CCC Ethics Study #8:

Beyond "FFP": Toward a Comprehensive Framework of Responsible and Irresponsible Practices in Research and Innovation

by

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I. Introduction

During the last quarter century, a number of episodes of actual or alleged misconduct on the part of U.S. researchers have come to light. In these episodes, the misconduct often took one or more of the following forms: concocting data or results, distorting an experimental research record, and copying text or ideas from work of other researchers without due credit.

After extensive internal debate and external comment, on December 6, 2000, the U.S. federal government published the U.S. Office of Science and Technology Policy's "Notification of Final Policy" about research misconduct. "Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results,"[1] a definition "commonly known as 'FFP.'"[2] This definition applies to all federally funded research and the Notification directed federal government agencies to implement it by the end of 2001.[3]

As of April 2023, FFP remains the only official U.S. government definition of research misconduct. However, this situation is triply problematic. First, FFP is too narrow a notion of misconduct. Granted, concocting data or results, tidying up or excising

[1] U. S. Office of the Federal Register, p. 76262.
[2] U.S. Office of Research Integrity.
[3] U. S. Office of the Federal Register, *loc. cit*.

data from an experimental record, and using another's (or one's own previously) published words, ideas, insights, techniques, or results in a published work without giving due credit are widely recognized forms of misconduct or wrongdoing. At bottom, the reason for regarding them as such is that they harm or create an unreasonable risk of harm to other researchers, research organizations, or people affected downstream by the flawed research. They do so by depriving others of due credit, by effectively wasting individual or organizational resources, and by exposing patients to risk from using flawed medical products.

While useful as far as it goes, "FFP" fails to encompass more subtle and less widely recognized kinds of irresponsible practice. For example, suppose a colleague produces and provides a researcher with a vital material resource that enables the investigator to conduct an experiment. The practitioner surely deserves acknowledgement for that assistance in any article in which the experiment's results are reported. However, unless the provider also made a substantive intellectual contribution to the experiment, such as helping conceive it, generating data, analyzing results, or helping write up a manuscript for publication, it would be misconduct on the part of the researcher to designate the provider a co-author of the resultant article.[4] Like FFP, these and other subtle forms of misconduct can also harm or create an unreasonable risk of harm, albeit indirectly. When gratitude for providing an enabling resource is shown by awarding the provider with co-authorship, the critical cultural institution of authorship is eroded.

[4] See McGinn, pp. 62-64, for detailed discussion of this point.

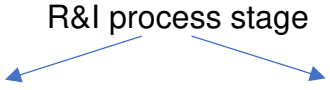
Second, FFP is closely associated with the work of *scientists*. However, scientists have no monopoly on technical misconduct. *Engineers* are also liable to engage in misconduct. However, many kinds of engineering misconduct are unrelated to FFP.

Third, FFP is closely associated with the *research* stage of the integrated research-and-innovation (hereafter: R-&-I) process. However, conceiving misconduct as "FFP" invites observers and practitioners to overlook the salient fact that misconduct by technical practitioners often occurs in the *innovation* stage of such endeavor.

Instead of reducing "misconduct" to three of its forms that pertain to "scientists" doing "research," it would be preferable to have an easy-to-remember framework that encompasses a wide range of what I shall call ethically irresponsible *and responsible* practices[5] in which scientists *and engineers* can engage in either the research *or the innovation stage* of R-&-I endeavor. What follows is intended to contribute to the elaboration of such a framework.

II. A Matrix of Responsible and Irresponsible R&I Practices

Consider a 2 x 2 'matrix.' The left cell of its top row contains kinds of ethically *responsible* practice that can occur in the *research* stage of R&I, while its right cell contains kinds of ethically *responsible* practice in the *innovation* stage. The left cell of the bottom row contains kinds of ethically *irresponsible* practice that can occur in the *research* stage, while its right cell contains kinds of ethically *irresponsible* practice in the *innovation* stage. This 'matrix' can be depicted thus:



[5] By an "ethically responsible practice" I mean one that is not only ethically acceptable but such that there is a *prima facie* ethical responsibility to carry it out. By an "ethically irresponsible practice" I mean one that is ethically unacceptable and such that there is a *prima facie* ethical responsibility to not carry it out.

