

1-1-2019

## The Combine and the Common Rule: Future NFL Players as Unknowing Research Participants

Christopher R. Deubert

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### Recommended Citation

Deubert, Christopher R. (2019) "The Combine and the Common Rule: Future NFL Players as Unknowing Research Participants," *Penn State Law Review*. Vol. 123 : Iss. 2 , Article 1.

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**Articles**

## The Combine and the Common Rule: Future NFL Players as Unknowing Research Participants

Christopher R. Deubert\*

### ABSTRACT

This Article analyzes the application of federal regulations governing human subjects research to the National Football League (NFL). More specifically, this Article examines research conducted via the NFL Scouting Combine. The NFL Combine is an annual event in which approximately 300 of the best college football players undergo medical examinations, intelligence tests, interviews, and multiple football and other athletic drills in the hopes of demonstrating their prowess and landing a spot in the NFL. Combine participants are under intense pressure to impress NFL clubs. Indeed, the Combine is routinely called the “biggest job interview of their lives.”

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\*Thank you to I. Glenn Cohen, Professor, Harvard Law School, and Faculty Director, Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics at Harvard Law School, and Holly Fernandez Lynch, John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics, Department of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine, for helpful comments and introducing me to the world of human subjects research regulation. All errors are my own.

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The examinations, tests and drills provide a plethora of data for NFL clubs to analyze in considering which players to select in the NFL Draft. NFL club medical personnel scour the data on behalf of the clubs, looking for medical conditions that might affect a player's short-term or long-term usefulness to the club. Many of these medical personnel have then also published studies utilizing the medical data from the NFL Combine. Such studies can provide a better understanding of the medical conditions faced by elite football players. At the same time, these studies help clubs predict how a Combine participant's medical condition or history might affect his performance on an NFL field.

Against this backdrop is the field of human subjects research regulation. Born out of some horrific historical incidents, bioethicists, doctors, lawyers and related experts constructed a paradigm setting forth the requirements for research—particularly medical research—involving humans as subjects. Included in this paradigm are federal regulations, known as the “Common Rule,” which typically require that research be reviewed and approved by an Institutional Review Board (IRB) and that the researchers obtain the participants' informed consent before proceeding. Moreover, the Common Rule requires that additional protections be implemented where the population being researched is considered “vulnerable.”

This Article examines whether 42 medical studies published using the medical records and data of NFL Combine participants comply with the Common Rule and other human subjects research guidelines. Given the intense pressure to please NFL clubs, and the precariousness of a career in the NFL, NFL Combine participants have significantly constrained choices about whether to participate in the research being conducted. Consequently, it is highly questionable whether informed consent—as required by the spirit and letter of the Common Rule—is being obtained.

Additionally, given most players' limited financial resources and the inequitable power relationship between players and NFL clubs, there is a strong argument that NFL Combine participants should be considered a vulnerable research population. This argument is bolstered by similarities between the workplaces of NFL players and military personnel—a population regularly recognized as vulnerable.

The Article concludes with five recommendations for better protecting NFL Combine participants in the context of human subjects research: (1) requiring researchers and/or the Combine participants to read the consent form aloud and audio record the process; (2) requiring all research to be approved by the National Football League Players Association; (3) requiring consent forms to be provided to the Combine participants' agents; (4) having IRBs engage the perspective of a player when evaluating research; and (5) requiring that Combine participants'

decision whether or not to participate in the research remain confidential. By requiring such protections, IRBs have the potential to ensure that NFL Combine participants are being subjected to research in the dignified and respectful manner required by the Common Rule.

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## I. INTRODUCTION

Research involving the National Football League (NFL) attracts public attention, elite universities and professionals, and tens of millions of dollars. For example, in 2016, the NFL committed \$100 million to research concerning head injuries.<sup>1</sup> Similarly, in 2014, the National Football League Players Association (NFLPA), the players' union, committed \$56 million to Harvard University for a variety of research projects related to NFL player health.<sup>2</sup>

Not surprisingly, the interest in NFL-related research has extended to players not yet in the NFL. More specifically, there is a considerable—and growing—body of research utilizing data from the NFL Scouting Combine, an annual event each February in which approximately three hundred of the best college football players undergo medical examinations, intelligence tests, interviews and multiple football and other athletic drills and tests in the hopes of demonstrating their prowess and being selected in the NFL Draft.<sup>3</sup> Between 2004 and June 2018, there have been 42 published medical studies utilizing data from the NFL Combine, 17 of which were published in just 2017 and 2018.

These studies—which are listed in Appendix A—analyze a wide range of medical issues that might affect NFL players, such as anterior cruciate ligament reconstruction, hip surgery, knee injuries, labral tears, and spine conditions. Notably, only one of the studies concerns concussions. The studies are principally concerned with either or both of two questions: (1) the prevalence of a condition in Combine attendees; and (2) the effect of such a condition on the player's performance in the NFL. Thus, while at least some of this research is designed to improve the diagnosis and treatment of conditions commonly faced by NFL players, a substantial portion of the research is clearly designed to better help NFL clubs evaluate the physical health and injury risks of Draft prospects. This is not surprising considering that all but one of the studies were co-authored by medical personnel affiliated with NFL clubs.

Nevertheless, medical research is generally highly-regulated. Research with human participants that is federally funded or which occurs at an institution that receives federal funds, with some exceptions, “is

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1. Ken Belson, *N.F.L. to Spend \$100 Million to Address Head Trauma*, N.Y. TIMES (Sept. 14, 2016), <https://nyti.ms/2gddYAP>.

2. See The Football Players Health Study at Harvard University, *FAQs*, <https://perma.cc/D9HG-KECK> (last visited Mar. 15, 2019) (answering the question of how the Football Players Health Study at Harvard University was funded). From May 2014 to May 2017, the author was a part of the Law & Ethics Initiative of the Football Players Health Study at Harvard University.

3. *NFL Scouting Combine*, NATIONAL FOOTBALL SCOUTING, <http://perma.cc/7ZSS-YBSP> (last visited Mar. 15, 2019).

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governed by a set of rules and procedures designed to protect study participants while enabling the advancement of important biomedical and social science research.”<sup>4</sup> These federal “regulations are formally known as the Federal Policy for the Protection of Human Subjects and are often referred to as the ‘Common Rule’ because they are held in common by many different federal agencies and departments.”<sup>5</sup> Since its promulgation in 1991 and through its amendment in 2017, the Common Rule has stood as the backbone for ethical research involving human subjects.

This Article raises questions about whether the medical research coming out of the Combine complies with the Common Rule. In particular, given the backgrounds of many NFL Combine participants (also referred to herein simply as “players”) and the pressure to make the NFL, it is questionable whether NFL Combine participants are providing the type of meaningful informed consent required by the Common Rule. The authors of these studies universally declined to provide further information about the studies, preventing a definitive answer. Consequently, this Article merely seeks to shed light on this important question, and to suggest meaningful ways in which researchers—and the institutional regulators overseeing them—can better ensure that NFL Combine participants are protected.

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This Article will proceed in 4 Parts: Part I provides background on human subjects research regulation and the Common Rule; Part II provides background on the NFL Combine; Part III examines the application of the Common Rule to the medical research performed with NFL Combine data; and, Part IV provides recommendations for better protecting NFL Combine participants when they become human subjects research participants. Finally, I conclude with thoughts on the importance of increased scrutiny to this issue for the purposes of better protecting future NFL players.

## II. HUMAN SUBJECTS RESEARCH REGULATION

The existing rules and regulations governing human subjects research in the United States grew out of a series of historical incidents in which humans were used in research in disturbing and unethical ways. This Part will provide the historical background on some of those incidents, the resulting evolution of bioethical consideration of these issues, the

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4. Barbara E. Bierer et al., *Revised ‘Common Rule’ Shapes Protections For Research Participants*, 36 HEALTH AFFAIRS 784, 784 (2017).

5. *Id.*

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subsequent enactment of the Common Rule, and the requirements of the Common Rule today.

A. *Historical Background*

There are two particularly important incidents in the history of human subjects research.

First, during World War II, Nazi doctors and scientists subjected thousands of prisoners to “painful and often deadly experiments . . . without their consent.”<sup>6</sup> Following the war, 16 Nazi doctors and personnel were convicted for war crimes and crimes against humanity as part of the Nuremberg Trials.<sup>7</sup> In handing down the convictions, the judges laid out ten principles that ought to govern medical experiments.<sup>8</sup> The first principle of the list, which came to be known as the Nuremberg Code, declared that “[t]he voluntary consent of the human subject is absolutely essential.”<sup>9</sup>

Second, between 1932 and 1972, the United States Public Health Service tracked the health of 399 black men from rural southern communities who had contracted syphilis.<sup>10</sup> However, the doctors involved with the study (known as the “Tuskegee Study”) did not advise the men they had the disease, did not treat the disease and discouraged other doctors from treating the men.<sup>11</sup> The study was stopped when its details were publicly reported and became the subject of widespread condemnation.<sup>12</sup> The United States government later agreed to create a \$10 million fund to cover the medical benefits and burial services of all living research participants, and President Bill Clinton formally apologized for the study in 1997.<sup>13</sup>

In 1974, Congress passed the National Research Act which, among other things, created the National Commission for the Protection of

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6. *Nazi Medical Experiments*, U.S. HOLOCAUST MEMORIAL MUSEUM, <https://perma.cc/M5RH-Q64M> (last visited Mar. 15, 2019).

7. Alexander Morgan Capron, *Subjects, Participants, and Partners: What Are the Implications for Research as the Role of Informed Consent Evolves?*, in HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE 143, 143–44 (I. Glenn Cohen & Holly Fernandez Lynch eds., 2014).

8. *Id.* at 144.

9. *Id.* (citing THE NUREMBERG CODE (1947), in *Timeline of Laws Related to the Protection of Human Subjects*, NAT’L INSTS. OF HEALTH (Joel Sparks ed., 2002), <https://history.nih.gov/about/timelines/nuremberg.html>). As will be discussed below, modern research ethics recognizes a variety of circumstances in which consent is not required or can be waived.

10. *U.S. Public Health Service Syphilis Study at Tuskegee*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/UE4K-EKS2> (last visited Mar. 15, 2019).

11. *Id.*

12. *Id.*

13. *Id.*

Human Subjects of Biomedical and Behavioral Research.<sup>14</sup> The Commission was charged with identifying “the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.”<sup>15</sup> In 1979, the Commission released a lengthy report, entitled “Ethical Principles and Guidelines for the Protection of Human Subjects Research,” which came to be known as the Belmont Report.<sup>16</sup>

The Belmont Report, which specifically referenced the Nazi and Tuskegee studies, “identified respect for persons, beneficence, and justice as three basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects in the United States.”<sup>17</sup> The Belmont Report also explained how these principles should be applied in research practice by (1) obtaining informed consent, (2) minimizing risks and ensuring a generally favorable risk-benefit ratio, and (3) selecting subjects fairly.<sup>18</sup> The Department of Health, Education and Welfare (now known as the Department of Health and Human Services) subsequently revised its regulations concerning human research to incorporate the conclusions of the Belmont Report.<sup>19</sup>

#### B. *Background on the Common Rule*

The Belmont Report’s influence did not end with the Department of Health and Human Services. In 1991, fourteen additional federal agencies and departments adopted the same basic regulations “in an effort to develop uniform and consistent policies for human subjects research across federal funding bodies.”<sup>20</sup> These regulations thus became known as the “Common Rule.”<sup>21</sup> “Today, the Common Rule governs research conducted or supported by the [sixteen] federal departments and agencies that have adopted it.”<sup>22</sup>

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14. *The Belmont Report*, OFFICE FOR HUMAN RESEARCH PROTS. (Apr. 19, 1979), <https://perma.cc/8HYF-3KZX> [hereinafter *The Belmont Report*].

15. *Id.*

16. *Id.*

17. Amy L. Davis & Elisa A. Hurley, *Setting the Stage: The Past and Present of Human Subjects Research Regulations*, in HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE 9, 10–11 (I. Glenn Cohen & Holly Fernandez Lynch eds., 2014).

18. *Id.* at 11.

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*; *Revised Common Rule*, OFFICE FOR HUMAN RESEARCH PROTS., <https://perma.cc/24WF-PWYB> (last visited Mar. 15, 2019).



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After a multi-year process, the Common Rule was amended in 2017,<sup>23</sup> with those amendments becoming effective in 2018. According to experts, the amendments were needed to correct “gaps in protections, on the one hand, and gross inefficiencies and overregulation, on the other.”<sup>24</sup> Modern research involving biospecimens was at least one of the driving forces behind the amendments,<sup>25</sup> and is generally not relevant to the analysis here.

All of the research examined in this Article was conducted pursuant to the former version of the Common Rule. Nevertheless, in this Article, the text from the revised version is generally provided so that the Article is useful moving forward. Additionally, the majority of the changes to the relevant provisions were cosmetic and did not fundamentally alter their purpose or effect. Where meaningful revisions have been made, both the former and revised versions of the Common Rule’s requirements are provided.

