CCC Ethics Study # 3:

Memorandum

21 October 2020

To: CCC faculty members, post-docs, and graduate students
From: Robert McGinn, CCC lead ethics investigator
Re: "responsible research and innovation": what CCC researchers should know

1. Does the phrase "responsible research and innovation" (RRI) mean anything specific to you, or does it seem too vague to be relevant to your work? What follows is basic information about RRI that every CCC researcher should know.

2. Almost all scientists and engineers believe that their respective research and innovation (R&I) endeavors are responsible. But, what makes a R&I endeavor responsible?

3. Since 2010, the expression "responsible research and innovation" and the acronym "RRI" have gained currency, mostly because the European Union (EU) made RRI an "objective" of its "Science With and For Society" program and a "cross-cutting issue" of its major "Horizon 2020" research and innovation funding program. According to the EU, "Responsible Research and Innovation (RRI) implies that societal actors (researchers, citizens, policy makers, business, third sector organizations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society." (https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation)

4. This EU statement is questionable. While 'alignment' with society's "values, needs and expectations" may make a R&I endeavor *responsive* to society, that is not enough to ensure that it is ethically *responsible*.

5. In late 2019, eight CCC-affiliated lab directors shared their views on what RRI means or involves. Each bullet point marks the views of a different CCC lab director.

   - RRI involves upstream consideration of a R&I endeavor's potential ramifications, including its potential harms and benefits, for all who could be affected by it.
   - RRI involves "playing the mental chess game," i.e., thinking ahead about the "cascading implications" of one's research and figuring out where it is going to lead. If one suspects something dangerous might result, RRI requires consulting

with others, in the research community and in society at large, about its implications and risks.

- One director focused on R&I endeavor at the lab level. Regarding the relationship between a lab director and her/his lab's researchers, RRI requires that the lab culture combat "disenfranchisement" in all forms. It must foster the fair treatment of all researchers, regardless of their sex, gender, race, ethnicity, sexual orientation, and religion.
- RRI requires that non-technical experts with ethical and social interests be embedded well upstream in the actual R&I process; that researchers share openly their visions, aims, and results; that they be open to inputs from other scientists and the non-science sector; and that they reach out to inform the community about what they are doing. There is more to RRI than avoiding fabrication, falsification, and plagiarism (FFP).
- RRI requires that "the [R&I] process and the outcome [be] done in a thoughtful manner, considering consequences, trying to illuminate potential impacts,…and spark[ing] conversation [about] whether this is a good thing to go forward with…"
- For a R&I endeavor to be responsible the innovation must be anchored in solid rather than "shoddy" scientific research.
- "Responsible research" requires that the researcher be able to say "in good conscience" that s/he has "done everything to minimize the risk that [her/his research] becomes something [negative or harmful]."
- The eighth director's approach to assuring that R&I endeavor is responsible involves ensuring that the choices about every aspect of her/his research, from "what kind of work I do" to "how I go about implementing that research," are made in accordance with her/his "ethical principles" and "inner values," especially "Do good!" and "Try and make the world a better place."

6. These comments suggest that, whatever the best way of defining RRI, it requires **upstream consideration of the potential ramifications, outcomes, and impacts of the R&I endeavor in question on all parties it is likely to affect, and, if any potential outcomes or impacts are likely to be harmful or otherwise controversial, exploration of them with peers and representatives of society at large.** This is a helpful start, but there is more to RRI than that.

7. Overall, for a particular R&I endeavor to qualify as "responsible," 3 things must be the case:
   A. the endeavor's actual/likely **outcome** must be responsible; (see section #6)
   B. the entire **process** leading to that outcome must be navigated in a responsible manner; and
   C. the general R&I **enterprise** in which the specific R&I endeavor is embedded must be responsible in nature.

   These 3 dimensions of responsible R&I endeavor are discussed further below (in section #9).
8. For a R&I endeavor to be responsible more is required than that its **outcome** be responsible. Regardless of how responsible its outcome may be, the endeavor does not qualify as fully responsible unless each of its various phases is navigated in a

responsible way. For example, suppose that the work of the researcher who, in 2018, edited the genes of human embryos using **CRISPR-Cas9**, ostensibly to make them immune to the AIDs virus, had been universally hailed by researchers and social authorities as highly likely to have an overwhelmingly positive outcome. Such an assessment notwithstanding, this R&I endeavor would still not qualify as fully responsible if, say, the process of recruiting the human subjects involved relied on deception about, or incomplete or distorted disclosure of, benefit and risk, or if the process of obtaining ethics board approval for the planned experiments involved fraudulent activity by the applicant.