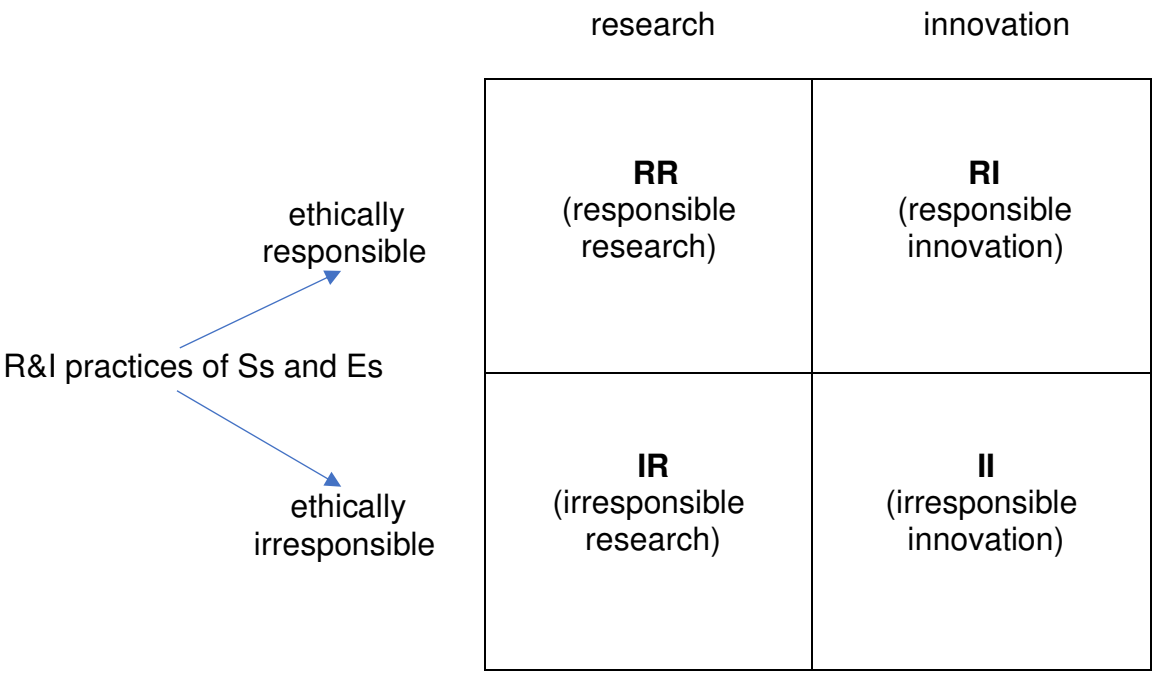


Fig. 1: Synoptic Matrix

Each of Figure 1's four cells – **RR**, **RI**, **IR**, and **II** – contains specific kinds of ethically responsible or irresponsible practice of scientists (Ss) or engineers (Es) that correspond to the stage of that cell. Scrutinizing the cells' respective contents provides an idea of the range of practices that weigh in favor of or against an R&I endeavor being deemed RRI.

A. Cell RR. The "responsible research" cell includes various kinds of ethically responsible practice that pertain to the research stage of R&I endeavor. To avoid overlooking non-obvious research-stage practices, rather than thinking of the research stage as an undifferentiated whole, it is critical to disaggregate it into a set of sometimes partly overlapping constituent phases, to one or more of which such practices can pertain. Seven of these research phases (**RP**) follow.

RP1	= selecting a specific research topic
RP2	= searching the scholarly literature
RP3	= seeking funding for a selected research project

RP4 = conducting (empirical and/or analytical) research activity
RP5 = publishing research findings
RP6 = reviewing a submitted manuscript
RP7 = reviewing a submitted funding proposal

Noteworthy kinds of ethically responsible practice by scientists and engineers working in the research stage of the overarching R&I process include the following:

RR 1: deciding to pursue a research topic only if convinced that the likely applications of the expected knowledge will not violate or erode any of society's core ethical values, e.g., liberty, justice, and environmental sustainability (**RP1**)[6]

RR 2: scrupulously recording and citing relevant research findings, quotes, and ideas discovered during the preliminary scholarly-literature search, and names of authors whose work merits credit in future publications that report one's research findings (**RP2, RP5**)

RR 3: accurately and realistically detailing the participants, benefits, risks, schedules, and budgets in proposals to secure funding for a planned research project (**RP3**)

RR 4: conscientiously following accepted "data-integrity" practices (**RP4**)

RR 5: keeping an accurate and secure "research data record" (**RP4**)

RR 6: wherever possible and appropriate, using standard methods and following standard procedures of empirical research inquiry (**RP4**)

RR 7: alerting an appropriate authority when one has good reason to believe that research is being conducted or reported in a fraudulent manner (**RP4**, **RP5**)

RR 8: properly designating the author(s) of a manuscript submitted for publication consideration (**RP5**)

RR 9: in a publication of which one is author or co-author, giving due credit to all who contributed to realizing the reported achievements (**RP5**)

RR 10: submitting a manuscript for publication only when strong evidence for its claimed findings is in hand (**RP5**)

RR 11: disclosing to a journal's editorial staff any relevant conflict of interest (COI) before accepting an invitation to review another researcher's submitted manuscript (**RP6**)

[6] The research phase – **RP** -- in which a specific kind of research practice typically occurs is indicated in parentheses.

RR 12: disclosing to a funding agency any relevant COI one has before accepting an invitation from that agency to review a researcher's submitted funding proposal (**RP7**)

RR 13: completing and submitting an invited review of a researcher's manuscript or funding proposal in a timely manner (**RP6**, **RP7**)

While some items in cell **RR** are straightforward, several merit clarification.

RR 4's "data integrity" practices include (i) recording and using all and only data derived from the experimental research inquiry in question, (ii) eschewing "cherry picking" in data analysis, and (iii) retaining and displaying apparent "outlier" data points.

RR 5's "research data record" practices include (i) keeping the data recorded during the experimental inquiry complete, unedited, and unenhanced, as well as (ii) maintaining the data record intact and accessible for a reasonable period after publication.