Some clarifications and definitions also provide important context. The Common Rule only applies to “research involving human subjects.”<sup>26</sup> A “human subject” is defined as “a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.”<sup>27</sup> Additionally, research under the Common Rule is broadly defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>28</sup>

Importantly, not all research is the same. A considerable portion of medical research is obviously devoted to understanding and treating (if not curing) the world’s most serious diseases, illnesses, and injuries. Of course, when human subjects are used in such research, they may be exposed to serious health risks as a result of experimental treatments. Nevertheless, there is a great deal of research involving human subjects that is much more benign. The Common Rule defines such research as “minimal risk,” meaning “that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance

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23. 82 Fed. Reg. 7149 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46).

24. Bierer et al., *supra* note 4, at 784.

25. *See id.* at 785.

26. 45 C.F.R. § 46.101(a) (West 2018).

27. 45 C.F.R. § 46.102(e)(1) (West 2018).

28. 45 C.F.R. § 46.102(l).

of routine physical or psychological examinations or tests.”<sup>29</sup> Most (if not all) of the research discussed in this article is likely minimal risk, an important contextual factor.

Additionally, there are exemptions to the Common Rule,<sup>30</sup> including for “secondary research.”<sup>31</sup> Secondary research in the medical field is research using “existing health data,”<sup>32</sup> *i.e.*, data that was not collected for purposes of the present research. Secondary research data often comes from existing medical records or samples or data from previous research studies. Secondary research relevant to this Article consists of one of two types: (1) research using “publicly available” “identifiable private information,”<sup>33</sup> or (2) research using information that “is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.”<sup>34</sup> As is discussed in Section III.C, this exemption potentially applies to some of the research involving NFL Combine participants.

Finally, the Common Rule does not apply to all human subjects research conducted in the United States. The Common Rule only applies to research “conducted” or “supported” by the federal departments that have adopted the Common Rule.<sup>35</sup> According to the Office for Human Research Protections (OHRP), a division of the Department of Health and Human Services responsible for overseeing human subjects research,<sup>36</sup> “federally-supported means the U.S. Government providing any funding or other support.”<sup>37</sup> As part of obtaining federal research funding,

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29. 45 C.F.R. § 46.102(j).

30. *See* 45 C.F.R. § 46.104 (West 2018) (listing exemptions to the Common Rule).

31. 45 C.F.R. § 46.104(d)(4).

32. Barbara J. Evans, *Why the Common Rule is Hard to Amend*, 10 Ind. Health L. Rev. 365, 378 (2013).

33. 45 C.F.R. § 46.104(d)(4)(i).

34. 45 C.F.R. § 46.104(d)(4)(ii). The former version of the Common Rule lumped these exemptions together in a more muddled fashion, defining exempt secondary research as “[r]esearch . . . involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.” 45 C.F.R. § 46.101(b)(4) (2005) (amended 2018).

35. 45 C.F.R. § 46.101(a) (West 2018).

36. *About OHRP*, OFFICE FOR HUMAN RESEARCH PROTS., <https://perma.cc/7NYM-TPYF> (last visited Mar. 15, 2019).

37. *Federalwide Assurance (FWA) for the Protection of Human Subjects*, OFFICE FOR HUMAN RESEARCH PROTS., <https://perma.cc/F6PL-VYPZ> (last visited Mar. 15, 2019).

institutions obtain what is known as a Federalwide Assurance (FWA), indicating their agreement to comply with the Common Rule.<sup>38</sup>

While colleges and universities often receive federal funding for research projects, many research projects are funded internally or by private donors.<sup>39</sup> This distinction creates the possibility that at a particular university, some of its research will be subject to the Common Rule and some will not. In order to avoid problems that might arise from having inconsistent research policies, approximately two-thirds of American colleges and universities voluntarily agree that all of its non-exempt human subjects research will comply with the Common Rule.<sup>40</sup> This practice has been known as “checking the box.”<sup>41</sup> Historically, in checking the box, the university was subjecting all of its research—federally and privately funded—to OHRP’s jurisdiction. However, under the revised Common Rule, while institutions can still voluntarily apply the Common Rule to all of their research, OHRP will no longer have jurisdiction over research that is not federally funded.<sup>42</sup>

With this background, we can now review the specific requirements of the Common Rule.

### C. *Requirements of the Common Rule*

The Common Rule’s principal requirements govern: (1) the constitution and operations of Institutional Review Boards (IRBs); and, (2) obtaining informed consent from research participants. Each requirement is discussed in turn.

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38. *Id.*; see also *Assurance Process Frequently Asked Questions (FAQs)*, OFFICE FOR HUMAN RESEARCH PROTS., <https://perma.cc/E9J6-LUQF> (last visited Mar. 15, 2019) (answering the question of “What is a Federalwide Assurance (FWA)?,” the OHRP states that, “[u]nder an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.”).

39. See Jeffrey Mervis, *Data check: U.S. government share of basic research funding falls below 50%*, SCIENCE (Mar. 9, 2017, 1:15 PM), <https://perma.cc/P84F-8XDH> (discussing sources of research funding); see also Art Jahnke, *Who Picks Up the Tab for Science?*, BU TODAY (Apr. 6, 2015), <https://perma.cc/FR3V-U6W7>.

40. See Harold Blatt et al., *When the Assurance comes a ‘Knocking’: OHRP’s FWA and IRB Registration Processes*, OFFICE FOR HUMAN RESEARCH PROTS. (Mar. 28, 2013), <https://perma.cc/5FE2-R248>.

41. *See id.*

42. E-mail from Jaime O. Hernandez, Public Health Advisor, Office for Human Research Protections, to author (July 20, 2018) (on file with author).

### 1. Institutional Review Boards (IRBs)

An IRB is “a group whose function is to review research to assure the protection of the rights and welfare of the human subjects.”<sup>43</sup> IRBs “review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by [the Common Rule].”<sup>44</sup>

In order for research to be approved under the Common Rule, the IRB must find that all of the following requirements are satisfied:

- (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. . . .
- (3) Selection of subjects is equitable. . . .
- (4) Informed consent will be sought from each prospective subject or the subject’s legally authorized representative. . . .
- (5) Informed consent will be appropriately documented or appropriately waived. . . .
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. . . .
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<sup>45</sup>

Additionally, the Common Rule requires that “[w]hen some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards [to] have been included in the study to protect the

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43. U.S. FOOD & DRUG ADMIN., *Institutional Review Boards Frequently Asked Questions - Information Sheet*, <https://perma.cc/G7MX-9J8P> (last visited Mar. 15, 2019).

44. 45 C.F.R. § 46.109(a) (West 2018).

45. 45 C.F.R. § 46.111(a)(1)–(7) (West 2018).

rights and welfare of these subjects.”<sup>46</sup> In Section III.F, we examine whether NFL Combine participants might be considered a vulnerable population under the Common Rule.

The Common Rule also contains detailed requirements for the composition of IRBs:

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.<sup>47</sup>

Understanding how IRB review works in practice is also important. Many IRBs have created forms through which researchers address the requirements of the Common Rule.<sup>48</sup> Researchers must also submit documents that will be used as part of the research, including scripts to be used to recruit participants and the forms to be used to document the subject’s consent to the research (if being used).<sup>49</sup> The materials will then be reviewed by the IRB, which frequently requires modifications to be

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46. 45 C.F.R. § 46.111(b).

47. 45 C.F.R. § 46.107(a) (West 2018).

48. *See generally Creating and Submitting a New Application in ESTR*, HARVARD UNIV., COMM. ON THE USE OF HUMAN SUBJECTS, <https://perma.cc/DD9Y-V6DK> (last visited Mar. 15, 2019); *see also 6 Tips For Speeding Up The Review of Your Application*, HARVARD UNIV., COMM. ON THE USE OF HUMAN SUBJECTS, <https://perma.cc/FR5H-AMAZ> (last visited Mar. 15, 2019).

49. *See, e.g., id.*

made to the documents before it can be approved.<sup>50</sup> Research cannot begin until all documents are approved by the IRB.<sup>51</sup>

## 2. Informed Consent

Informed consent is considered the “ethical cornerstone” and a “central tenet of biomedical research.”<sup>52</sup> The Belmont Report declared that “[r]espect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.”<sup>53</sup> Moreover, the Belmont Report explained that informed consent generally requires “three elements: information, comprehension and voluntariness.”<sup>54</sup>

The former version of the Common Rule codified these principles:

[N]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.<sup>55</sup>

The revised Common Rule retains all of the above admonishments, only in a slightly altered format.<sup>56</sup> In addition, the revised Common Rule provides some additional requirements and guidance:

The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want

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50. See Steven Joffe, *Revolution or Reform in Human Subjects Research Oversight*, 40 J. L. MED. & ETHICS 922, 922–23 (2012) (discussing bureaucracy of IRBs); see also Todd J. Zywicki, *Institutional Review Boards as Academic Bureaucracies: An Economic and Experiential Analysis*, 101 NW. U. L. REV. 861, 866–67 (2007).

51. See 45 C.F.R. § 46.102(h) (West 2018) (“IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution with the constraints set forth by the IRB and by other institutional and federal requirements.”).

52. Capron, *supra* note 7, at 143 (internal citations omitted).

53. *The Belmont Report*, *supra* note 14 (emphasis added).

54. *Id.*

55. 45 C.F.R. § 46.116 (2005) (amended 2018).

56. See generally 45 C.F.R. § 46.116(a) (West 2018).

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to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. . . .

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.<sup>57</sup>

The Common Rule outlines the information that must be provided to the research participant "in seeking informed consent":

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and

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57. 45 C.F.R. § 46.116(a)(4)–(5) (internal numbering omitted); *see also* Bierer, *supra* note 4, at 785 (“[T]here are still important gaps in the empirical data related to developing, organizing, and synthesizing what a reasonable person would want to know to make an informed decision. Questions also remain about how best to assess comprehension of prospective research participants.”).

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whom to contact in the event of a research-related injury to the subject; and

- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.<sup>58</sup>

The revised Common Rule added a ninth requirement concerning secondary research:

- (9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
- (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.<sup>59</sup>

This new requirement codifies the practice of “broad consent.”<sup>60</sup> Broad consent permits researchers to use data from one study in future studies (1) if the data is de-identified, and (2) the research subject is made aware of this potential future use as part of the initial consent process. The practice of broad consent is intended to lessen the burdens in conducting secondary research<sup>61</sup> and, as will be discussed below, may have future applicability in the NFL Combine setting.

The Common Rule also identifies “[a]dditional elements” that might

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58. 45 C.F.R. § 46.116(a)(1)–(8) (2005) (amended 2018).

59. 45 C.F.R. § 46.116(b)(9) (West 2018).

60. See generally Mary Bernadette Ott & Gary Yingling, *The Common Rule*, 1 GUIDE TO GOOD CLINICAL PRACTICE ¶ 1250 (West 2018).

61. See *id.*



need to be provided to the research participant in seeking informed consent:

- (1) A statement that the particular treatment or procedure may involve risks to the subject . . . that are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may related to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.<sup>62</sup>

Despite the extensive requirements concerning informed consent, the Common Rule permits "an IRB to waive or alter consent" if five criteria are met:

- (i) The research involves no more than minimal risk to the subjects;
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.<sup>63</sup>

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62. 45 C.F.R. § 46.116(c)(1)–(6) (West 2018). The revised Common Rule added additional provisions concerning biospecimens and clinical research that are not relevant here. *See* 45 C.F.R. § 46.116(c)(7)–(9).

63. 45 C.F.R. § 46.116(f)(3).

Lastly, as a general rule, the Common Rule requires consent to be documented with the subject's signature.<sup>64</sup> Additionally, "[t]he investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed."<sup>65</sup> However, the IRB can waive documentation of consent if: (i) "the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality"; (ii) "the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context"; or (iii) "the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm . . . ."<sup>66</sup>

Importantly, the Common Rule does not say that providing a research participant with the above information—or having the participant sign a form indicating they were provided with such information—establishes informed consent. Indeed, OHRP, in its guidance on the Common Rule, states that "even if a signed consent form is required, it alone does not constitute an adequate consent process."<sup>67</sup>

Determining when informed consent for purposes of human subjects research is obtained is not clear. The Common Rule requires "legally effective informed consent."<sup>68</sup> According to OHRP, "[i]nformed consent is legally effective if it is both obtained from the subject or the subject's legally authorized representative and documented in a manner that is consistent with the [Common Rule] and with applicable laws of the jurisdiction in which the research is conducted."<sup>69</sup> While this definition appears somewhat circular, OHRP's guidance also states that "[t]he informed consent process should ensure that all critical information about a study is completely disclosed, and that prospective subjects or their legally authorized representatives adequately understand the research so that they can make informed decisions."<sup>70</sup>

The Common Rule provides additional guidance by indicating that informed consent requires investigators to "minimize the possibility of coercion or undue influence."<sup>71</sup> Nevertheless, this requirement raises the

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64. 45 C.F.R. § 46.117(a) (West 2018).

65. 45 C.F.R. § 46.117(b)(1).

66. 45 C.F.R. § 46.117(c)(1).

67. *Informed Consent FAQs*, OFFICE FOR HUMAN RESEARCH PROTS., <https://perma.cc/99A8-8JMT> (last visited Mar. 15, 2019) [hereinafter *Informed Consent FAQs*].

68. 45 C.F.R. § 46.116(a)(1) (West 2018).

69. *Informed Consent FAQs*, *supra* note 67.