Conversely, the fact that all phases of a R&I endeavor were navigated in responsible ways – put differently: the fact that all phase-specific responsibilities were fulfilled -- does **not** ensure that the endeavor's outcome is responsible. For example, all phases of the R&I endeavors that yielded the herbicide and defoliant **Agent Orange** and the **anti-personnel bomb**, both used by the U.S. military in the Vietnam War, may have been navigated in responsible ways. But that does not by itself make the outcomes of those endeavors ethically responsible, especially given the social context in which those innovations were foreseeably likely to be used by the organizations that possessed them, e.g., the U.S. military.

9. What follows is a bit more about each of the 3 dimensions of R&I endeavor that must be appropriately addressed for a R&I endeavor to qualify as RRI. Each of those dimensions has certain responsibilities associated with it that must be fulfilled.

    A. Responsibilities related to the actual or likely **outcome** of a R&I endeavor include ensuring that the outcome does not lend itself to causing significant unjustifiable harm to individuals or society, or violate any important consensual societal need or value; and ensuring that the expenditure of resources on pursuing a R&I outcome deemed unlikely to significantly benefit society does not effectively squander an otherwise viable opportunity to realize significant societal benefit. It should be noted that a R&I endeavor can fail to be responsible because it causes or contributes to causing a foreseeably harmful outcome (or one that carries an unreasonable risk of harm), through acts of **commission** or **omission** (negligence).

    B. Responsibilities related to the entire **process** of a R&I endeavor can arise in any of the following phases:
        i. problem selection
        ii. literature search practices
        iii. preliminary conceptualization
        iv. fundraising practices
        v. experiment design
        vi. human subjects research practices
        vii. execution practices
        viii. data practices
        ix. analysis practices

x. authorship practices
xi. publication practices
xii. design practices
xiii. prototype practices
xiv. patent practices
xv. manufacturing practices
xvi. marketing practices
xvii. diffusion practices
xviii. regulatory practices
xix. maintenance practices
xx. design-revision practices

Phases i through xi make up the *research* stage, while phases xii through xx make up the *innovation* stage. (Note: there can sometimes be research in a phase of the innovation stage and innovation in a phase of the research stage). Each of these stages, and their respective phases, must be navigated in a responsible manner. Put differently, for a R&I endeavor to be responsible, the **responsibilities** that a researcher or innovator has in navigating each phase must be fulfilled.

Among the recognized responsibilities of the ***research*** stage are to avoid FFP in phases viii, ix, x, and xi; to ensure that all human subjects involved in one's research give their voluntary informed consent to participating in the experiments involved; and to grant authorship only to those who have made a significant intellectual contribution to achieving the findings.

Among the recognized responsibilities of the ***innovation*** stage are to design products that do not pose unreasonable risks of harm to users (phase xiii); to conscientiously test prototypes for safety and usability (phase xiv); to avoid manufacturing an innovative product prematurely, e.g., before safety testing is completed (phase xv); and to avoid deception in marketing an innovation to consumers (phase xvi).

It is prudent to assume that there are harm-based responsibilities to be fulfilled by researchers and innovators in ***each*** of these R&I phases. However, to date, systematic work has **not** been done to identify a comprehensive set of phase-specific ethical responsibilities for the research and the innovation stages.

C. Responsibilities related to the general R&I **enterprise** in a lab or firm, arise from the relationships of parties involved in a lab's or firm's R&I operation with each other, and with pertinent outside parties with whom one or more in-house parties interact. They include the responsibilities of lab directors and senior faculty to mentor junior faculty, post-docs, and grad students; to foster their career-preparedness; to help them become independent researchers and innovators; and to insure that no one involved in the general R&I enterprise is disenfranchised on the basis of irrelevant factors such as sex, gender, sexual

orientation, disability status, or religion. They also include responsibilities to avoid hype, distortion, and deception in interactions with representatives of mass media, governmental, or legal institutions. Non-fulfillment of such context-dependent responsibilities counts against a R&I endeavor being deemed fully responsible.

10. CCC-affiliated lab directors were asked to identify practices and policies in their labs that reflect their respective ideas of RRI. Each bullet precedes practices a director highlighted.