Given certain conditions, "whistleblowing" (**RR 7**) is an ethically responsible research practice when its intent is to prevent other lab researchers, readers of fraudulent published articles, and those likely to be affected by applications of fraudulent research, from being put in harm's way.[7]

Ethically responsible authorship practices (**RR 8**) include (i) listing as co-authors all and only those who made significant intellectual contributions to the achievements reported in the publication in question, (ii) listing bona fide co-authors in proper order depending on their relative contributions and on the conventions followed in the established journals in the publication field, and (iii) describing the specific contribution of each co-author in published reports on collaborative research.

[7] For the conditions under which *public* whistleblowing is a technical practitioner's ethical responsibility, see McGinn, pp. 157-159.

B. Cell RI. The "responsible innovation" cell contains various kinds of ethically responsible practice that typically occur in the innovation stage of an R&I endeavor. As was done with the research stage, to decrease the chance of overlooking non-obvious ethically irresponsible practices, the innovation stage must be disaggregated into its constituent phases. Such practices can arise in any of the following innovation phases (**IP**) that help comprise the innovation stage:

IP1	=	fundraising
IP2	=	intellectual property acquisition
IP3	=	team building
IP4	=	product development
IP5	=	government regulation
IP6	=	manufacturing
IP7	=	product distribution
IP8	=	feedback
IP9	=	product revision
IP10	=	marketing

Cell **RI** contains the following kinds of ethically responsible practices that Ss and Es can (and should) pursue in the innovation stage[8]:

RI 1: conducting product testing fastidiously and conscientiously and reporting all test results truthfully and completely (**IP4, IP5**)

RI 2: being on the alert for potential, previously unrecognized sources of risk to product or system users and to affected non-users (**IP4**)

RI 3: informing a cognizant superior or product manager about newly discovered sources of product or system risk (**IP4, IP8**)

RI 4: combatting or exposing factors that lead uninformed consumers to underestimate product risk or overestimate product performance (**IP4, IP10**)

RI 5: alerting an appropriate authority when one has good reason to believe that a product, system, or process, with which one is familiar and about which one is technically knowledgeable, poses an unreasonable risk of harm to parties it is likely to affect (**IP4, IP5, IP6, IP7**)

[8] The innovation phase – **IP** -- in which a specific kind of practice typically occurs is indicated in parentheses.

RI 6: taking user feedback seriously when it could lead to product improvement

RI 7: when charged with doing so, producing and disseminating product or system risk assessments that reflect the socio-technical realities of likely contexts of projected use (**IP4**, **IP5**)

RI 8: doing due diligence on a startup's management and projected product before recommending to non-technical venture capitalists that they invest in the firm (**IP1**)

RI 9: refraining from recommending to non-technical prospective investors that they invest in a startup if the recommender has a COI, e.g., standing to gain economically by recruiting new investors in the firm (**IP1**)

RI 10: doing due diligence before accepting a technology firm's offer of a technical position to work on a planned innovation (**IP3**)

RI 11: releasing (or recommending the release of) a product prototype to manufacturing only after adequate safety and performance testing has been completed and proved successful (**IP4**)

RI 12: designing a product to be usable, safe, environmentally friendly, reliable, and compatible with the cultures in which it will be used (**IP4**)

RI 13: a faculty researcher promptly disclosing to her/his university a potentially patentable invention that s/he conceived or first reduced to practice in whole or in part while carrying out her/his university duties, or with more-than-incidental use of university resources (IP 2)

Items **RI 2, RI 4, RI 10**, and **RI 12** merit clarification.

RI 2 is "being alert for possible, previously unrecognized sources of risk to product or system users and to affected non-users." Aaron Moore, an engineer at defunct startup Theranos, was concerned that although the firm's engineering and chemistry groups were testing the parts of the Theranos 1.0 blood-testing system for which they were responsible, no one was carrying out overall system tests. That troubled him, even after Theranos introduced the first version of its Edison blood-testing prototype. Concerned about a pilot project Theranos was carrying out for Pfizer on elderly patients with terminal cancer, Moore launched informal human-factors field

research on the Edison system. He concluded it was naive to believe elderly terminally ill patients could operate the system flawlessly in their homes each day, something seemingly taken for granted in the pilot study. To Moore, the Edison's poor usability compromised its reliability and increased the risk it posed to users. He informed his engineer-boss of his conclusions, but to no avail. Moore exited the company shortly thereafter. Doing a human-factors field study of the Edison system to probe a neglected source of product risk, and calling management's attention to the finding that the prototype's usability was lacking, exemplify ethically responsible practice in the innovation stage.[9]

RI 4 is "combatting factors that lead uninformed consumers to underestimate product risk or overestimate product performance." Biomedical scientist Mark Pandori became codirector of Theranos's clinical lab in December 2013. However, he resigned five months later, the day the COO rejected his request that the CEO run claims about prototype testing capabilities past the lab codirectors for vetting before releasing them to the press.[10] Making inflated medical-test-capability claims in the media can engender serious risks of harm, since they may prompt misguided medical decisions by patients who believe false company performance claims. Thus, public hyperbole about a product's medical test accuracy falls within the purview of ethics. Through his direct request to top management, Pandori hoped to prevent the release of claims likely to engender incremental risks of harm to potential test patients who would be led by such claims to underestimate the risk and/or overestimate the accuracy of Edison system

[9] Carreyrou, pp. 33-53.
[10] *Ibid.,* p. 214.

tests. For that reason, the precautionary request was ethically responsible practice in the innovation stage.