70. *Id.*

71. 45 C.F.R. § 46.116(a)(2).

question of the meanings of coercion and undue influence in the human subjects research context.

a. Defining Coercion and Undue Influence

The Common Rule does not define coercion or undue influence but nevertheless, there is guidance on the issue. The Belmont Report states that:

An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. **Coercion** occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. **Undue influence**, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.<sup>72</sup>

In responding to the frequently asked question “What does it mean to minimize the possibility of coercion or undue influence?”, OHRP’s guidance is nearly identical to that of the Belmont Report’s.<sup>73</sup> One key distinction is that OHRP’s guidance states that coercion can also occur through an “implicit” threat of harm.<sup>74</sup> This additional language might be important, as discussed in Section III.E.

While some IRB members might conflate the two terms,<sup>75</sup> coercion and undue influence should be thought of as distinct concepts.<sup>76</sup> Generally speaking, coercion occurs where the potential participant faces a “worse consequence,” while undue influence occurs where the potential participant is being offered a “positive good.”<sup>77</sup>

When coercion or undue influence has taken place is still an unclear issue. Research has not revealed any case decisions on the matter and OHRP’s database of “determinations of noncompliance”<sup>78</sup> also does not provide any helpful guidance. While the database does include a variety

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72. *The Belmont Report*, *supra* note 14 (emphasis added).

73. *See Informed Consent FAQs*, *supra* note 67.

74. *Id.*

75. *See* Emily A. Largent & Holly F. Lynch, *Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward*, 17 *YALE J. HEALTH POL’Y L. & ETHICS* 61, 115 (2017) (detailing survey conducted of IRB members and their understanding of the terms “coercion” and “undue influence”).

76. *See id.*

77. *See id.* at 112 (quoting Ezekiel J. Emanuel, *Ending Concerns About Undue Inducement*, 32 *J.L. MED. & ETHICS* 100, 101 (2004)).

78. *OHRP Determination Letters and Other Correspondence*, OFFICE FOR HUMAN RESEARCH PROTS., <https://perma.cc/47GP-LYUP> (last visited Mar. 15, 2019).

of letters to various institutions concerning informed consent in particular research studies, OHRP's responses merely express a general concern that all of the enumerated elements of informed consent required by the Common Rule have been established.<sup>79</sup>

Without specific guidance or findings in the ethical and regulatory fields, state law might provide another useful avenue for examining compliance with the Common Rule. As stated above, the informed consent process must also comply with the law of the state in which the research is being conducted.<sup>80</sup> There is a large body of case law on coercion and undue influence within each state's jurisprudence, particularly on issues concerning criminal law,<sup>81</sup> contracts<sup>82</sup> and wills and estates.<sup>83</sup> On this front, the Restatements of Law from the American Law Institute, which seek to summarize general principles of law, are a helpful generalization of state laws.

Multiple Restatements of Law categorize coercion as a synonym for "duress."<sup>84</sup> According to the Restatement (Second) of Contracts, duress occurs where: (1) "a person physically compels conduct that appears to be a manifestation of assent by a party who has no intention of engaging in that conduct"; or, (2) "a person makes an improper threat that induces a

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79. See, e.g., Letter from Kristina C. Borrer, Director, Division of Compliance Oversight, Office for Human Research Protections, to Harry W. Orf, Senior Vice President for Research, Massachusetts General Hospital (Oct. 11, 2016), <https://perma.cc/Q7MS-VJEG>; Letter from Kristina C. Borrer, Director, Division of Compliance Oversight, Office for Human Research Protections, to Stephen Welter, Vice-President for Research, San Diego State University (Feb. 2, 2016), <https://perma.cc/BKK9-X55Z>.

80. See *Informed Consent FAQs*, *supra* note 67 ("Informed consent is legally effective if it is both obtained from the subject or the subject's legally authorized representative and documented in a manner that is consistent with the [Common Rule] and with applicable laws of the jurisdiction in which the research is conducted.") (emphasis added); 45 C.F.R. § 46.116(i) (West 2018) ("The informed consent requirements in [the Common Rule] are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order to for informed consent to be legally effective.").

81. See, e.g., *People v. Case*, 418 P.3d 360, 379–80 (Cal. 2018) (examining whether criminal defendant's statements were coerced); *People v. Zadran*, 314 P.3d 830, 833–35 (Colo. 2013) (same); *State v. Garcia*, 743 A.2d 1038, 1044–47 (R.I. 2000) (examining whether witnesses' statements were coerced).

82. See, e.g., *Gelber v. Glock*, 800 S.E.2d 800, 815–18 (Va. 2017) (examining whether to set aside a contract for undue influence); *Albert v. Albert*, 108 A.3d 388, 392–93 (Me. 2015) (same).

83. See, e.g., *Kinsel v. Lindsey*, 526 S.W.3d 411, 418–21 (Tex. 2017) (examining whether trust was amended before death as a result of undue influence); *Williams v. Hubbard*, 455 S.W.3d 426, 433–39 (Mo. 2015) (en banc) (examining whether decedent's nonprobate transfers resulted from undue influence).

84. See RESTATEMENT (THIRD) OF RESTITUTION AND UNJUST ENRICHMENT Index C100 (AM. LAW INST. 2018) (instructing reader to "See DURESS"); RESTATEMENT (THIRD) OF PROP.: WILLS AND OTHER DONATIVE TRANSFERS Index C360 (AM. LAW INST. 2018) (same); RESTATEMENT (FIRST) OF JUDGMENTS Index C190 (AM. LAW INST. 2018) (same).

party who has no reasonable alternative to manifesting his assent.”<sup>85</sup> In the first case, no enforceable contract can be created, while in the second, the contract is voidable at the victim’s discretion.<sup>86</sup> The wrongful conduct can be implied.<sup>87</sup>

On undue influence, the Restatement (Second) of Contracts states that:

Undue influence involves unfair persuasion, a milder form of pressure than duress. Such persuasion nevertheless makes the contract voidable if it is exercised on a party who is under the domination of the person exercising it or is, by virtue of his relation with that person, justified in assuming that this person will not act in a manner inconsistent with his welfare.<sup>88</sup>

Finally, an additional persuasive authority on the definitions of coercion and undue influence under state law is *Black’s Law Dictionary*, the leading legal dictionary. *Black’s* defines coercion as “[c]ompulsion of a free agent by physical, moral, or economic force or threat of physical force”<sup>89</sup> and undue influence as “[t]he improper use of power or trust in a way that deprives a person of free will and substitutes another’s objective; the exercise of enough control over another person that a questioned act by this person would not have otherwise been performed, the person’s free agency having been overmastered.”<sup>90</sup>

The definitions used by the Restatement (Second) of Contracts and *Black’s Law Dictionary* differ slightly from those of the Belmont Report and OHRP. This is important for the fact that conduct that might not rise to the level of illegality, might still be ethically problematic. Nevertheless, because research governed by the Common Rule must comply with both the Common Rule and state law, these definitions should only expand the type of conduct that could be considered in violation of the Common Rule.

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85. RESTATEMENT (SECOND) OF CONTRACTS ch. 7, topic 2, intro. note (AM. LAW INST. 1981).

86. *See id.*

87. RESTATEMENT (SECOND) OF CONTRACTS § 175 cmt. a (AM LAW INST. 1981) (“[I]f one person strikes or imprisons another, the conduct may amount to duress because of the threat of further blows or continued imprisonment that is implied.”); *see also* King v. Donnkenny, Inc., 84 F. Supp. 2d 736, 738–40 (W.D. Va. 2000); Comcast of Oregon II, Inc. v. City of Eugene, 155 P.3d 99, 107 (Or. Ct. App. 2007); State Nat’l Bank v. Farah Mfg. Co., 678 S.W.2d 661, 685 (Tex. Ct. App. 1984).

88. RESTATEMENT (SECOND) OF CONTRACTS ch.7, topic 2, intro. note (AM. LAW INST. 1981).

89. *Coercion*, BLACK’S LAW DICTIONARY (10th ed. 2014).

90. *Undue Influence*, BLACK’S LAW DICTIONARY (10th ed. 2014).

Ultimately, determining whether informed consent has been obtained, taking into account the factors mentioned in these definitions, is the IRB's responsibility.<sup>91</sup>

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With the above understanding of the Common Rule's requirements, background on the NFL Combine is provided, before analyzing the two together.

### III. THE NFL COMBINE

The NFL Combine is an annual event each February in which approximately three hundred of the best college football players undergo medical examinations, intelligence tests, interviews and multiple football and other athletic drills and tests in the hopes of demonstrating their prowess and landing a spot in the NFL.<sup>92</sup> Although called the NFL Combine, the event is technically organized by National Invitational Camp, Inc., the legal entity that is the Combine,<sup>93</sup> a subsidiary of National Football Scouting, Inc. National Football Scouting is an organization that provides scouting services to NFL clubs and which is owned and managed as a joint endeavor by 20 of the NFL's 32 clubs.<sup>94</sup> Nevertheless, the NFL exercises considerable control over the Combine, including helping to make decisions about the drills that players perform, selling public tickets, and broadcasting the event on television.<sup>95</sup>

The importance of the Combine to its participants cannot be understated—it is routinely called the “biggest job interview of their lives.”<sup>96</sup> NFL club executives, coaches, scouts, doctors and athletic trainers attend the Combine to evaluate the players for the upcoming NFL

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91. See *Informed Consent FAQs*, *supra* note 67 (“It is up to the IRB to use its discretion in determining which circumstances give rise to undue influence. . . . IRBs must be vigilant about minimizing the possibility for coercion and undue influence.”).

92. NFL SCOUTING COMBINE, <http://www.nflcombine.net/> (last visited Mar. 15, 2019).

93. See Bill Bradley, *Jeff Foster Talks About Challenges of Hosting NFL Scouting Combine*, NFL.COM (Feb. 18, 2014, 2:53 PM), <https://perma.cc/JEX3-FY3H> [hereinafter Bradley, *Jeff Foster*] (discussing National Football Scouting, Inc.'s operation of the NFL Combine).

94. Bill Bradley, *Too much overlap caused NFL to create annual Scouting Combine*, NFL.COM (Feb. 17, 2014, 2:27 PM), <https://perma.cc/FH4X-XZK8>.

95. Albert Breer, *NFL Scouting Combine's evolution raises questions about future*, NFL.COM (Feb. 18, 2013, 12:17 PM), <https://perma.cc/579Q-6Y2N>.

96. See Ali Bhanpuri et al., *The Ultimate Interview: Preparing for the NFL Scouting Combine*, NFL.com, <http://www.nfl.com/combinestories> (last visited Mar. 15, 2019); see also Keiana Martin, *NFL Scouting Combine 101: What You Need to Know*, CHIEFS.COM (Feb. 23, 2016), <https://perma.cc/EZ7H-94A7>.

Draft (usually in April).<sup>97</sup> In the 2016 NFL Draft, 83.6% of players that were drafted participated at the NFL Combine.<sup>98</sup> And, of those draftees that were not invited to the Combine, none were selected before the 4th round of the Draft.<sup>99</sup> One of the most important parts of the Combine are the 15 minute interviews in which club executives and coaches question players about football, but also their personal lives and a wide variety of other topics.<sup>100</sup> The players are undoubtedly under immense pressure to impress the clubs during the multi-day Combine.<sup>101</sup>

While the interviews are critical, according to Jeff Foster, the President of National Football Scouting, *all 32 NFL clubs* consider the medical exams (and not the athletic drills or interviews) to be the most important part of the Combine.<sup>102</sup> Since 1987, doctors with IU Health,<sup>103</sup> a healthcare system affiliated with Indiana University School of Medicine, perform x-rays, MRIs and other exams at each year's Combine.<sup>104</sup> The IU Health examinations are performed on behalf of the Combine, who then provides the results to NFL clubs. After the examinations performed by IU Health doctors, club doctors also examine the participants. The medical examinations at the Combine generally include x-rays, MRIs, echocardiograms, and blood analysis.<sup>105</sup> Participants must also take a drug test.<sup>106</sup> Dr. Richard Kovacs, a cardiologist with IU Health describes the

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97. See NFL SCOUTING COMBINE, *supra* note 92.

98. See *Notable current NFL players who weren't invited to the combine*, NFL.COM (Feb. 6, 2018, 12:39 PM), <https://perma.cc/DML9-8SMX>.

99. See *id.*

100. See Jenny Vrentas, *Behind Closed Doors at the NFL Combine*, SPORTS ILLUSTRATED (Mar. 1, 2016), <https://perma.cc/PL8G-CNWG>; see also Rodger Sherman, *The Weirdest, Dumbest Questions NFL Teams Ask Players at the Combine*, SBINATION.COM (Feb. 25, 2016, 4:29 PM), <https://perma.cc/YC9U-QDT8>.

101. See *id.*

102. See Breer, *supra* note 95.

103. See Bradley, *Jeff Foster*, *supra* note 93.

104. See *id.* (describing IU doctors as “handl[ing] all of the testing, imaging and reporting of the standard and special battery of tests that we do on each athlete”); see also Breer, *supra* note 95 (describing IU doctors as having been “a combine partner for 28 years,” and noting that “350 MRIs were conducted on 330 players in a four-day period, with IU Health”); see also *About IU Health*, IND. U. HEALTH, <https://iuhealth.org/about-our-system> (last visited Mar. 15, 2019).