    - To forestall ownership conflicts, one director has a policy of not allowing graduate students or post-docs to work on anything that is "core to the lab." To foster their becoming autonomous researchers, their research topics are not tightly restricted; they must work on topics that are "their own thing."
    - Another director has fostered a lab culture where researchers can legitimately have "nontechnical discussions about the science," and feel physically and socially safe in the lab. S/he also promotes discussion about "where things might go" as a result of the lab's research.
    - One director has established multiple levels of social interaction in her/his lab, from the use of group software to link subgroups, to group meetings, to periodic student talks to the whole lab, to establishing a norm whereby young researchers are expected to ask questions about each other's talks, to the director's walking the lab several times a day to facilitate one-on-one interaction.
    - Another director established outreach activities at local schools and science museums to familiarize the public with what the researchers, using public money, are doing. S/he also delivers an annual State of the Lab Address on the day of the State of the Union Address, and encourages and supports students launching startups. More generally, the director has established and nurtured "a culture of support" in her/his lab, including strengthening the norm of free-flowing communication and launching initiatives to promote good paper-writing, researcher empowerment, and career development.
    - Yet another director has established a culture of rigorous and fastidious research and publishing in her/his lab, which s/he considers a robust form of mentorship.
    - One director requires that any researcher in her/his lab who writes a piece of code must place a copy of her/his work product in the lab's software "repository," indicating the product's state of development, the degree to which it has been checked, and its known domain of valid application.
    - Another director has not introduced any practices or policies aimed at promoting RRI. Rather s/he takes a more personal approach, taking care to ensure that "what we're doing, whom we present it to, [and] whom we partner with," in fact "basically all aspects of the activity," reflect her/his ethical principles and values.

11. Finally, each participating lab director was asked to describe an actual case with which s/he is familiar that s/he believes illuminates RRI, either its presence, absence, or challenges to it. Each bullet precedes a brief characterization of a case that the director described.

    - ***Data accessibility***. A post-doctoral fellow, F, moved from lab director L's lab to take a job in industry. F's paper was not completed before s/he left. L allowed F to take with her/him the data set F needed to finish the paper. However, it is difficult to finish a paper while holding a full-time job. Thus, L's lab lacked the data set for a considerable time, even though the university arguably owned the data since the work that generated it was done on a government grant. L wondered how to get the data set back without causing F to feel personally 'persecuted.' The RRI problem is that because L accommodated F, the remaining researchers in L's lab lacked the data they needed to move their own projects forward, something arguably unfair to them. L has since adopted a policy that a complete and updated copy of the data on which a researcher is working must be given periodically to L. To what extent does L's handling of this situation re her/his departing researcher and remaining researchers qualify as responsible?
    - ***Manufacturing organs***. A lab director had an idea for how to manufacture organs using tissue engineering. Her/his applications for funding support for proof of concept were unsuccessful. However, thinking through the ethics of her/his vision proved intellectually fruitful. The director is concerned that, since access to new medical products and processes in the United States generally depends on ability to pay their going market prices, one consequence of being involved in developing expensive manufactured organs could be that the rich get immediate access to them while the poor do not. Hence, social inequality could be exacerbated, arguably a "social harm." Thus, two difficult questions arise: (i) can a R&I endeavor reasonably be deemed RRI if its likely outcome, in the society in question, is both a *direct private* benefit for those able to access its products and an *indirect public harm*, such as intensified social inequality? and (ii) is the best guide to responsible conduct in such a situation the Golden Rule, applied in a sophisticated way, or careful consideration of the possible and likely harm-related consequences involved?
    - ***Biosynthesizing new medicines***. A lab director, D, and one of her/his collaborators are interested in "making a strain that's viable for producing a wide range of BIAs, a family, a small percentage of [whose]… members, 2,500 natural products, is the opiates." The goal is to screen for therapeutics. For D, a problem with illicit opiate production is that the titer needed to produce an illicit high is much less than the titer needed to complete commercially with the poppy. This lower titer could probably be achieved in a couple of years. Yet, the director has been encouraged to try out her/his method on an opiate. This raises difficult RRI questions: should her/his method and data be published? Should something be withheld? Should the strain that's produced not be shared with others? Should it only be under

special circumstances that another researcher can get the strain to verify the director's experiment? What the responsible thing to do would be in such a situation can be difficult to discern.