RI 10 is "doing due diligence before accepting a technology firm's job offer of a technical position to work on a planned innovation." It is ethically responsible conduct for a technical professional to inquire into both the company offering her/him such a position and the position being offered. Doing so could uncover important information about the workplace culture and economic condition of the company in question, and about the state of development and promise of the product or process on which the individual is being recruited to work. Such inquiry could also reveal to the recruit whether the company respects the views of its technical workers or simply expects them to do as they are told -- no questions asked or suggestions accepted. Knowing that could indicate to the recruit whether, if s/he accepted the offer, s/he'd likely find her/himself in a situation in which s/he'd be pressured to go along with a course of action s/he deems irresponsible.

RI 12 is "designing a product to be usable, safe, environmentally friendly, reliable, and compatible with the cultures in which it will be used." Mechanical engineer Martin Fisher co-founded and is CEO of KickStart International.[11] The company designs human-powered irrigation products for small-scale sub-Saharan African farmers. Its most influential product to date is a micro-irrigation pump called the "Super Money-Maker." The word "micro" indicates that the pump is small and light enough to make it mobile. Its design is sensitive to the local conditions of targeted buyers and users in four ways.

[11] Kickstart International.

First, since the pump is portable, it can be moved inside at night rather than being left in the field. This feature appeals to prospective buyers because, given local social conditions, rural African farmers are often concerned about theft. Second, the pump produces a spray of water, not a stream. This is critical because a developed network of irrigation ditches does not exist in some African countries, e.g., Kenya. Third, the treadles on the pumps were designed for comfortable barefoot operation since rural Africans who farm typically do not wear shoes. Fourth, the pumps were designed to have a short, low treadle stroke, so that "when women use them, they do not display provocative hip movements at eye level."[12] The women wear long garments and do not want to appear to be dancing suggestively when they are working. If they did, local men might get angry with them and restrict their economic activity, something that has happened to women in other less developed countries.[13] The pump's design insured that movements of female users did not appear socially unacceptable.

The firm's ethically responsible design practice occurs at its Technology Development Centre in Nairobi, Kenya, where…

> The vast majority of this design work is done by a small team of engineers, designers, and technicians in our workshop in Nairobi, Kenya. They research raw material properties and ergonomics, use CAD and stress analysis to develop the designs, incorporate design for manufacturability from the start, and do many hours of building and testing of prototypes to ensure the performance and wear characteristics, cultural acceptability and durability. As a result, it takes many months to invent, design and produce each new technology.[14]

[12] Fisher, p. 23.
[13] For example, women of "the impoverished Wapishana and Macushi tribes of Guyana" started selling "their intricate hand-woven hammocks over the Web at $1,000 each." The money they earned angered the status-sensitive tribal males who proceeded to drive out the young woman who ran the business website. See Romero.
[14] Fisher, p. 20.

Such practices are a far cry from conventional technology transfer, whose products are sometimes serious mismatches with the cultures of the societies into which they are introduced and to whose features transferers expect recipient users to adapt. In short, Fisher designs affordable technologies that address local needs, use local natural resources, and are good matches with rural social, material, and cultural conditions. The features built into KickStart's micro irrigation pump count toward Fisher's design practices in the innovation stage being reasonably deemed ethically responsible.

C. Cell IR. The degree to which an R&I episode qualifies as responsible depends not only on the extent to which the involved scientists and engineers engage in ethically responsible practices in the research and innovation stages, but also on the extent to which they avoid engaging in ethically irresponsible practices in both stages. Thus, it will be useful to flesh out the bottom row of the 2 x 2 matrix of R&I practices.

IR, the "irresponsible research" cell, includes the following kinds of ethically irresponsible practices that typically arise in the research stage:

IR 1: pursuing a specific research topic without considering its likely downstream consequences, or when suspecting that the resultant knowledge is likely to be applied in ways that undermine a core societal value, such as liberty, justice, or environmental sustainability (**RP1**)

IR 2: fabricating experimental data (**RP4**)

IR 3: falsifying the research data-record (**RP4**)

IR 4: taking prohibited shortcuts in the research lab (**RP4**)

IR 5: remaining silent when one has good reason to believe that another researcher is conducting or publishing research in a fraudulent manner and that alerting an appropriate authority stands a good chance of stopping the fraud (**RP3, RP4**)

IR 6: misrepresenting the participants, benefits, risks, schedule, and budget in a research-funding proposal (**RP3**)

IR 7: prematurely submitting a manuscript for publication consideration (**RP5**)

IR 8: failing to list as co-authors of a manuscript submitted for publication all and only individuals working on a project who made significant intellectual contributions to realizing its reported achievements (**RP5**)

IR 9: failing to give due credit in a publication of which one is author or co-author to all individuals and groups whose ideas, suggestions, and prior published work contributed to realizing the reported achievement (**RP5**)

IR 10: listing as an article's co-author an individual who, although s/he made no intellectual contribution to achieving the reported findings, aided the main author by providing a needed enabling resource (**RP5**)

IR 11: not disclosing a COI when reviewing another researcher's submitted manuscript (**RP6**)

IR 12: not disclosing a COI when reviewing another researcher's funding proposal (**RP7**)

As noted above, the official definition of "research misconduct" in the United States is FFP. However, FFP is far too narrow a notion of ethically irresponsible research practice. There are more subtle and less widely recognized kinds of ethically irresponsible research practice, They too harm or create an unreasonable risk of harming others, albeit often indirectly. In this connection, consider items **IR 4**, **IR 7**, and **IR 10**.