105. See Shalise Manza Young, *Healthy status: Lotulelei at top after heart scare*, BOS. GLOBE, Apr. 19, 2013, 2013 WLNR 9554561; see also Jarrett Bell, *NFL Combine: All the Buzz*, USA TODAY, Feb. 28, 2005, 2005 WLNR 3112818; see also Mike Chappell, *NFL's health assurance plan*, INDIANAPOLIS STAR, Feb. 19, 2004, 2004 WLNR 23116329.

106. See Matt Bowen, *McClellin's shift to LB, plus fresh talent have potential to help defense*, CHI. TRIB., June 22, 2014, 2014 WLNR 16913612 (discussing player's failed drug test at Combine); see also Ralph Vacchiano, *NY Giants cornerback Jayron Hosley gets four-game suspension for violating NFL's drug policy*, N.Y. DAILY NEWS (June 5, 2014), <https://perma.cc/U64B-K6AN> (same).

medical exams as “the choke point, . . . [n]o one goes to [the Combine] until they go through us.”<sup>107</sup>

In a 2017 University of Pennsylvania Law Review article, my co-authors and I explained the ways in which the medical exams at the NFL Combine likely violate the Americans with Disabilities Act (ADA).<sup>108</sup> The ADA prohibits pre-employment medical exams.<sup>109</sup> As discussed above, the NFL Combine is principally a forum for pre-employment medical exams of prospective NFL players. Despite their apparent violation of the law, the medical exams at the Combine have existed for decades and continue to exist.

To facilitate these examinations and the exchange of medical information that takes place, participants in the Combine are requested to sign two documents: (1) an authorization for the use and disclosure of records and information; and, (2) an authorization for release and disclosure of medical and mental health records.<sup>110</sup>

The authorization for use and disclosure of records and information form permits a wide range of individuals and entities to use, release and disclose a player’s medical records, including but not limited to the Combine, the NFL, all NFL clubs, NFL club medical staff, and various NFL health-related consultants. Similarly, the authorization for the release and disclosure of medical and mental health records authorizes any entity that possess a player’s medical records, including healthcare providers, schools and others, to release those records to the Combine, the NFL, all NFL clubs, NFL club medical staff, and various NFL health-related consultants.<sup>111</sup> As discussed at the outset, many of the authors of the research studies at issue were NFL club medical staff and thus, under these documents, were authorized to receive and use player medical information.

As a practical matter, players sign the authorizations as requested. If a player refused to sign the authorization, a club might lack medical information essential in considering whether to draft the player, potentially preventing the player from being drafted at all. Additionally, the player

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107. Dana Hunsinger Benbow, *The real reason for the NFL Scouting Combine*, INDIANAPOLIS STAR (Feb. 25, 2016, 9:06 AM), <https://perma.cc/4WU7-ZKVM>.

108. See Jessica L. Roberts, I. Glenn Cohen, Christopher R. Deubert & Holly Fernandez Lynch, *Evaluating NFL Player Health and Performance: Legal and Ethical Issues*, 165 U. PA. L. REV. 227, 263–64 (2017).

109. 42 U.S.C. § 12112(d)(2)(B) (2012 & Supp. 2017).

110. See Roberts et al., *supra* note 108, online apps. B, C.

111. The authorization forms may also raise concerns as to compliance with the Health Insurance Portability and Accountability Act (HIPAA). For more on HIPAA and the NFL, see CHRISTOPHER R. DEUBERT ET AL., PROTECTING AND PROMOTING THE HEALTH OF NFL PLAYERS: LEGAL AND ETHICAL ANALYSIS AND RECOMMENDATIONS, THE FOOTBALL PLAYERS HEALTH STUDY AT HARVARD UNIV. 102–03 (2016), <https://perma.cc/2G2X-NL4R>.



does not want to risk angering the NFL or a club by refusing to sign, which would also threaten his Draft status. As a result, players, throughout their NFL careers, routinely sign such authorizations or waivers when requested.<sup>112</sup>

There is an additionally relevant point about the nature of the authorization forms. Both of the authorizations state that they were “collectively bargained for by the National Football League and the National Football League Players Association [NFLPA],” the players’ labor union. However, the NFLPA has no authority to collectively bargain on behalf of Combine participants because the Combine participants are not yet part of the bargaining unit represented by the NFLPA. As stated in the NFL-NFLPA collective bargaining agreement (CBA), the bargaining unit consists of:

- (1) All professional football players employed by a member club of the National Football League;
- (2) All professional football players who have been previously employed by a member club of the National Football League who are seeking employment with an NFL Club;
- (3) All rookie players once they are selected in the current year’s NFL College Draft; and
- (4) all undrafted rookie players once they commence negotiation with an NFL Club concerning employment as a player.<sup>113</sup>

Combine participants do not fit into any of these categories, and thus, the fact that the NFLPA agreed to the authorization forms has no legal effect.

Finally, clarifying the role of these authorization forms as they relate to studies governed by (and thus not exempt from) the Common Rule is important. While these forms permit the broad disclosure and use of player medical information, they cannot be used to justify the use of player medical information in medical studies as they do not meet the requirements of the Common Rule. For example, they do not include the information generally required as part of seeking informed consent, such as an explanation of the research,<sup>114</sup> a description of any reasonably foreseeable risks or discomforts,<sup>115</sup> or a description of any benefits to the subject or others which may reasonably be expected from the research,<sup>116</sup> among others.<sup>117</sup> Thus, if studies utilizing data gathered from the NFL Combine are subject to the Common Rule (as will be analyzed below),

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112. *Id.* at 99 n.k.

113. *See* NFL-NFLPA COLLECTIVE BARGAINING AGREEMENT pmb1. (2011), <https://perma.cc/M8S9-UAVH> [hereinafter NFL-NFLPA CBA].

114. *See* 45 C.F.R. § 46.116(a)(1) (West 2018).

115. *See* 45 C.F.R. § 46.116(a)(2).

116. *See* 45 C.F.R. § 46.116(a)(3).

117. *See* 45 C.F.R. § 46.116(a) (listing the information that must be provided to the research participant “in seeking informed consent”).

they must use their own forms in gaining players' informed consent (or otherwise obtain permission to waive consent), an issue discussed in Section III.E below.

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With an understanding of the NFL Combine, this article moves on to examine the research that has been conducted via the NFL Combine, and applying human subjects research regulations to this research.

#### IV. APPLYING HUMAN SUBJECTS RESEARCH REGULATIONS TO RESEARCH CONDUCTED VIA THE NFL COMBINE

By searching PubMed, an online database of biomedical publications maintained by the United States National Library of Medicine at the National Institutes of Health,<sup>118</sup> I identified 42 studies that have been published using medical data gathered at the NFL Combine. A list of these studies is included as Appendix A.

The studies variably provide information relevant to analyzing their compliance with the Common Rule. In an attempt to gain more information, I emailed at least one co-author of all 42 studies. As some doctors were co-authors of several studies, in total I contacted 14 doctors.<sup>119</sup> I emailed the doctors a total of three times each during the summer of 2018. No doctors provided a substantive response.

The doctors' failure to respond limits the analysis. Nevertheless, using the information provided in the studies, this Part examines the studies through the lens of the Common Rule. More specifically, I consider: (a) whether the studies are "research" as defined by the Common Rule; (b) whether the research is governed by the Common Rule; (c) whether the research is exempt from the Common Rule; (d) whether an IRB approved the research; (e) whether informed consent could have been waived; (f) whether informed consent was obtained; and (g) whether NFL

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118. See *PubMed Help*, NAT'L CTR. FOR BIOETHICAL INFO. (Oct. 22, 2018), <https://www.ncbi.nlm.nih.gov/books/NBK3827/#pubmedhelp.FAQs>.

119. Specifically, I contacted: Matthew T. Provencher (co-author of studies 1, 3, 5, 6, 8, 9, 11, 12, 13, 15, and 16 in Appendix A); Derrick M. Knapik (studies 2, 7, 10, 14, and 17); Brian J. Rebolledo (study 4); Daniel Gibbs (studies 18, 19, 20, and 21); Gary Solomon (study 22); Chris Brown (study 23); Gary Kiebzak (studies 24 and 25); Dominic Carreira (study 26); Chris Larson (study 27); Robert Brophy (studies 28, 29, 30, 32, 33, 35, 36, 38, and 39); Lee Kaplan (studies 31, 37, and 40); Kurt Hirshorn (study 34); Jon E. Browne (study 41); Helene Pavlov (study 42); and Russell F. Warren (study 42). I asked the doctors: (1) Was informed consent obtained from the NFL Combine participants? (a) If so, can you please briefly describe the process for obtaining consent or provide me with a copy of the consent form? (b) If informed consent was not obtained, why not? (2) Was the medial data you analyzed de-identified? (3) Did any players decline to participate in the study?

Combine participants should be considered a vulnerable research population.

A. *Is it Research?*

As an initial matter, research is only subject to the Common Rule if it fits within the definition of research as defined by the Common Rule.<sup>120</sup> As mentioned earlier, the Common Rule defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>121</sup> The medical studies discussed in this Article are a classic type of research contemplated by the Common Rule.<sup>122</sup> The studies do not concern the treatment of an individual patient, but are instead designed to “test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge”<sup>123</sup> in the field through publication.

Indeed, the American Journal of Sports Medicine, the journal in which 12 of the studies have been published, states that “[t]he journal acts as an important forum for independent orthopaedic sports medicine research and education, allowing clinical practitioners the ability to make decisions based on sound scientific information.”<sup>124</sup> For example, in a 2010 article in the journal utilizing medical data from the Combine, the researchers concluded that “[a] history of shoulder stabilization shortens the expected career of a professional football player, particularly for linemen and linebackers. Further research is warranted to better understand how these injuries and surgeries affect an athlete’s career and what can be done to improve the long-term outcome after treatment.”<sup>125</sup> This article contributed to the “generalizable knowledge” of NFL clubs and their medical personnel, particularly in the Draft analyses. There is thus little doubt that the studies published using medical data gathered at the NFL Combine are research within the meaning of the Common Rule.

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120. See 45 C.F.R. § 46.101(a) (West 2018) (“[T]his policy applies to all *research* involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research.”) (emphasis added).

121. See 45 C.F.R. § 46.102(d) (West 2018).

122. See BARUCH A. BRODY, *THE ETHICS OF BIOMEDICAL RESEARCH* 37–38 (1998).

123. See *id.* (quoting *The Belmont Report*, *supra* note 14, and discussing what constitutes “research”).

124. See *The American Journal of Sports Medicine*, SAGE PUBLISHING, <https://bit.ly/2ODScWO> (last visited Mar. 15, 2019).

125. Robert H. Brophy et al., *Effect of Shoulder Stabilization on Career Length in National Football League Athletes*, 39 AM. J. SPORTS MED. 704, 704 (2010).

*B. Is the Research Governed by the Common Rule?*

As explained in Section I.B, the Common Rule has historically only governed research supported by the federal government or that is being conducted at an institution that has agreed that all of its research will comply with the Common Rule, *i.e.*, “checking the box,” via an FWA. None of the studies indicate that they were supported by the federal government. Thus, the Combine studies are only subject to the Common Rule if one or more of the investigators worked at an institution that provided an FWA and “checked the box.”

By searching OHRP’s database of approved FWAs,<sup>126</sup> I determined that all 42 of the studies utilizing medical data collected at the NFL Combine were conducted by at least one medical professional that worked at an institution that *currently* has an FWA, indicating that the institution has likely sought federal research funding and thus agreed to comply with the Common Rule as a result.

Nevertheless, information on whether an institution checked the box is not publicly available.<sup>127</sup> Thus, it cannot be said with certainty that all of the research was being conducted by at least one institution that checked the box, and therefore, voluntarily agreed to comply with the Common Rule. However, as noted above, approximately two-thirds of American colleges and universities did previously check the box.<sup>128</sup> Moreover, given that the vast majority of the researchers worked at large, national universities and/or medical centers, it seems likely that most (if not all) of the research discussed herein was subject to the Common Rule.

*C. Is the Research Exempt from the Common Rule?*

As discussed in Section III.B, some secondary research is exempt from the Common Rule.<sup>129</sup> Secondary research relevant to this Article consists of one of two types: (1) research using “publicly available” “identifiable private information,”<sup>130</sup> or (2) research using information that “is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.”<sup>131</sup>

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126. See Office for Human Research Protections (OHRP) Database for Registered IORGs & IRBs, Approved FWAs, and Documents Received in Last 60 Days, OFFICE FOR HUMAN RESEARCH PROTS., <https://bit.ly/2yCK7rj> (last visited Mar. 15, 2019).

127. E-mail from Jaime O. Hernandez, *supra* note 42.

128. See Blatt et al., *supra* note 40.

129. See 45 C.F.R. § 46.101(b) (West 2018) (listing exemptions to the Common Rule).

130. 45 C.F.R. § 46.104(d)(4)(i) (West 2018).

131. 45 C.F.R. § 46.104(d)(4)(ii).

The secondary research exemption thus requires us to consider three questions. First, did the data studied exist prior to the study? If the answer is “no,” then the study is not secondary research and is thus not exempt from the Common Rule under the secondary research exemption. If the answer is “yes,” then we must turn to the second question—is the data publicly available? If the answer is “yes,” then the study is exempt from the Common Rule. If the answer is “no,” we turn to the third question—was the data recorded and maintained in a de-identified manner? If the answer is “yes,” then the study is exempt from the Common Rule. But if the answer is “no,” the study must comply with the Common Rule.

