that will be most beneficial for and conducive to the innovation processes of neuro-entrepreneurs. We are optimistic that this research will help bolster the creation of neuro-innovations that are most beneficial for society and will assist neuro-entrepreneurs throughout the neuro-innovation process.

6. References:

1. Hooper, C. (2015, June 23). The ethical dilemmas of the genomic revolution. Retrieved March 23, 2020, from https://www.weforum.org/agenda/2015/06/the-ethical-dilemmas-of-the-genomic-revolution/
2. International Neuroethics Society . (n.d.). International Neuroethics Society. Retrieved March 21, 2020, from https://www.neuroethicssociety.org/about
3. Farah, M. J. (2012). Neuroethics: The Ethical, Legal, and Societal Impact of Neuroscience. *Annual Review of Psychology*, *63*(1), 571–591. https://doi.org/10.1146/annurev.psych.093008.100438
4. Greely, H. T., Grady, C., Ramos, K. M., Chiong, W., Eberwine, J., Farahany, N. A., … Serrano, E. E. (2018). Neuroethics Guiding Principles for the NIH BRAIN Initiative. *The Journal of Neuroscience*, *38*(50), 10586–10588. https://doi.org/10.1523/JNEUROSCI.2077-18.2018
5. Neuroscience Startups. (n.d.). Retrieved March 21, 2020, from https://www.crunchbase.com/hub/neuroscience-startups)
6. Binder, J. K., McBride, R., Sud, A., Wuebker, R. J., Cesinger, B., Costa, S. F., … Pereira, D. (2015). Is "Neuroentrepreneurship" Worth Pursuing? *Academy of Management Proceedings*, *2015*(1), 15922. https://doi.org/10.5465/ambpp.2015.15922symposium
7. Rommelfanger, K. S., Jeong, S.-J., Ema, A., Fukushi, T., Kasai, K., Ramos, K. M., … Zheng, J. C. (2018). Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives. *Neuron*, *100*(1), 19–36. https://doi.org/10.1016/j.neuron.2018.09.021
8. Australian Brain Alliance. (2019). A Neuroethics Framework for the Australian Brain Initiative. *Neuron*, *101*(3), 365–369. https://doi.org/10.1016/j.neuron.2019.01.004

9. Rommelfanger, K. S., Jeong, S.-J., Montojo, C., & Zirlinger, M. (2019). Neuroethics: Think Global. *Neuron*, *101*(3), 363–364. https://doi.org/10.1016/j.neuron.2019.01.041
10. Welz, G. (2003). The cultural swirl: anthropological perspectives on innovation. *Global Networks*, *3*(3), 255–270. https://doi.org/10.1111/1471-0374.00061
11. Bierly, P. Kolodinsky, R. , Charette, B. (2008). Understanding the complex relationship between creativity and ethical ideologies. *Journal of Business Ethics*, 86(1), 101-112.
12. Dr. Donelson R. Forsyth. (n.d.). Retrieved March 21, 2020, from https://jepson.richmond.edu/faculty/bios/dforsyth/
13. Buchholz, R. A., & Rosenthal, S. B. (2005). The Spirit of Entrepreneurship and the Qualities of Moral Decision Making: Toward A Unifying Framework. *Journal of Business Ethics*, *60*(3), 307–315. https://doi.org/10.1007/s10551-005-0137-0
14. Hannerz, U. (2002). *Transnational Connections*. Abingdon, United Kingdom: Taylor & Francis.
15. National Science Foundation. (2004). Workshop on Scientific Foundations of Qualitative Research.
16. Weiss, R. (1994). Learning from Strangers. New York, New York. The Free Press.
17. Fabian, C., & Fabricant , R. (2014). The Ethics of Innovation. *Stanford Social Innovation Review*. Retrieved from https://ssir.org/articles/entry/the_ethics_of_innovation#
18. OECD Recommendation on Responsible Innovation in Neurotechnology - OECD. (n.d.). Retrieved March 21, 2020, from https://www.oecd.org/science/recommendation-on-responsible-innovation-in-neurotechnology.htm

7. Figures Listed



How would ethics fit with the neuro-innovation/creative process?
1. Ensuring/Maximizing impact: Ethics is desired for preventing harm to the end-user and ensuring impact; bringing end-users/patients in is important along with other diverse stakeholders. In order to maximize impact, ethics also needs to be as nimble as the tech, keeping up with the science.

2. Restrictive vs Guiding: Ethics enforcement is viewed as restrictive and slowing, primarily through the lens of regulation; however, ethical guidelines are helpful tools throughout the innovation process.
3. Lacking incentives: Incentivization of ethical behavior is missing and desired.
4. ROI, ethics, and scale: Neuro-entrepreneurs should be focusing on maximizing the use of their products while also mitigating negative uses. This responsibility to both ROI and ethics results in tension.
What are the key (neuro)ethical tensions of neuro-entrepreneurs?
1. Data Ownership: Users should own their data, but the business model doesn't allow for it (Small companies are more incentivized to sell data for growth).
2. Access and Justice: Neuro-innovation will alter societal norms and statuses. Innovations can empower society, but the tech and insights are not always shared with everyone in society who might benefit.
3. Neurodata and Misuse: Current data regulations suffice, but may not be sufficient for future implications and possible uses of brain data. Misuse of neurodata is lack of transparency to the user or patient.
4. Societal Norms: Unintended uses or access to data may lead to stigma, discrimination, power imbalances, and other uses, but the implications are not apparent to users (or the entrepreneurs who sold the data).
5. Autonomy: Neurotechnology / neuro-innovation can enhance or diminish autonomy.
What is the purpose of neuro-innovation(s)?
1. Reducing suffering and increasing happiness: from disease and injury to lack of access. Ethics is seen as facilitating this alleviation.
2. Clinical: Neurotechnology can be used to meet unmet clinical needs, improve treatment, and provide extra diagnostic accuracy/prediction, impacting how diseases are labeled and defined.
3. Non-clinical: Off-label use or diagnostic neurotechnology that moves into or is created for the commercial domain raises ethical concerns.
4. Empowerment: Neurotechnology / neuro-innovation should aim to help people and enhance "autonomy" of the public, empowering them to have greater bandwidth of knowledge, choices, and behaviors.