For example, taking a prohibited shortcut in the research lab (**IR 4**) may put other lab workers at risk of harm, directly or indirectly, e.g., by undermining the lab's safety culture.

Prematurely submitting a manuscript (**IR 7**) in order to be 'first into print' can lead some who read the ensuing publication to take actions that waste precious resources of time, effort, and money, not to mention the harm-extending opportunity costs that action may have.

As argued earlier, a colleague whose sole contribution to a paper is to produce and make available to a researcher a material resource[15] that enables the researcher's experiment deserves acknowledgement in the article in which the results are published, but not listing as a co-author. Conflating acknowledgement of assistance with bona fide co-authorship (**IR10**) causes social harm by compromising the valuable social-intellectual idea of authorship.

D. Cell II. The "irresponsible innovation" cell contains various kinds of ethically irresponsible practices that typically occur in one or more phases of the understudied innovation stage of the R&I process. Noteworthy kinds of such practices include the following:

II 1: organizing or participating in deceptive innovative product demos (**IP1**)

II 2: a faculty member downplaying or concealing from her/his university a discovery s/he made while a researcher or research administrator at that university and that s/he believed had patent potential, and founding a start-up that applies for a patent on the same invention (**IP2**)

II 3: not doing due diligence in connection with a technology firm's technical job offer before deciding whether to accept it (**IP3**)

II 4: disregarding or responding dishonestly to concerned user feedback on a product on which one had worked (**IP8**)

II 5: cheating or being negligent in innovative product testing (**IP4**)

II 6: remaining silent when one has good reason to believe that an innovative product, project, or process with which one is familiar or about which one is technically knowledgeable poses an unreasonable risk of harm to parties likely to be affected by it (**IP4, IP5, IP6, IP7**)

II 7: knowingly contributing to or acquiescing in the imposition of significant incremental risk on uninformed product users (**IP4, IP8**)

[15] The "resource" could be a needed piece of equipment or a steady supply of a critical human-made material, such as "high quality single crystals of organic materials." See McGinn, pp. 62-64.

II 8: producing or acquiescing in the dissemination, use, and/or public support of a decontextualized risk assessment (**IP4**)

II 9: treating a paradigm-departing engineering product or system design conventionally (**IP4**)

II 10: designing a new technological product or system for a less developed society without considering whether its design features, manufacture, and requirements of use are compatible with the prevailing culture of the target society (**IP4, IP7, IP9, IP10**)

Attention has occasionally been paid to some egregious ethically irresponsible innovation-phase practices in the scholarly literature[16] and, to a limited extent, in science and engineering education, often in the wake of some harmful accident. The focus here will be on kinds of ethically irresponsible practice in the innovation stage that are far less widely recognized. They are explored in items **II 2**, **II 3**, **II 8**, and **II 9**.

II 2 is "a faculty member downplaying or concealing from her/his university an idea or discovery made while serving as a researcher or research administrator at that university and that s/he believed had patent potential, and founding a start-up that applies for a patent on the same invention." Startups often arise from faculty research that yielded potentially useful scientific discoveries. A researcher involved in the inquiry, as practitioner or supervisor, may decide to establish a start-up to turn that knowledge into a commercial product. The start-up firm may attempt to secure sufficient intellectual property rights to enable it to be the exclusive owner of the innovation for the maximum permitted period and reap the resultant profit.

Concerns about irresponsible conduct may arise when the university in which the faculty research work was done does not file a patent application on its own behalf. This

[16] For example, see discussions of the space shuttle Challenger, Union Carbide pesticide plant in Bhopal, India, and Kansas City Hyatt Regency hotel cases in McGinn (2018).

may happen because the researcher did not promptly disclose to the university IP office the truth about a scientific discovery s/he made while a faculty member at that university, including its potential patentability. If the faculty researcher founds a start-up and the economic stakes are high -- often the case in the biotechnology sector -- s/he may file a patent application in the startup's name that effectively appropriates the university's intellectual property and disregards its role in enabling and facilitating the underlying research.

For example, in 2012 an elite university and an affiliated cancer research laboratory filed lawsuits against a biotech startup founded by a former faculty member. The suits accused the former faculty member and the startup of filing for at least twenty patents on research he had done and/or overseen while a faculty member and research administrator at the university and affiliated laboratory.[17] The parties eventually settled the lawsuits. However, since the settlement terms were kept confidential and no party admitted wrongdoing, it remains unclear whether this was a case of a researcher engaging in ethically irresponsible practice **II 2**. However, pursuant to the settlement, the university acquired intellectual property it claimed was its due and the startup agreed to license the discoveries in question from the university.[18]

II 3 is "not doing due diligence in connection with a firm's technical job offer."[19] Two former Theranos employees, chemical biologist and systems engineer Dave Philippides and biochemist Douglas Matje, accepted job offers from the company with

[17] Weisman.
[18] Pollack.
[19] While this item is the opposite of ethically responsible practice B10, it is important to emphasize that just as there is more to responsible research practice than not engaging in FFP, there is more to RRI than not succumbing to any irresponsible research or innovation practice.