The answer to the first question is “yes.” A review of the studies at hand shows that *all* 42 studies relied on pre-existing data.<sup>132</sup> Specifically, all of the studies relied largely on the medical information collected by doctors and athletic trainers working at the Combine. In 2012, the NFL clubs and the Combine instituted a “fully digitized” system of player medical records, making review and research much easier.<sup>133</sup> Since that time, several studies have referenced having “obtained [data] from the database organized by the NFL medical personnel for compilation of the medical and physical performance examination results of [players] participating in the NFL Combine.”<sup>134</sup> Since the studies are relying on pre-existing data, they are secondary research potentially exempt from the Common Rule, requiring consideration of the second question.

The answer to the second question—whether the player medical data collected at the NFL Combine is publicly available—is “no.” As a general rule, the federal Health Insurance Portability and Accountability Act (HIPAA) and certain states’ laws require healthcare providers covered by the law to obtain an individual’s authorization before disclosing health information.<sup>135</sup> While the Combine participants execute broad waivers that permit their medical information to be shared with the NFL, NFL clubs

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132. See *infra* Appendix A.

133. Derrick M. Knapik et al., *Recurrent Labral Tearing on Magnetic Resonance Imaging Is Not Predictive of Diminished Participation Among National Football League Athletes*, 34 *ARTHROSCOPY* 66, 67 (2018).

134. Catherine A. Logan et al., *Posterior Cruciate Ligament Injuries of the Knee at the National Football League Combine: An Imaging and Epidemiology Study*, 34 *ARTHROSCOPY* 681, 682 (2018); see also Jorge Chahla et al., *Posterolateral Corner Injuries of the Knee at the National Football League Combine: An Imaging and Outcomes Analysis*, 34 *ARTHROSCOPY* 687, 688 (2018); Leigh-Anne Tu et al., *Prevalence of Jones Fracture Repair and Impact on Short-Term NFL Participation*, 39 *FOOT & ANKLE INT’L* 6, 7 (2018) (referencing having obtained data from “the NFL Combine database”).

135. See 45 C.F.R. § 164.502(a) (West 2018) (“A covered entity or business associate may not use or disclose protected health information, except as permitted or required by [other law].”). See generally Morgan Leigh Tendam, *The HIPAA-POTA-Mess: How HIPAA’s Weak Enforcement Standards Have Led States to Create Confusing Medical Privacy Remedies*, 79 *OHIO ST. L. J.* 411, 425-26 (2018).

and related parties,<sup>136</sup> the waivers do not permit the disclosure of their medical information to the general public.<sup>137</sup>

With the second question answered in the negative, the studies can only be exempt from the Common Rule as secondary research if the data “is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.”<sup>138</sup> This is where the analysis gets more challenging and uncertain.

As an initial matter, medical data about Combine participants is certainly collected in an identifiable manner in the first instance—the entire purpose of the medical examinations at the Combine is to understand specific players’ medical conditions as part of the clubs’ evaluations of the players. From there, none of the studies in Appendix A mentions any efforts to record the data for their studies in a de-identified manner, though that is not generally information included in a research article.

Understanding the studies discussed is helpful in analyzing this issue. Twenty-four of the studies analyzed the NFL performance of Combine participants whose Combine medical records revealed certain medical conditions.<sup>139</sup> These studies necessarily involved creating a database of players with the medical condition being examined and then inputting the NFL playing statistics of those players. It is challenging—but not impossible—to imagine that the researchers recorded *their* study data—as opposed to the Combine’s database—in a de-identified manner. To do so, the researchers seemingly would have had to: (1) have had access to player medical records in an identified form; (2) not copy or record those medical records in an identified form; (3) use that access to count the number of players with the condition and their position (or other information relevant to the study) but without recording their identity; (4) also use that access to find the players with the condition without recording their identity; and (5) then record those players’ statistics without also recording their identity. This process is burdensome and seems prone to mistake, particularly if the statistical analysis is being done prospectively or contemporaneously with the player’s NFL career. It seems more likely that the researchers: (1) examined player medical records through the NFL Combine’s database; (2) identified those players with the medical

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136. See PRITTS *supra* note 112 and accompanying text.

137. By comparison, once in the League, players do execute waivers permitting public disclosure of their medical information for, among other things, NFL injury reports. See DEUBERT ET AL., *supra* note 111, at 17.

138. 45 C.F.R. § 46.104(d)(4)(ii) (West 2018).

139. See *infra* Appendix A, studies 1–3, 6–10, 12–21, 25–26, 32–33, 35–36, 38.

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condition at issue; (3) created a new database of those afflicted players; and (4) inserted and analyzed the statistical performance of those players.

Moreover, there are certain factors that would also make de-identification challenging for these performance studies. Ten of the studies had study populations of less than 50 players.<sup>140</sup> When you begin including those players' years played, positions, and statistics, it would seem that at least some of them could be easily identified by looking at NFL.com's database of player statistics. For example, a hypothetical 2015 Combine attendee who suffered a torn ACL in college, plays wide receiver, and scored 4 touchdowns in his rookie year would likely be a population of very few. Nevertheless, none of the studies described their processes in a level of detail sufficient to definitively state whether or not they were using de-identified data.

In addition to the performance studies, two studies analyzed whether players with certain medical conditions were drafted.<sup>141</sup> These studies would likely have gone through one of the processes described above to collect their data. Nevertheless, without the additional component of examining multiple years of NFL player statistics, these studies might be more amenable to de-identified recording.

Removing the 26 performance and draftee studies discussed above leaves 16 other studies to consider. These studies are varied but many concern the prevalence of a condition<sup>142</sup> or the success of prior treatments of various conditions<sup>143</sup> among the NFL Combine participant population. These studies could have fairly easily recorded their study data in a de-identified manner depending on the manner in which the NFL Combine player data was initially stored. With the advent of the NFL Combine's digital medical records system, it seems likely that a player's name and other identifying information (such as position, college, hometown, etc.) could be removed as necessary. Nevertheless, as will be elaborated on below, 10 of these 16 studies<sup>144</sup> mention having received IRB approval—suggesting the authors did not believe their studies were exempt from the Common Rule.

In sum, whether the studies discussed in this Article are exempt from the Common Rule is unclear. At the same time, there are various pieces of evidence that suggest many of them are not. If the studies are not exempt, the Common Rule requires their approval by an IRB.

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140. See *infra* Appendix A, studies 2, 7–8, 12–14, 16, 18–19, 32.

141. See *infra* Appendix A, studies 3, 27.

142. See *infra* Appendix A, studies 5, 23, 30, 34, 39–42.

143. See *infra* Appendix A, studies 11, 28–29.

144. See *infra* Appendix A, studies 4–5, 22, 24, 29–30, 34, 37, 39–40.

*D. Was IRB Approval Obtained?*

Assuming the studies are subject to the Common Rule—as it seems most are—we can now turn to examining whether the studies complied with the Common Rule. The first part of this analysis is evaluating whether the studies were approved by an IRB, as required by the Common Rule for non-exempt research.<sup>145</sup> Twenty-seven of the 42 studies specifically reference IRB approval.<sup>146</sup> Thus, while it is possible that some of the studies did not obtain IRB approval, it is unlikely. As explained above, the studies were generally conducted by highly-qualified medical professionals affiliated with respected universities and medical institutions. IRBs are a fact of life in academic medicine and there is no reason to think these studies were handled any differently.

*E. Could Informed Consent Have Been Waived?*

As discussed in Section 1.C.2, informed consent is an important requirement of the Common Rule. Nevertheless, as also discussed in that Section, informed consent can be waived if five criteria are met:

- (i) The research involves no more than minimal risk to the subjects;
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.<sup>147</sup>

Some of the studies possibly met the criteria to waive consent.

First, most (if not all) of the studies are minimal risk. “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those

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145. 45 C.F.R. § 46.109(a) (West 2018) (“An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.”).

146. See *infra* Appendix A, studies 1-10, 12-17, 22, 24, 25, 29-31, 33-34, 37, 39, 40.

147. 45 C.F.R. § 46.116(f)(3) (West 2018).



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ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”<sup>148</sup> Generally speaking, none of the studies involved medical interventions and all of the medical data came from exams that the players were already undergoing as part of the NFL Combine. The players did not suffer any medical harm or discomfort from the studies.

Second, consent could have been impractical for some of the studies. For studies that used data from multiple years ago, it would have been extremely challenging to track down hundreds or thousands of former NFL Combine participants and ask for their consent to the research. But for studies that began on or around the same year for which data was analyzed, the researchers could have sought the participants’ consent at the Combine.

Third, which studies could or could not have been conducted without using identifiable private information is questionable. As discussed in Section III.C, determining which of the research might have been able to, as a practical matter, successfully record their study data in a de-identified manner is challenging.

Fourth, there is a strong argument that waiver of consent could adversely affect the rights and welfare of the subjects. As discussed above, most of the studies are aimed at understanding how a player’s medical condition might affect his performance in the NFL. If a study revealed that players with a certain knee condition were statistically less successful than comparable players without the knee condition, the players with the knee condition would likely have serious reservations about participating in such a study. It would not make sense for a player to voluntarily participate in a study that decreased his Draft status and prospects in the NFL.

Fifth, the studies likely did not provide the subjects with additional information after participation. Indeed, for reasons discussed below, it seems unlikely players have any idea this research is occurring. Moreover, providing the NFLPA with additional information is also not sufficient. As discussed in Section II, the NFLPA does not represent Combine participants because the participants are not yet within the NFLPA’s bargaining unit and thus the NFLPA would not qualify as a legally authorized representative.

In sum, while some of the studies might have met the criteria to waive consent, in general the sum of the factors weighs against waiver.

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148. 45 C.F.R. § 46.102(j) (West 2018).

F. *Was Informed Consent Obtained?*

Assuming informed consent could not be waived, whether the Combine participants are providing informed consent for the research studies is unclear. As discussed in Section I.C.2, the Common Rule lists the information that must or should be provided to a research subject as part of obtaining informed consent. However, as also discussed in that Section, obtaining a signed consent form does not mean that informed consent was actually obtained. Instead, informed consent is a process that ensures that the research subject can make an informed decision reasonably free of coercion and duress.<sup>149</sup>

As discussed above, nearly all (if not all) of the studies utilizing NFL Combine participants as research subjects were IRB-approved. Additionally, as discussed above, most of the studies likely do not meet the requirements permitting waiver or alteration of informed consent. Consequently, it seems highly likely that the researchers created and had players sign consent forms that included the information required by the Common Rule. Only six studies mention having obtained consent from the participants.<sup>150</sup> However, even among these studies, the sufficiency of the consent is unclear. Two studies rely on consent forms executed by the players for purposes of being evaluated at the Combine, but not for the research specifically.<sup>151</sup> Additionally, two of the studies state that “[a]ll players signed a consent form allowing use of their data by teams for the annual Draft and also for research purposes.”<sup>152</sup>

In fact, as discussed earlier, Combine participants execute broad waivers concerning the use of their medical information.<sup>153</sup> One of the waivers provides that the player is authorizing the disclosure of his medical records for purposes relating to, among other things, “NFL player health and safety initiatives and projects, in accordance with the August 4, 2011 Collective Bargaining Agreement and amendments to it, including

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149. See 45 C.F.R. § 46.116(a)(2).

150. See *infra* Appendix A, studies 3, 22, 24–25, 31, 40.

151. See Lee D. Kaplan et al., *Incidence and Variance of Foot and Ankle Injuries in Elite College Football Players*, 40 AM. J. ORTHOPEDICS 40, 41 (2011) (“All players attended [the 2006 Combine] voluntarily and provided written consent to be evaluated.”); Lee D. Kaplan et al., *Prevalence and Variance of Shoulder Injuries in Elite Collegiate Football Players*, 33 AM. J. SPORTS MED. 1142, 1143 (2005) (“All players attended [the 2004 Combine] voluntarily and signed waivers for their evaluation.”).

152. See John E. Zvijac et al., *Isokinetic Concentric Quadriceps and Hamstring Normative Data for Elite Collegiate American Football Players Participating in the NFL Scouting Combine*, 28 J. STRENGTH & CONDITIONING RES. 875, 877 (2014); John E. Zvijac et al., *Isokinetic Concentric Quadriceps and Hamstring Strength Variables From the NFL Scouting Combine Are Not Predictive of Hamstring Injury in First-Year Professional Football Players*, 41 AM. J. SPORTS MED. 1511, 1512 (2013).

153. See *supra* notes 112 and accompanying text.

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without limitation the Side Letter Agreement regarding the Injury Surveillance System and Player Health Information Analysis, Dissemination and Research, dated December 2014 . . . .”<sup>154</sup> This provision suggests that there is an agreement between the NFL and NFLPA about the use of Combine participant medical information, and that that agreement permits the information to be used for research purposes. Neither the NFL nor NFLPA responded to my requests for a copy of this side letter. All the same, as discussed above, the NFLPA cannot negotiate on behalf of Combine participants. Thus, the enforceability of any such agreement as it applies to Combine participants is dubious.

Additionally, these waivers are terribly vague. The waivers do not provide any of the numerous pieces of information required of the Common Rule,<sup>155</sup> including but not limited to “an explanation of the purposes of the research,” “[a] description of any reasonably foreseeable risks or discomforts,” or “[a] statement that participation is voluntary.”<sup>156</sup> More broadly, as required by the newer version of the Common Rule, no reasonable person could argue that the waiver provides “[t]he prospective subject . . . with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.”<sup>157</sup> Simply put, these waivers do not provide the meaningful informed consent required by the Common Rule.