- ***Lab safety and the research community***. Director D described two safety-related episodes in the lab. One involved "a pathogenic virus that, when it infects something, expresses a protein in cells that causes them to fuse." The other involved "bringing an influenza virus into the lab in order to carry out research on it." D "really wanted" to do some experiments with the new reagents and the pertinent formal university regulations could easily be followed to gain approval to bring the new reagents into the lab. But some lab members were uncomfortable about the risks of doing so. The question for D was "how do we address the topic… how do we handle that responsibly?" D chose to engage her/his lab's members in detailed discussion of the issue for an extended period until a consensus was reached about the acceptability of bringing the new reagents into the lab under certain conditions. This arguably inconvenient approach was RRI-promoting, since taking the young researchers' discomfort seriously, rather than dismissing it, may encourage researchers to come forward in the future and voice their concerns rather than suppressing them because of belief that they would not be taken seriously.
- ***Intellectual Property and Collaborative R&I***. A director related a case in which a post-doc (PD) entered into a collaboration with a senior principal investigator (PI) to exploit two technologies on which they had been working individually. PD trained PI's students on PD's technology, which was progressing well, but PD did not believe PI's technology had "a good path forward." Eventually, after several years, PI came to PD and told her/him that PI needed to have her/his students take over the parts of the joint project that were working so they could get papers out of them and that PD should work only on the part that was not working well. Moreover, PI later demanded that s/he be credited as the co-founder of the part that was successful. PD eventually "decided to cut off the interaction" even if it meant s/he didn't get the credit due her/him. The director emphasized that s/he tries "to encourage students to recognize when they're being bullied or exploited and just stand up for themselves and refuse [to go along with what they're being told to do], and [to] trust that things will be okay if they have to switch labs, lose a year at work, switch projects, or something like that." A general RRI issue here is under what conditions does a collaborative R&I endeavor between a senior researcher with significant leverage and a junior researcher with negligible leverage cease qualifying as responsible, depending on how the collaborators are treating each other?
- ***Incomplete Disclosure of Code***. A director found it difficult to recall a specific episode of R&I endeavor that stood out as irresponsible. S/he did, however, describe an episode in which a researcher withheld code from a manuscript the director and the junior researcher submitted for publication. The code had been applied to a data set and a reviewer noted that the included code did not suffice to generate some of the paper's data. For the

director, the researcher "was taking credit for somebody else's work without giving credit and [s/he] was taking more credit than he or she should have in regard to the code that he or she had written. I didn't think it was ethically good." The assumed norm in the director's lab was that 'everything had to be written down and included in a manuscript.' Apparently that norm had not been internalized by the junior researcher. That this part of the code had been omitted struck the director as "breaking a contract." The junior researcher claimed s/he was not hiding the code used and that it was obvious which omitted code, one already in the literature, had been used. One RRI issue is whether a lab director can reasonably assume or has a responsibility to see to it that all researchers in her/his lab undergo strong socialization such that they have acquired a disposition to always follow all rules of good practice in their research work, including in writing up a manuscript for publication. A R&I endeavor which unfolds in a lab which lacks an effective socialization process may not be fully RRI.

- ***Gender Transition***. One director described an episode involving the general R&I *enterprise* in a large technical firm. One of the firm's male engineers, transitioning from masculine to feminine gender, was subjected to ridicule, critical looks, and negative comments in group settings by colleagues. The transitioning individual's manager had the courage and sense of responsibility to stand up for and defend the individual. The company as a whole, while ostensibly concerned with being politically correct, "punted" re supporting the transitioning researcher. One RRI question this situation raises is this: given how the engineer was treated at work, can the firm's R&I enterprise be deemed as fully responsible?
- ***Military Contracts***. A lab director related an episode involving a start-up, of which s/he was a co-founder. One of this co-founder's technological inventions was the key intellectual property of the young firm. The director had left the firm before the firm, relying on her/his invention, signed a lucrative contract with a branch of the military. The timing of director's departure spared her/him from grappling with a major ethical conflict: her/his invention brought in big money and made the startup successful, yet its use for military purposes would likely have outcomes the director deemed problematic. One of the director's colleagues chose to leave the firm because s/he objected to being involved with military work. If the director or her/his colleague had remained with the firm and been involved with the R&I endeavor to adapt the invention to military purposes for major corporate profit, would that endeavor have qualified as RRI?

12. Conclusion

Just as there is more to the responsible conduct of research (RCR) than avoiding fabrication, falsification, and plagiarism (FFP), there is more to responsible research and innovation (RRI) than RCR. **The innovation stage of R&I endeavors remains largely unmapped as regards responsibilities**. Researchers must navigate each of the innovation stage's phases in a

responsible way; i.e., the responsibilities of the technical practitioner related to each phase must be fulfilled. If researchers and innovators are to become conversant with RRI in a way that improves upon the EU's questionable emphasis on 'aligning' R&I with societal "values, needs and expectations," the innovation stage must be unpacked into its constituent phases and the ethical responsibilities linked with each phase must be identified.

The CCC lab directors' notions of RRI and accounts of RRI-promoting practices exhibited considerable diversity. No specific definition of RRI is likely to gain the support of all or even most R&I practitioners, including those working on cellular engineering. However, cellular-engineering practitioners can enrich their conceptions of RRI by familiarizing themselves with the wide range of practices that directors have introduced in their labs to foster responsible conduct of research (RCR; see section #10 above). Doing so would set the stage for the next step: thinking critically and comprehensively about the innovation stage of R&I endeavor, one in which CCC researchers may eventually become active, e.g., in bioengineering startups.

Articulating a robust notion of RRI and identifying phase-specific ethical responsibilities that arise in the innovation stage are tasks that merit serious attention going forward.