little idea of what their work would involve. In his job interview, Philippides was told nothing…

> "…about how [the company's testing process] worked or what the technology was. They just said, 'You'll be working with consumables,' which was kind of vague."[20]

When asked "How did they describe the project to you?" Matje replied, "They didn't." Asked further, "So how did you know what you were signing onto?" he replied, "...I had a very vague idea, but I didn't [know]."[21]

One problem with not doing due diligence before accepting an offer of employment with a technical startup is that it can easily result in the recruited scientist or engineer finding her/himself in a difficult bind: either go along with employer orders or expectations that the employee believes are ethically questionable, or refuse to do so and be fired. Failing to do due diligence about the offering company or about the offered technical job before deciding whether to accept the latter, say for reasons of salary, status, or stated corporate mission, is negligently irresponsible. It puts the new employee in a position in which, to avoid being fired, s/he may be compelled to act in a way that effectively puts others at risk of harm.

While at Theranos, Matje also took part in ethically irresponsible conduct covered by **II 1**. He described deceptive product demos at Theranos thus:

> "[W]hen we had demos, they would bring investors or executives from some company to a room which would have different styles of Edison they were prototyping. They would do a fingerstick on the executives, so they they'd take a fingerstick of blood. They would put the blood into a cartridge, and then they'd put the cartridge into this Edison. They'd walk the executives out of the room to go give them a tour, or to go

[20] Gibney, 19:55-20:37.
[21] *Ibid.*

> have a meeting, or go have lunch or whatever, and immediately afterwards, an engineer would run in, grab the cartridge, bring it out to the lab, where my team would do the assays at the bench. We were on call, so this could be done in an hour. We got reasonable data every time and then we would get those results, the engineer would run into the room with the results and these guys would come back in and they'd say, 'Well, here's your results from running your tests.'"[22]

Thus, Matje and his team knew that the results they were generating "at the bench" were being used to deceive visiting VIPs, a practice covered by **II 1**. That Matje both omitted to do due diligence about his Theranos job offer and participated in deceptive Theranos product demos may not be coincidental. Failure of a prospective employee to do due diligence about a company or a job may make her/him vulnerable to being pressured on the job into participating in other ethically irresponsible firm practices.

II 8 is "producing or acquiescing in the dissemination, use, and/or public support of a decontextualized risk assessment." While it may not seem so at first glance, doing so is a type of ethically irresponsible innovation-stage practice.

When evaluating the risk of a new technology or technological system, it is critical that the engineer doing the assessment avoid idealization. That is, s/he must not base the risk assessment on the idealized assumption that the new technology or system will always function exactly as designed, or on the utopian belief that the social institutions and organizations expected to interact with the new technology will consistently function perfectly. It is naive (or disingenuous) for an engineer to contend that the risk of the innovative technology or system depends only on its built-in design features. In doing risk assessment, it is imperative that the engineer also take into

[22] *Ibid.*, 48:02-49:00.

consideration the range of contingent, context-specific social factors related to the creation, operation, and maintenance of the technological product or system whose risk is being assessed.[23]

Such factors include the training, experience, professionalism, and work schedules and cultures of the workers who will be involved with the technology; the track records, resources, and cultures of the companies that will construct, operate, and maintain the technology; and the track records, leadership, resources, training of field personnel, and culture of the cognizant government agency.

A risk assessment that takes into consideration only the inherent design features of the technology or technical system in question is incomplete, and apt to lead the engineer to provide the public with an unrealistically low, unduly optimistic estimate of the new product's or system's actual risk. This may skew public debate about its acceptability, possibly to the point of engendering a risk of harm. It is negligently irresponsible for the engineer to succumb to such idealization and misrepresentation. S/he must ensure that the risk assessment also reflects the contingent social realities related to all aspects of the technology's life cycle. A new product or system risk assessment based on technical design features and contingent, context-specific social factors is critical if the risk level resulting from the analysis is to be ethically acceptable.[24]

[23] For illuminating discussions of this contextual approach to engineering risk assessment, see Beder *et al*. and Hornig.

[24] How low the risk level must be to be ethically acceptable will depend on (i) the nature, magnitude, distribution, and indispensability of the likely benefits; (ii) the nature, magnitude, distribution, and reversibility of the risks and other costs; and (iii) whether there are viable alternative courses of action that would likely distribute the risks more equitably without significantly decreasing the benefit-cost ratio or difference.

That the idealization of technological systems and disregard of relevant, contingent, local social realities can lead to an over-optimistic risk assessment is painfully clear from the most lethal industrial accident in recorded history: the Bhopal disaster of December 1984. The advanced technological features designed for and built into the Union Carbide methyl isocyanate pesticide plant in Bhopal, India, may have been impressive and been deemed low risk, but they were trumped by contingent social factors pertaining to the local plant. Those factors included irregular plant operations that failed to adhere to procedures spelled out in official manuals, increasingly superficial and narrow worker training, delays in plant maintenance, ineffective local zoning regulations regarding location of civilian residences, infrastructural deficiencies, deficient regulatory resources and practices, inadequate emergency-planning practices, and budget-driven cutbacks in safety personnel.[25]

II 9 is "treating a paradigm-departing engineering product or system design conventionally." While seemingly innocuous at first glance, this practice is in fact one of the most dangerous kinds of ethically irresponsible innovation practice, one that can arise in any engineering field. To understand clearly what this key pattern of practice means, let us explore two examples, one from civil engineering, the other from biomedical engineering.