Importantly, the waivers would not have to provide the information described above if the research were secondary research exempt from the Common Rule. However, for reasons discussed above in Section III.C, that does not appear to be the case for many studies.

In the absence of a universal waiver that the NFL, its clubs and their doctors have tried to impose upon Combine participants, it seems very unlikely that players would carefully read and consider consent forms from multiple studies. For example, 17 of the studies utilize data from the 2015 NFL Combine. It is difficult to imagine that a 2015 NFL Combine participant carefully reviewed 17 different consent forms in addition to the various other documents and pieces of information presented to them at the Combine.

At this point, pausing and looking forward is useful. Above is an explanation of why the existing NFL Combine waivers were likely not sufficient to establish informed consent under the Common Rule.

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154. See Roberts et al., *supra* note 108, online app. C.

155. See *supra* notes 147 and accompanying text.

156. 45 C.F.R. § 46.116(b) (West 2018).

157. 45 C.F.R. § 46.116(a)(4).

Nevertheless, the revised Common Rule likely makes things easier for the NFL, its clubs and related researchers. As discussed in Section I.C.1, the revised Common Rule codifies a “broad consent” process through which a research subject can consent to the data, information or biospecimens gathered as part of an initial study to be used in a subsequent study provided the data, information or biospecimens are de-identified. The studies discussed herein all rely on the same principal data source—the NFL Combine database. Moreover, there is considerable overlap in the co-authors. Thus, a future in which researchers could obtain consent for one study and then thereafter fairly easily conduct other studies with de-identified data is possible.

Nevertheless, until players provide informed consent to even one study, it is debatable whether NFL Combine participants have previously executed the waivers provided to them free of coercion or undue influence. As discussed above, the definitions of coercion and undue influence are slightly amorphous among the bioethical and legal literature.<sup>158</sup> Nevertheless, the literature identifies as troubling circumstances where the research subject faces a “worse consequence,” “unfair persuasion,” or “economic force[s]” that compel the subject’s participation.<sup>159</sup> Moreover, OHRP identified an “implicit” threat of harm as being coercive.<sup>160</sup>

NFL Combine participants have a significantly constrained choice about whether to participate in much of the research being conducted. As discussed above, the NFL Combine is generally considered the “biggest job interview” of these young men’s lives.<sup>161</sup> Approximately 300 players attend the NFL Combine,<sup>162</sup> competing amongst each other and with players not invited to the Combine for approximately 255 spots in the NFL Draft.

The medical exams conducted at the Combine—and which are the empirical basis for the research discussed in this Article—provide a useful comparator. As discussed above, the medical examinations, according to the clubs, are crucial to their evaluation of players.<sup>163</sup> According to Jeff Foster, President of the organization that hosts the NFL Combine, skipping a medical test could serve as “red flag” to NFL clubs “and would not be good for the player.”<sup>164</sup> Indeed, Foster explained that “‘if you’re not going to participate [in the medical exams], there’s no reason to be’” at the

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158. See *supra* note 72-79 and accompanying text.

159. See *id.*

160. *Informed Consent FAQs*, *supra* note 67.

161. See Bhanpuri et al., *supra* note 96.

162. Roberts et al., *supra* note 108, at 235.

163. See *supra* note 102 and accompanying text.

164. Rick Maese, *The NFL Combine: Pro football’s intrusive and compulsory, job interview*, WASH. POST (Feb. 26, 2017), <https://wapo.st/2Pb7By3>.

Combine.<sup>165</sup> Given the pressure to impress clubs, there can be no doubt that NFL Combine participants are reluctant to do anything that might negatively affect their hopes of being drafted and having a career in the NFL. There is certainly a strong “implicit” threat that if a player does not cooperate, he will suffer adverse employment consequences. Consequently, it seems very unlikely that any player has refused to participate in the medical exams.

Combine participants likely feel similar pressure to consent to medical research. The request for cooperation is coming from the same source—NFL club medical personnel. While the club medical personnel are likely more interested in the player’s medical examination than his consent to participate in research, there is little difference to the player—they do not want to disappoint or anger an NFL club.

Given the pressures involved, it seems very unlikely that a player would not sign whatever consent or waiver form presented to them at the Combine—whether for a medical exam or for research. In this respect, the waivers are contracts of adhesion—a “standard-form contract prepared by one party, to be signed by another party in a weaker position.”<sup>166</sup> Via email, I asked Foster whether, to his knowledge, any NFL Combine participant had ever refused to sign a waiver requested of him;<sup>167</sup> he did not respond.

Moreover, bioethics experts have questioned the voluntariness of health waivers used by professional sports organizations. Kartina Karkazis and Jennifer R. Fishman argued that athletes are effectively “coerc[ed]” into executing such waivers “because of concerns about keeping a job, renewing a contract, or simply getting playing time.”<sup>168</sup> Similarly, Mark A. Rothstein argues that such “waivers are unethical,” because “[i]ndividual players have no choice but to sign a waiver, and thus they are inherently coercive.”<sup>169</sup> While these comments were not addressed specifically at the waiver or consent forms used for the research studies, as discussed above, the contexts are substantially similar.

OHRP has specifically recognized that “when employees are the subjects of research”:

investigators and IRBs must be cautious about the potential for coercion and undue influence and the need to protect confidentiality.

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165. *Id.*

166. *Adhesion Contract*, BLACK’S LAW DICTIONARY (10th ed. 2014).

167. E-mail from author to Jeff Foster, President of National Football Scouting (June 18, 2018) (on file with author).

168. Katrina Karkazis & Jennifer R. Fishman, *Tracking U.S. Professional Athletes: The Ethics of Biometric Technologies*, AM. J. BIOETHICS, Jan. 2017, at 45, 56.

169. Mark A. Rothstein, Commentary, *Preventing Conflicts of Interest of NFL Team Physicians*, HASTINGS CTR. REP. (SPECIAL ISSUE), Nov.-Dec. 2016, at S35, S36.

Employee participation raises questions about the ability of employees to exercise free choice, for example, because of the possibility that a decision to participate could affect performance evaluations or job advancement, even if it is only the employee's perception that this is the case . . . . Employees are likely to view their employers as authority figures to whom they must show deference, which could undermine the freedom of their choice.<sup>170</sup>

Although Combine participants are not yet employees of NFL clubs, the same concerns exist. Indeed, the fact that they are not yet employees heightens the concerns of coercion and undue influence, since the Combine participants are seeking a job they do not yet have.

In another analogous setting, OHRP recognizes the risks of coercion or undue influence “when students are involved in research in a college or university setting.”<sup>171</sup> OHRP “recommends that institutions have policies in place that clarify for students and faculty that any participation of students in research must be voluntary.”<sup>172</sup> Moreover, according to OHRP, “some research institutions use a so-called ‘student subject pool’ to identify students who might be willing to participate in research, even when the exact nature of the research to be conducted has not yet been determined.”<sup>173</sup> Importantly, “[s]tudents who sign up for such pools have not legally consented to participate in a research study since they have not been provided with sufficient information concerning the exact study in which they would participate.”<sup>174</sup> Student subject pools thus bear considerable resemblance to NFL Combine participants. In both cases, the research participants have positioned themselves to potentially be included in a research study. Nevertheless, informed consent cannot be obtained until they are provided with the appropriate information concerning the exact study in which they might participate.<sup>175</sup>

Lastly, the consent process is all the more suspect given the strong argument that NFL Combine participants should be considered vulnerable research subjects, a possibility discussed next.

G. *Should NFL Combine Participants Be Considered a Vulnerable Population?*

As mentioned earlier in Section III.C.1, the Common Rule requires that “[w]hen some or all of the subjects are likely to be vulnerable to

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170. *Informed Consent FAQs*, *supra* note 67.

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

175. Relatedly, OHRP also instructs that “[e]nsuring an adequate consent . . . process may require repeating or supplementing the initial consent procedure.” *Id.*

coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards [must be] included in the study to protect the rights and welfare of these subjects.”<sup>176</sup>

NFL Combine participants are clearly not explicitly identified in that list. Nevertheless, the “[t]he words ‘such as’ suggest that these groups are simply examples of vulnerable populations, rather than an exhaustive list.”<sup>177</sup> Academics in the field have recognized that “vulnerability is an elusive concept,”<sup>178</sup> but one that should be given “the most expansive construction.”<sup>179</sup>

Various expert organizations have proffered guidelines to help assess whether a population is vulnerable within the context of human subjects research. The Council for International Organizations of Medical Sciences (CIOMS) identified vulnerable persons “a[s] those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.”<sup>180</sup> CIOMS further explained that “[t]he quality of the consent of prospective subjects who are junior or subordinate members of a hierarchal group requires careful consideration, as their agreement to volunteer may be unduly influenced . . . by the expectation of preferential treatment if they agree or by fear of disapproval or retaliation if they refuse.”<sup>181</sup> The Presidential Commission for the Study of Bioethical Issues, an advisory panel within the U.S. Department of Health & Human Services, defines vulnerability in substantially the same way.<sup>182</sup>

Without examining all of the factors that might be considered in determining whether a population should be considered vulnerable, this Section focuses on two factors that support the position that NFL Combine participants should be considered vulnerable for purposes of human subjects research: (1) Combine participants’ economic status; and (2) an inequity in power between a player-participant and NFL clubs. In closing, this Section analogizes the situation of NFL Combine participants with

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176. 45 C.F.R. § 46.111(b) (West 2018).

177. Carl H. Coleman, *Vulnerability as a Regulatory Category in Human Subject Research*, 37 J. L. MED. & ETHICS 12, 12 (2009).

178. Efthimios Parasidis, *The Military Biomedical Complex: Are Service Members A Vulnerable Population?*, 16 HOUS. J. HEALTH L & POL’Y 113, 114 (2016).

179. *Id.* at 156.

180. INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS, COUNCIL FOR INT’L ORGS. OF MED. SCI. Guideline 13 cmt. (2002), <http://bit.ly/2DjWCvW> [hereinafter INT’L ETHICAL GUIDELINES].

181. *Id.*

182. See VULNERABLE POPULATIONS BACKGROUND, PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES 2 (2016), <http://bit.ly/2AM1Eid> [hereinafter VULNERABLE POPULATIONS].

another population generally considered to be vulnerable for purposes of human subjects research—military service members.

It is well recognized that lower income individuals should generally be considered a vulnerable population for human subjects research.<sup>183</sup> “Individuals with limited resources might be vulnerable to exploitation in clinical research if researchers take advantage of their poor socioeconomic circumstances by offering unfair benefits in relation to the burdens of a study, or if individuals perceive that they have no choice but to participate.”<sup>184</sup> Such situations create the risk that the study participant is being taken advantage of, or being used merely as a “means for the ends of others.”<sup>185</sup> While NFL Combine participants might one day make millions of dollars, at the time of the Combine they have not yet made a single dollar from playing football (provided they abided by NCAA rules). Research has found that “over one-half” of black Division I college football players come from low socioeconomic backgrounds,<sup>186</sup> and from hometowns that are more “socioeconomically disadvantaged” than the national average.<sup>187</sup> There is also considerable research about the importance of a career in sports for black men, for whom fewer resources and opportunities limit their upward mobility.<sup>188</sup> With this background, it is clear that a significant portion of NFL Combine participants<sup>189</sup> will feel pressure to comply with the requests of NFL club and Combine personnel, or risk losing a tremendous opportunity for a lucrative career.

The limited financial resources and opportunities for many NFL Combine participants leads to the next consideration in finding the population to be vulnerable: the inequity in power between the player-participants and NFL clubs. While the above medical studies may lead to better treatment methods for NFL players in the future, they are also largely devoted to player evaluation on behalf of NFL clubs. The doctors performing the Combine medical exams—and publishing the studies—are doing so principally to help NFL clubs, not players. As discussed above,

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183. See 45 C.F.R. § 46.111(b) (West 2018); see also Christine Grady, *Vulnerability in Research: Individuals with Limited Financial and/or Social Resources*, 37 J. L. MED. & ETHICS 19, 19 (2009).

184. Grady, *supra* note 183, at 21.

185. *Id.* at 23.

186. Komanduri S. Murty et al., *Race and Class Exploitation: A Study of Black Male Student Athletes (BSAs) on White Campuses*, 21 RACE, GENDER & CLASS, nos. 3–4, 2014, at 156, 156.

187. Rachel Allison et al., *A Comparison of Hometown Socioeconomics and Demographics for Black and White Elite Football Players in the U.S.*, 53 INT’L REV. FOR THE SOC. OF SPORT 615, 615 (2018).

188. See *id.* at 616–19, 25.

189. In 2017, 69.7% of NFL players were black. Richard Lapchick & Saahil Marfatia, *The 2017 Racial and Gender Report Card: National Football League*, INST. FOR DIVERSITY AND ETHICS IN SPORT 5 (Oct. 18, 2017), <http://bit.ly/2F0ywrF>.