The CitiCorp Center high-rise office building, constructed in New York City in the 1970s, was an unusual structure. Whereas the typical high-rise office building has its support columns at the corners of its four sides, the CitiCorp Center's columns were at the midpoints of its four sides. This enabled the building to be put on 125-foot-tall "stilts"

[25] McGinn, pp. 92-111.

and cantilevered out over the new church Citicorp had agreed to build at the northwest corner of the property it had purchased from St. Peter's Lutheran Church. Citicorp engaged renowned structural engineer William LeMessurier and his firm to do the structural engineering design work for the building.

A key issue was how strong to make the support structure of the building to enable it to survive the forces that would strike it during hurricanes of the sort that periodically battered New York City. LeMessurier did the structural analysis and calculated the strengths needed in the various members of the building's support structure. The building was constructed starting in 1974 and put into operation in 1977.

Things soon took an unexpected turn. In 1978, with the building fully occupied, a senior-year undergraduate civil engineering student at Princeton telephoned LeMessurier's office and stated that, having studied the building for her senior honors thesis, she had concluded that it was unstable and vulnerable to being toppled by hurricane winds of the sort and scale that periodically pummel New York City. Shocked, LeMessurier rechecked his analysis and concluded that the student was right. The building was unstable and needed emergency retrofitting. The retrofitting effort was completed in August 1978, just as a hurricane approached New York City.[26]

What had gone wrong? It turns out that LeMessurier had unwittingly engaged in an ethically irresponsible practice covered by **II 9**. To grasp his mistake at a deeper level, consider the following.

At a given point in time, the R&I activity surrounding a particular mature technological product is shaped by the reigning paradigm for that technology. The

[26] For accounts of the basic facts of the Citicorp Center episode, see Morgenstern and Kremer.

prevailing “paradigm” for a particular kind or type of mature technological product is a prescriptive intellectual construct that consists of a set of assumptions about how any technological product of that sort should be and function. The prevailing paradigm of a particular kind of mature technological product consists of assumptions about five product dimensions or aspects[27]:

- its normal configuration,
- its normal operational or structural principle(s),
- its normal constitutive material(s),
- the normal parametric domain(s) within which it safely, accurately, and/or reliably operates, and
- the normal method(s) and process(es) with which it is designed, produced, and used.

Prevailing paradigms exert powerful influences on the engineers who internalize them, inducing them to adhere in their design work to what the dominant paradigm prescribes as normal, conventional, and proper.[28]

How did the paradigm for the product we call the high-rise office building come into play in the design of Citicorp Center? When LeMessurier calculated the strength of the connections in the building’s support structure, he paid careful attention to perpendicular winds (that would hit the building at ninety-degree angles to its sides). But he neglected quartering winds (that would hit the building at forty-five-degree angles to its sides). Neglecting quartering winds would have been the proper thing to do if he had been dealing with a paradigmatic high-rise office building with columns at its four corners. But the fact that the building’s support columns were at the midpoints of its four sides meant that LeMessurier was working on a paradigm-departing engineering

[27] McGinn, pp. 87-91.
[28] The great bulk of technical professionals working on a particular kind of mature technological product share those assumptions. They absorb them from textbooks used in their formal coursework and by working with senior professional colleagues.

product.[29] Hence, he could not reasonably assume that the mode of structural analysis that was appropriate for working on paradigmatic high rises also applied to a paradigm-departing highrise such as the one he conceived. In short, LeMessurier designed a building that was radically innovative in its configuration and proceeded to structurally analyze it in a conventional way, paying attention only to perpendicular winds. This shows the serious risk of harm that can arise in the innovation stage from "treating a paradigm-departing engineering product or system design conventionally" (**II 9**).

Ethically responsible practice calls for the engineer working on an innovative design to be ever alert to the possibility that s/he is working or about to work on a paradigm-departing product or system and, if so, to be extra vigilant not to extend standard engineering analysis that applies to products of normal or conventional engineering design to products of radical engineering or paradigm-departing designs. By failing to realize that he had elaborated a paradigm-departing engineering design and proceeding to structurally analyze it 'in the usual manner,' LeMessurier unwittingly created a serious risk of devastating harm.[30]

The same kind of ethically irresponsible practice can also occur in the innovation stage in biomedical engineering endeavors. Let us revisit the Theranos blood-testing episode. Under pressure because the deadline for launching on-site blood testing in Walgreens' pharmacies was fast approaching, two Theranos engineers hacked into a Siemens Healthcare machine, the ADVIA 1800 blood analyzer, that Theranos had purchased.[31] They adapted it to test finger-stick blood samples that the much ballyhooed

[29] McGinn, pp. 273-274.
[30] The building could have fallen onto nearby Bloomingdale's department store, killing many shoppers. "A Red Cross estimate indicated that if the building collapsed, up to 200,000 people could lose their lives." See Kremer, p. 6.
[31] Carreyrou, p. 169.

but severely limited Edison prototype could not do.[32] The adaptation involved diluting with a saline solution the small blood samples taken from patients and transferring the diluted samples into sample-holding cups half the size of the ADVIA's normal ones.[33]