24 of the studies compared players' Combine medical records against their performance or longevity in the NFL.<sup>190</sup> Moreover, as discussed above in Section III.E, NFL Combine participants are extremely unlikely to resist research requests, for fear of irritating the NFL clubs that want the research data. Such situations present a problem of “deferential vulnerability,” where prospective participants “have the cognitive capacity to consent but are subject to the authority of others who might have independent interests in whether the prospective participant agrees to enroll in the research study.”<sup>191</sup> As a result, there can be problematic and “inequitable distributions of the burdens and benefits of research.”<sup>192</sup>

This inequity in power leads to a final consideration in evaluating NFL Combine participants as a vulnerable research population—their similarity to military service members. Professor Efthimios Parasidis of The Ohio State University Moritz College of Law has persuasively made the case that service members should be considered a vulnerable research population.<sup>193</sup> Professor Parasidis's argument is based on six factors: (1) a military command structure in which a subordinate officer must obey a lawful order of a superior officer; (2) a nebulous boundary between treatment and research in military settings; (3) liberal use of waivers waiving informed consent; (4) a military culture which stresses conformity; (5) the priority of the health of the group over that of the individual; and (6) governmental immunities and limitations on tort claims by military personnel.<sup>194</sup> All of these factors—except the sixth—are also present in the NFL workplace (including at the NFL Combine), as will be elaborated on below.

There is a long history of players, coaches, fans, media and others analogizing the physical and strategic nature of football with that of war.<sup>195</sup> A list of famous quotes from legendary coach Vince Lombardi repeatedly mentions “battle” and “war.”<sup>196</sup> These comparisons have rightly drawn

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190. See *infra* Appendix A, studies 1, 2, 6, 7, 8, 9, 10, 13, 14, 15, 16, 19, 20, 21, 25, 26, 27, 32, 33, 35, 36, 38.

191. NAT'L BIOETHICS ADVISORY COMM'N, 1 REPORT ON ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS (2016), <https://bit.ly/2qfUL2Q>.

192. INT'L ETHICAL GUIDELINES, *supra* note 180, Guideline 13 cmt.

193. See *generally* Parasidis, *supra* note 178.

194. *Id.* at 131–51.

195. See *generally* Shaun Scott, *How the NFL sells (and profits from) the inextricable link between football and war*, SPORTS ILLUSTRATED (Sept. 9, 2016), <https://perma.cc/K4LT-S2HM>; Tricia Jenkins, *The Militarization of American Professional Sports: How the Sports-War Intertext Influences Athletic Ritual and Sports Media*, 37 J. OF SPORT & SOCIAL ISSUES 245 (2013); LZ Granderson, *Sports teams are not at war*, ESPN (Oct. 31, 2010), <https://perma.cc/3M9C-YCGV>.

196. See *Famous Quotes by Vince Lombardi*, VINCELOMBARDI.COM, <https://perma.cc/5T8Z-XKBR> (last visited Mar. 15, 2019).

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criticism<sup>197</sup>—as the playing of a sport for considerable economic gain should not rightfully be likened to facing life and death situations in service of your country. Nevertheless, there are substantial similarities between the cultures relevant to the vulnerability analysis.

The Presidential Commission for the Study of Bioethical Issues aptly summarized the challenging environment in the military:

Military personnel also might feel pressure to participate in research because of the structured hierarchy in which they live and work. They might feel that participation could contribute to promotions, easier assignments, or special privileges; or that refusal to participate could result in demotions or other punitive measures. Moreover, the success of military operations depends in part on giving up some individual autonomy for the good of the whole; for this reason, soldiers might be coerced to participate in research if it is considered to be for the greater good; for example, accepting an experimental vaccine to ensure that the entire force would be protected.<sup>198</sup>

Now consider the below description of the NFL workplace by former NFL Commissioner Paul Tagliabue, while serving as an arbitrator in a 2012 case in which New Orleans Saints players<sup>199</sup> faced potential discipline for allegedly participating in a program created by coaches that offered financial rewards for big plays and injuries to opponents:

In determining player discipline for involvement in performance pools - - whatever form they may take - - that are developed, encouraged and managed by coaches, the coach-player relationship is also material.

NFL players on average have short careers; their careers can end suddenly through injury or declining skills; players want to be good, cohesive members of the team, or unit, not complainers or dissenters; and players accept that they work for coaches, in “programs” conceived by coaches. . . .

In such circumstances, players may not have much choice but to “go along,” to comply with coaching demands or directions that they may question or resent. They may know - - or believe - - that from the coaches’ perspective, “it’s my way or the highway.” Coaching legends such as George Halas and Vince Lombardi are not glorified or remembered because they offered players “freedom of choice.”

While more recent and current coaches may debate whether and how much coaching approaches to “do it my way” have changed over time,

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197. See sources cited *supra* note 195.

198. VULNERABLE POPULATIONS, *supra* note 182, at 11.

199. My law firm at the time, Peter R. Ginsberg Law, LLC., represented one of the Saints’ players in this matter.

it is clear that directions such as those given by the Saints' coaches in creating the Program are usually followed by most players. NFL head coaches told me in my seventeen years as Commissioner, "If players don't do it our way, they can find another team to pay them."<sup>200</sup>

The similarities are considerable. In both the military and the NFL, the personnel are under tremendous pressure to obey the orders of their superiors and sacrifice themselves for the betterment of the organization. If they fail to do so, they will suffer serious consequences. Admittedly, the consequences at stake are disparate. In the NFL, a player's non-compliance could result in the loss of his job or career. In the military, non-compliance can lead to court martial and imprisonment.<sup>201</sup> Without diminishing the pressures faced by military members, I nonetheless believe the culture of the NFL is sufficiently similar to learn from special considerations that may be given to military members.

Returning to the factors outlined by Professor Parasidis in support of categorizing military personnel as vulnerable, the above descriptions demonstrate the similarity between the NFL and the military as to three of them: the command structure; a culture of conformity; and the priority of the health of the group over that of the individual.

A fourth factor identified by Professor Parasidis is also relevant in the NFL context—a nebulous boundary between treatment and research. Club doctors are hired, paid, and reviewed by the clubs.<sup>202</sup> The doctors then examine players for, at least in part, the purpose of providing the club with information concerning the health status of players for both short-term and long-term purposes.<sup>203</sup> At the same time, club doctors are obligated by the CBA and codes of ethics to provide medical care that prioritizes the players' interests.<sup>204</sup> The club doctors' dual roles is a structural conflict of interest that can cause confusion and concern.<sup>205</sup> While these characteristics describe the situation for players already in the NFL—as opposed to those at the NFL Combine—the environment is still very similar. The purposes of the medical exams at the NFL Combine might not always be clear to the players. On the one hand, the doctor might examine the player and make a diagnosis meaningful to the player's health. On the other hand, the doctor is also making note of any medical

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200. *In the Matter of New Orleans Saints Pay-for-Performance/"Bounty"* (Dec. 11, 2012) (Tagliabue, Arb.), <https://bit.ly/1HWgk7g> ("it is clear that [the player] was under tremendous pressure to follow the chain of command in order to keep his job.").

201. *See* 10 U.S.C. § 892 (2012 & Supp. 2017).

202. *See* I. Glenn Cohen et al., *A Proposal to Address NFL Club Doctors' Conflicts of Interest and to Promote Player Trust*, HASTINGS CTR. REP. (SPECIAL ISSUE), Nov.-Dec. 2016, at S2, S14 (2016).

203. *See id.* at S13, S17.

204. *See id.* at S9–S10.

205. *See id.* at S6–S13.

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concerns that might affect the player's usefulness to NFL clubs. Such an environment blurs the boundaries between medical care and analysis or research for other purposes.

Lastly, Professor Parasidis identified the liberal use of waivers as supporting a finding of vulnerability. As explained above, NFL Combine participants execute broad waivers permitting their medical information to be shared with the NFL, NFL clubs and related parties.<sup>206</sup> This process is repeated once players are in the NFL and, according to one current player, no one refuses to sign the waivers: "it's you sign this and you play football or you don't sign it and you don't, everybody signs it. I don't know anybody who hasn't."<sup>207</sup>

In sum, NFL Combine participants are strongly deserving of consideration as a vulnerable population for human subjects research in light of their socioeconomic demographics and the disparity in power between themselves and those supporting and conducting the research. Finally, the considerable similarities between Combine participants and military personnel—a population often considered vulnerable for research purposes—further supports a finding that Combine participants merit additional protections and considerations when subjects of research.

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With the above understanding of how the Common Rule applies to research conducted on NFL Combine participants, and how at times such research might not comply with the Common Rule, in Part IV I discuss ways in which NFL players can be better protected when they are human subjects research participants.

#### V. PROTECTING NFL COMBINE PARTICIPANTS MOVING FORWARD

Above, a number of uncertainties concerning the potential application of the Common Rule to the studies discussed herein are highlighted. It is possible that many (if not most) of the studies complied with the Common Rule or perhaps were even exempt in various ways. Nevertheless, from what is known, there are still ethical concerns related to research involving NFL Combine participants, particularly concerning the informed consent process.

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206. See *supra* notes 112 and surrounding text.

207. DEUBERT ET AL., *supra* note 111; see also Karkazis & Fishman, *supra* note 168, at 51 ("one [NBA] team lawyer noted that he had never heard of a player not signing" a health information authorization).

Protecting future NFL Combine participants in the context of medical research might be achieved in two ways: (1) seeking to enforce the participants' existing rights; and (2) improving the process through which players consent to and participate in such research.

*A. Players' Enforcement Options*

Unfortunately, players who might believe that they participated in research that did not comply with the Common Rule do not have meaningful recourse. First, the Common Rule does not create a private cause of action, meaning human subjects research participants cannot sue to enforce the Common Rule or obtain damages for a party's failure to comply with it.<sup>208</sup> Second, while research participants can report potential violations of the Common Rule to OHRP,<sup>209</sup> OHRP has no authority to compensate the participant for any harm suffered,<sup>210</sup> particularly now that it no longer has authority over institutions "checking the box." With a lack of meaningful enforcement options, it is all that more important that the process of using Combine participants of human subjects research comply with both the letter and spirit of the Common Rule. The next Section recommends solutions to reach this outcome.

*B. Recommendations for An Improved Process*

There have been a variety of protections implemented and recommended for certain vulnerable groups. The Common Rule includes specific "additional protections" for human fetuses, and neonates,<sup>211</sup> as well as for prisoners<sup>212</sup> and children.<sup>213</sup> The additional protections for human fetuses, neonates and children are medically-driven; aimed to protect the health of the subjects.<sup>214</sup> The additional protections for

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208. See *Cabi v. Boston Children's Hosp.*, 161 F. Supp. 3d 136, 155 (D. Mass. 2016); *Bilinski v. Wills Eye Hosp.*, 2016 WL 6247569, at \*2 (E.D. Pa. 2016); *Tilousi v. Arizona State Univ.*, 2005 WL 6199562, at \*2 (D. Ariz. 2005).

209. *Submitting a complaint*, OFFICE FOR HUMAN RESEARCH PROTS., <https://perma.cc/6MB9-QTUI> (last visited Mar. 15, 2019).

210. See *Compliance Oversight Procedures for Evaluating Institutions*, OFFICE FOR HUMAN RESEARCH PROTS. (Oct. 14, 2009), <https://perma.cc/6UCQ-8NBZ> (limiting enforcement authority to requiring "corrective action" by institution).

211. 45 C.F.R. §§ 46.201–07 (West 2018).

212. 45 C.F.R. §§ 46.301–06 (West 2018).

213. 45 C.F.R. §§ 46.401–09 (West 2018). The former version of the Common Rule also described "pregnant women" as vulnerable, 45 C.F.R. § 46.111(b) (1991) (amended 2018), and, as a result, required additional protections when they were research subjects. See 45 C.F.R. §§ 46.201–07. However, pregnant women were removed as category of vulnerable research subjects to "help facilitate their inclusion in clinical trials." Bierer et al., *supra* note 4, at 787.

214. See 45 C.F.R. §§ 46.204–05, 46.405–06 (West 2018).

prisoners exist out of concern that prisoners' "incarceration . . . could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research."<sup>215</sup>

Otherwise, various bioethics committees have suggested a variety of protections for vulnerable groups, including but not limited to selecting participants less burdened by their circumstances, ensuring that the research is responsive to the health needs of the population, obtaining permission from appropriate representatives, assessing the vulnerability of the population, and additional oversight by the IRB.<sup>216</sup>

Drawing from the Common Rule protections, others proposed for vulnerable populations, and other safeguards occasionally required by IRBs, there are a variety of ways in which human subjects research utilizing NFL Combine participants can be done in a more fair and appropriate manner.

First, the researchers and/or the Combine participants could be required to read the consent form aloud and audio record the process. A process whereby the subjects have more time to think about the research rather than quickly scribbling their signature on a consent form would certainly enhance the subjects' decision-making power. The audio recording merely ensures the process was completed properly. This is not an uncommon practice and thus it is certainly possible some of the studies discussed herein went through such a process.

Second, the NFLPA could insist upon the right to approve any research utilizing NFL Combine participants. In fact, two studies reference having obtained NFLPA approval.<sup>217</sup> There is additional precedent for this recommendation. The CBA prohibits NFL clubs from utilizing wearable technologies worn by players "for health or medical purposes" without the NFLPA's consent.<sup>218</sup> Similarly, the Accountability and Care Committee, jointly staffed by the NFL and NFLPA, is charged with "conduct[ing] research into prevention and treatment of illness and injury commonly experienced by professional athletes," and "conduct[ing] a confidential player survey at least once every two years to solicit the players' input and opinion regarding the adequacy of medical care provided by their respective medical and training staffs."<sup>219</sup> As explained above, the NFLPA's negotiation of the medical authorization forms for Combine

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215. 45 C.F.R. § 46.302 (West 2018).