The Theranos engineers seem to have made questionable assumptions about the relationship between extent of blood-sample dilution and analyte concentration in the undiluted sample drawn from the patient, as well as about the reliability of using the adapted Siemens machine outside the parametric domain (regarding analyte concentration levels) that the manufacturer and the FDA had approved for the original ADVIA. This author knows of no evidence that the engineers exercised special vigilance by conducting rigorous tests to assure the reliability of analyte tests done with the hacked-and-adapted machine and doubly-diluted samples. To the extent that no such tests were done, the hacking-and-adaptation project was at odds with ethically responsible practice in the innovation stage. For without fastidious quality-control testing of the adapted machine when it analyzed doubly diluted blood samples using half-sized, custom-designed cups, thus operating with a testing protocol outside of the domain approved for the original machine, unreliable results were likely, some of which could pose risks of harm to patients tested with it.

For both the Citicorp Center building and the Theranos Siemens ADVIA 1800 adaptation examples, a key takeaway is that it is ethically irresponsible for an innovation-stage engineer to rely on paradigmatic modes of analysis or testing when, because a

[32] The Edison could only perform immunoassays, whereas the ADVIA specialized in high-demand general chemistry assays. *Ibid.*

[33] "Reducing the sample cup's size brought its bottom closer to the probe's tip and diluting the blood created more liquid to work with…The Siemens analyzer already diluted blood samples when it performed its assays." Hence, the Theranos engineers' adaptation meant that the finger-stick blood samples would be diluted *twice*, lowering the concentrations of the analytes in the samples "to levels below the ADVIA's FDA-sanctioned analytic measuring range." *Ibid.*, p. 170.

product or system is paradigm-departing, it cannot reasonably be assumed to be treatable in the normal/conventional way.

III. Conclusion

Many kinds of ethically responsible practices in the research stage are essentially the opposites of kinds of ethically irresponsible practices in that stage. However, there is considerably more to ethically responsible conduct in the research stage than honesty with data while conducting and publishing research.[34] This becomes clearer when the research stage is disaggregated into its (sometimes overlapping) constitutive phases, such as the problem-selection, fund-raising, literature-search, manuscript-review, and funding-proposal-review phases.

Similarly, there is more to ethically responsible practice in the innovation stage than engaging in patently responsible practices, such as adequately testing new products for safety and informing supervisors or management about the discovery of unrecognized sources of product risk. Ethically responsible – not just ethically acceptable -- practices in one or another phase of the innovation stage include conditional private or public whistleblowing, taking early-user-feedback seriously, doing due diligence on job offers, and designing environmentally friendly and culturally compatible products.

The most widely recognized forms of ethically irresponsible practice in the research stage are fabrication, falsification, and plagiarism (FFP). But ethically irresponsible practices in that stage also include remaining silent when knowing of fraudulent research or publication, premature submission of manuscripts, submitting

[34] As Wallace Marshall observed, "most…traditional RRI training is essentially a list of bad things that people might do, like fabricate data (FFP), and then the trainees are simply admonished to not do anything on that list." After scrutinizing the lists of practices in the four cells, readers should realize that, as Marshall put it, "there is a lot more to being [ethically] responsible than just not doing overtly evil things." (Marshall email to author, October 18, 2022).

hyperbole-laden or otherwise misleading funding proposals, taking prohibited shortcuts in the lab, and being unduly permissive or restrictive in recognizing co-authorship or intellectual indebtedness. Recognition of such practices is aided by keeping in mind the range of research-stage phases in which such practices can occur.

Finally, and arguably most importantly, ethically irresponsible practice in the innovation stage is not limited to obvious malfeasance, such as cheating on prototype safety tests or remaining silent about a serious risk of harm carried by a defective product or system with which one is familiar (and about which one is technically knowledgeable). Less obvious but critically important ethically irresponsible practices include producing, disseminating, using, and/or supporting decontextualized risk assessments of innovative products and systems; indifference to or negligence about designing or diffusing new products whose designs are incompatible with the cultures of the societies into which they are to be introduced; inattentiveness to whether one is working on a paradigm-departing engineering design; and treating a paradigm-departing engineering design, product, or system conventionally. Recognition of such inconspicuous problematic practices is made more likely by keeping in mind the wide range of innovation-stage phases delineated in section II.B., during any of which ethically irresponsible practices can occur.

Hopefully, disaggregation of the research and innovation stages into their respective sets of constitutive phases, delineation and discussion of phase-specific ethically responsible and irresponsible practices that pertain to and can occur in those stages, and the ranges of practices reflected in the lists associated with the cells of the matrix in Figure 1, will enhance the specificity of readers' concepts of responsible and

irresponsible R&I endeavor.

The sets of practices delineated in the four matrix cells are not definitive. The list of noteworthy items in each cell is likely to grow over time. However, even as works in progress~~,~~ the lists of specific kinds of responsible and irresponsible R&I practices arguably offer more practical guidance to practicing scientists and engineers than vague exhortations to engage in responsible R-&-I endeavor.

Familiarity with Fig. 1's Synoptic Matrix, including its lists of responsible and irresponsible R&I practices, some of which are inconspicuous, would enrich thinking about technical practitioner misconduct. Hence, consideration should be given to including study, discussion, and possible expansion of this matrix and its lists in the education of future scientists and engineers.

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