216. See VULNERABLE POPULATIONS, *supra* note 182.

217. See Brendin R. Beaulieu-Jones et al., *Epidemiology of Injuries Identified at the NFL Scouting Combine and Their Impact on Performance in the National Football League*, ORTHOPAEDIC J. SPORTS MED., July 2017, at \*2 (2017); Kevin J. McHale et al., *Epidemiology and Outcomes of Lisfranc Injuries Identified at the National Football League Scouting Combine*, 45 AM. J. SPORTS MED. 1901, 1902 (2017).

218. NFL-NFLPA CBA, *supra* note 113, art. 51, § 13(c).

219. *Id.* art. 39, § 3(c).

participants is without legal effect since the participants are not yet within the bargaining unit represented by the NFLPA.<sup>220</sup> This fact raises questions about the propriety of the NFLPA screening research conducted on NFL Combine participants. The crucial distinction is that in negotiating the waivers, the NFLPA is seemingly purporting to act as a representative of the players concerning their legal rights, *i.e.*, negotiating the disclosure and use of player medical records. Screening research does not go that far. The NFLPA can review and assess research studies without affecting players' legal rights. The NFLPA is a stakeholder on this issue and has valuable expertise that it should exercise in support of its future members.

Third, as a proxy for the oversight provided by the NFLPA, the consent process could require that the consent form be provided to the Combine participants' agent. By virtue of the National Labor Relations Act, agents—formally known as “contract advisors”—are agents of the NFLPA for the purposes of representing players in matters concerning their employment.<sup>221</sup> Rather than represent all players by itself, the NFLPA certifies and regulates contract advisors for the purposes of protecting and assisting NFL players.<sup>222</sup> Thus, reviewing a consent form for a player is within the scope of a contract advisor's duties. Moreover, providing the consent form to a professional who has a fiduciary obligation to look out for the player's best interests will help ensure that the player's rights and interests are being protected.<sup>223</sup>

Fourth, in reviewing research involving NFL Combine participants, IRBs could seek out the perspective of a player, former player, or someone sufficiently representative of their perspective. Indeed, in research involving prisoners, “[a]t least one member of the [Institutional Review] Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.”<sup>224</sup> Given the unfortunate fact that there are far less current and former NFL players than there are current or former prisoners, the IRB need not necessarily include such an individual as a Board member. But at a minimum, the IRB should seek out their perspective on how the research—including the consent process—might be received by or affect the player population. To facilitate this, it might be advisable to take advantage of a change in the Common Rule that now permits a single IRB to review research being conducted at multiple sites and institutions.<sup>225</sup> A single IRB might be able

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220. See *supra* note 113 and surrounding text.

221. See DEUBERT ET AL., *supra* note 111, at 304–05.

222. See *id.*

223. See *id.* at 307–08.

224. 45 C.F.R. § 46.304(b) (West 2018).

225. See *Single IRB Policy for Multi-site Research*, NAT'L INSTS. OF HEALTH, <https://perma.cc/PZ3Q-5LD2> (last visited Mar. 15, 2019).

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to develop the necessary expertise—while taking into account the various concerns discussed herein—to ensure the research is conducted appropriately and effectively.

Fifth, and perhaps most importantly, the IRB should require that the Combine participants' decision whether or not to participate in the medical research remain confidential. It is of course common for the identity of research subjects to remain confidential. However, the risks of disclosure are particularly serious here where a player could suffer serious adverse employment action as a result of his refusal to participate in a research study. That risk is compounded by the fact that the research studies are being conducted by doctors and athletic trainers affiliated with NFL clubs. Those doctors and athletic trainers provide advice to clubs about potential draftees. If those doctors or athletic trainers have a negative experience with the player as a result of a player's refusal to participate in a research study, that could negatively affect the doctor or athletic trainer's opinion of the player and thus also the player's Draft status. Appropriate safeguards and firewalls are necessary to ensure that the NFL and NFL clubs cannot learn the identities of players who refused to participate in medical research requested of them. For example, it would likely be best that medical personnel affiliated with the NFL or an NFL club not be involved in any way in the consent process and only review de-identified research data.

These recommendations do not suggest that federal regulations concerning the NFL Combine are needed. Rather, these are recommendations best considered by the IRBs overseeing studies with NFL Combine participants as subjects.

## VI. CONCLUSION

Medical personnel for NFL clubs are often leading experts in their field. Nevertheless, they also work in an environment in which their loyalties and duties are divided between players and the clubs. The medical studies discussed in this Article are further evidence of this conflict. These research studies, which were overwhelmingly run by NFL club medical personnel, generally analyze NFL Combine participant medical information for the principal purpose of being able to better evaluate the usefulness of those players to NFL clubs. In the process, the players' rights and interests are subordinated. This is unacceptable. Given that the structure of NFL club medical staffs is unlikely to change anytime soon,<sup>226</sup> other options and authorities must be considered in protecting

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226. See Letter from Jeffrey A. Miller, Executive Vice President of Health & Safety Initiatives, NFL, to Christopher R. Deubert, I. Glenn Cohen, & Holly Fernandez Lynch



players. In this specific context, IRBs have the potential to ensure that NFL Combine participants are being subjected to research in the dignified and respectful manner required by the Common Rule.

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10–14 (Nov. 1, 2016), <https://bit.ly/2RneYzj> (denying conflict of interest in structure of NFL club medical care).

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APPENDIX A – MEDICAL STUDIES UTILIZING DATA COLLECTED AT THE  
NFL COMBINE

Matthew T. Provencher et al., *A History of Anterior Cruciate Ligament Reconstruction at the National Football League Combine Results in Inferior Early National Football League Career Participation*, 34 ARTHROSCOPY 2446 (2018).

Derrick M. Knapik et al., *Prevalence and Impact of Hip Arthroscopic Surgery on Football Participation in Elite American Football Athletes*, ORTHOPAEDIC J. SPORTS MED., Feb. 2018.

Matthew T. Provencher et al., *Body Mass Index Versus Body Fat Percentage In Prospective National Football League Athletes: Overestimation of Obesity Rate in Athletes at the National Football League Scouting Combine*, 32 J. STRENGTH & CONDITIONING RES. 1013 (2018).

Brian J. Rebolledo et al., *The Association of Vitamin D Status in Lower Extremity Muscle Strains and Core Muscle Injuries at the National Football League Combine*, 34 ARTHROSCOPY 1280 (2018).

Catherine A. Logan et al., *Posterior Cruciate Ligament Injuries of the Knee at the National Football League Combine: An Imaging and Epidemiology Study*, 34 ARTHROSCOPY 681 (2018).

Matthew T. Provencher et al., *Symptomatic Focal Knee Chondral Injuries in National Football League Combine Players Are Associated With Poorer Performance and Less Volume of Play*, 34 ARTHROSCOPY 671 (2018).

Leigh-Anne Tu et al., *Prevalence of Jones Fracture Repair and Impact on Short-Term NFL Participation*, 39 FOOT & ANKLE INT'L 6 (2018).

Jorge Chahla et al., *Posterolateral Corner Injuries of the Knee at the National Football League Combine: An Imaging and Outcome Analysis*, 34 ARTHROSCOPY 687 (2018).

Jorge Chahla et al., *Meniscectomy and Resultant Articular Cartilage Lesions of the Knee Among Prospective National Football League Players*, 46 AM. J. SPORTS MED. 200 (2018).

Derrick M. Knapik et al., *Recurrent Labral Tearing on Magnetic Resonance Imaging Is Not Predictive of Diminished Participation Among National Football League Athletes*, 34 ARTHROSCOPY 66 (2018).

Gilbert Moatshe et al., *Clinical Radiologic Outcomes After Scaphoid Fracture: Injury and Treatment Patterns in National Football League Combine Athletes Between 2009 and 2014*, 33 ARTHROSCOPY 2154 (2017).

George F. LeBus et al., *The Latarjet Procedure at the National Football League Scouting Combine*, ORTHOPAEDIC J. SPORTS MED., Sep. 2017.

Bryan Vopat et al., *Epidemiology of Navicular Injury at the NFL Combine and Their Impact on an Athlete's Prospective NFL Career*, ORTHOPAEDIC J. SPORTS MED., Aug. 2017.

Derrick M. Knapik et al., *Prevalence and Impact of Glenoid Augmentation in American Football Athletes Participating in the National Football League Scouting Combine*, ORTHOPAEDIC J. SPORTS MED., Aug. 2017.

Brendin R. Beaulieu-Jones et al., *Epidemiology of Injuries Identified at the NFL Scouting Combine and Their Impact on Performance in the National Football League*, ORTHOPAEDIC J. SPORTS MED., July 2017.

Kevin J. McHale et al., *Epidemiology and Outcomes of Lisfranc Injuries Identified at the National Football League Scouting Combine*, 45 AM. J. SPORTS MED. 1901 (2017).

Derrick M. Knapik et al., *Prevalence of Surgical Repair for Athletic Pubalgia and Impact on Performance in Football Athletes Participating in the National Football League Combine*, 33 ARTHROSCOPY 1044 (2017).

Caitlin C. Chambers et al., *Superior Labrum Anterior-Posterior Tears in the National Football League*, 45 AM. J. SPORTS MED. 167 (2016).

Daniel B. Gibbs et al., *Preexisting Rotator Cuff Tears as a Predictor of Outcomes in National Football League Athletes*, 8 SPORTS HEALTH 250 (2016).

Gregory D. Schroeder et al., *Pre-existing Lumbar Spine Diagnosis as a Predictor of Outcomes in National Football League Athletes*, 43 AM. J. SPORTS MED. 972 (2015).

Gregory D. Schroeder et al., *The Impact of a Cervical Spine Diagnosis on the Careers of National Football League Athletes*, 39 SPINE 947 (2014).

Gary D. Solomon & Andrew Kuhn, *Relationship Between Concussion History and Neurocognitive Test Performance in National Football League Draft Picks*, 42 AM. J. SPORTS MED. 934 (2014).

Christopher A. Brown et al., *Prevalence of Abnormal Patellofemoral Congruence in Elite American Football Players and Association with Quadriceps Isokinetic Testing*, 27 J. KNEE SURGERY 47 (2014).

John E. Zvijac et al., *Isokinetic Concentric Quadriceps and Hamstring Normative Data for Elite Collegiate American Football Players Participating in the NFL Scouting Combine*, 28 J. STRENGTH & CONDITIONING RES. 875 (2014).

John E. Zvijac et al., *Isokinetic Concentric Quadriceps and Hamstring Strength Variables From the NFL Scouting Combine Are Not Predictive of Hamstring Injury in First-Year Professional Football Players*, 41 AM. J. SPORTS MED. 1511 (2013).

Dominic S. Carreira & Scott M. Sandilands, *Radiographic Factors and Effect of Fifth Metatarsal Jones and Diaphyseal Stress Fractures on Participation in the NFL*, 34 FOOT & ANKLE INT'L 518 (2013).

Christopher M. Larson et al., *Increasing Alpha Angle is Predictive of Athletic-Related "Hip" and "Groin" Pain in Collegiate National Football League Prospects*, 29 ARTHROSCOPY 405 (2013).

Jeffrey J. Nepple et al., *Radiographic Findings of Femoroacetabular Impingement in National Football League Combine Athletes Undergoing Radiographs for Previous Hip or Groin Pain*, 28 ARTHROSCOPY 1396 (2012).

Nathan A. Mall et al., *Relation Between Anterior Cruciate Ligament Graft Obliquity and Knee Laxity in Elite Athletes at the National Football League Combine*, 28 ARTHROSCOPY 1104 (2012).

Jeffrey J. Nepple et al., *Full-Thickness Knee Articular Cartilage Defects in National Football League Combine Athletes Undergoing Magnetic Resonance Imaging: Prevalence, Location, and Association With Previous Surgery*, 28 ARTHROSCOPY 798 (2012).

Lee D. Kaplan et al., *Incidence and Variance of Foot and Ankle Injuries in Elite College Football Players*, 40 AM. J. ORTHOPEDICS 40 (2011).

Robert H. Brophy et al., *Effect of Shoulder Stabilization on Career Length in National Football League Athletes*, 39 AM. J. SPORTS MED. 704 (2011).

E. Scott Paxton et al., *Effect of Hyperconcavity of the Lumbar Vertebral Endplates on the Playing Careers of Professional American Football Linemen*, 38 AM. J. SPORTS MED. 2255 (2010).

Kurt C. Hirshorn et al., *Magnetic Resonance Imaging-Documented Chondral Injuries About the Knee in College Football Players: 3-Year National Football League Combine Data*, 26 ARTHROSCOPY 1237 (2010).

Robert H. Brophy et al., *Effect of Anterior Cruciate Ligament Reconstruction and Meniscectomy on Length of Career in National Football League Athletes*, 37 AM. J. SPORTS MED. 2102 (2009).

Robert H. Brophy et al., *Predictive Value of Prior Injury on Career in Professional American Football Is Affected by Player Position*, 37 AM. J. SPORTS MED. 768 (2009).

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