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Frequency of concealment, fabrication and falsification of study data by deceptive subjects

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ABSTRACT

Purpose: Many studies have found evidence that research subjects engage in deceptive practices while participating in health-related studies. Little is known, however, about how often subjects use deception and the percentage of studies a typical subject will contaminate with false data. This study examined the frequency of use of different types of deception among a sample of subjects who admit to using deception.

Methods: A sample of 59 subjects who had participated in at least two health-related studies in the past 12 months and admitted to using deception in at least one were interviewed. Subjects were asked a series of questions about **concealing information** and **fabricating information** to gain entry into studies. Subjects were also asked about **falsifying data after being enrolled** in a health-related study. All study data reported pertains to only subjects who reported using deception in health-related studies and is based on subjects' study participation only within the last 12 months from the date of the interview.

Results: Subjects who conceal information in order to enroll in trials reported using concealment in about two thirds (67%) of the trials they participated in over the past 12 months. On average, these subjects' use of concealment was highest for mental health information (58% of studies) and physical health information (57% of studies). The average frequency of fabricating information in order to enroll in trials was 53% with exaggerating health symptoms (45% of studies) and pretending to have a health condition (39% of studies) as the two most widely used strategies. Subjects who falsify study data after enrollment reported doing so 40% of the time. These subjects falsely reported improvement in the health condition being studied in 38% of the trials they took part in. Subjects who admitted to throwing away study medication to create the appearance of compliance reported doing so 32% of the time.

Limitations: Although this study provides evidence that subjects who admit to using deception contaminate a high percentage of studies, larger and more geographically diverse samples are needed to understand the full extent of the problem of deceptive subjects in research. Regional economic, cultural, or organizational factors may be related to the rate of subjects using deception. It is also possible that this sample underrepresents the use of deception as there are likely subjects who use deception that would be unwilling to admit the extent of this behavior.

Conclusion: Deceptive subject's behavior poses a threat to the integrity of research findings. Given that deceptive subjects contaminate a high percentage of studies they take part in by concealing information, fabricating information, and falsifying study data after enrollment, efforts to identify and exclude these subjects is important to the integrity of research findings. Strategies to exclude deceptive subjects from health research should be used to inform study designs. Widespread adoption of research subject identity registries could greatly reduce the scope of studies that a single deceptive subject could contaminate. Technological solutions that provide an objective measure of medication compliance may be valuable tools for limiting fraudulent reports of compliance.

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1. Introduction

Over the past 10 years there has been mounting evidence that research subjects engage in a range of deceptive practices in order to enroll in health-related studies. These subjects have been described as “professional Guinea pigs,” [1] “subversive research subjects,” [2] “professional research subjects” [3,4] and “duplicate subjects,” [5] among others. Although some subjects are motivated by pursuit of profit as a source of income as described by Abadie [1], subjects may also use deception to improve their chances of receiving interventions to improve healthcare outcomes [5]. For example, in an HIV prevention trial testing medication for HIV pre-exposure prophylaxis that was conducted in sub-Saharan Africa, it was discovered that 34% of the sample was simultaneously enrolled in another HIV prevention trial [6], presumably to minimize their risk of HIV infection. Irrespective of subjects’ motivations for using deception or the labels we choose to describe them, these subjects pose a substantial risk to the integrity of our studies because they conceal exclusionary information, enroll in the same study more than once, enroll in multiple studies concurrently, pretend to have the health condition being studied and enroll in studies for which they have no intention of benefitting from [1,2,4,5,7–9]. The potential impact of subjects who pretend to have a health condition and then report improvement once enrolled – making these subjects’ treatment “destined to succeed” – has been modeled by McCann and colleagues and it is estimated that sample size requirements more than double if just 10% of the sample is comprised of subjects who are destined to succeed [10]. Similarly, there is mounting evidence that once enrolled in a trial, subjects who engage in deceptive behaviors frequently fabricate medication compliance [10]. The potential impact of this deception on sample size requirements has been modeled and even small percentages (e.g. 10%) of subjects who report fraudulent medication compliance within a trial can increase the sample size requirements for valid results by as much as twenty percent [11].

Although the evidence is clear that subjects use various forms of deception both before enrollment and once enrolled in a study, few studies have been conducted that attempt to understand the scope of the problem. Much of what we know about the scope of deception is derived from studies in which subjects were caught using deception, leaving us to wonder how much deception is being used in research that is not identified by current data quality control processes. One study that has attempted to answer this question was a survey of “experienced subjects,” in which participants were asked direct questions about their utilization of various forms of deception [4]. Although this yielded important information about subjects’ use of deceptive strategies, the findings were limited to understanding whether subjects have ever used these strategies (lifetime use) and did not attempt to quantify how often deceptive strategies were used (frequency of use). To date, no researcher has enrolled a sample of “deceptive subjects” to assess how often they use deception while participating in health-related research. The present study was undertaken to assess the frequency in which subjects use deception while participating in health-related research. Understanding the frequency that subjects use deception will help researchers to better gauge the risk to study design and provide some data to help calibrate our response to the threat that deceptive subjects pose to study integrity.

2. Materials and methods

In total, 75 subjects were recruited using advertisements posted both online and in local newspapers. The advertisement targeted subjects who use deception as a strategy to enroll in research (e.g., “Do you sometimes pretend to have a condition to qualify for a study?” and “Do you sometimes conceal your health conditions from researchers in order to qualify for a study?”). The advertisement was posted on craigslist, in two popular local newspapers (Boston Globe and Boston Herald) and in one free local newspaper distributed to commuters using local public transportation (Boston Metro). Subjects who responded to the

advertisements underwent a brief telephone screening to determine eligibility. Subjects were enrolled if they had 1) participated in at least 2 health-related studies in the past 12 months, 2) used deception in health-related research at least once in the past 12 months and 3) had never participated in any studies at the Boston Medical Center Clinical Studies Unit. Participation in any of our prior studies was exclusionary because we expected that subjects known to us would be reluctant to be transparent about past use of deception.

Eligible subjects were consented and given a breathalyzer test to ensure that their blood alcohol concentration was ≤ 0.020 so as to avoid decisional impairment at the time of consent. Consented subjects then completed a demographics questionnaire and interview to assess their history of health-related study participation and use of deception while participating in health research. Three categories of deception used by research subjects were assessed: concealment of exclusionary characteristics in order to qualify, fabrication of information in order to qualify, and falsification of data after being enrolled in a study. To minimize the risk that subjects would use deception in the present study, participants were assured that their responses would remain confidential and be coded with no link to their identity. Their names were retained in order to prevent subjects from enrolling in the study multiple times but no linking key was created to link study data to subject identity. Subjects were compensated \$20 for completion of the entire study, consisting of the demographics questionnaire and interview. All study procedures were approved by the Boston University Medical Campus and Boston Medical Center Institutional Review Board (IRB Number: H-35707). Subjects provided informed consent in compliance with IRB requirements.

2.1. Analytic procedures

The percentage (%) of subjects who reported using each method of deception was determined by dividing the number of subjects (n) who responded YES to using this method in the past 12 months by the total number of subjects with evaluable data who enrolled in the study (59). The mean number of studies in which each type of deception was used was calculated by including only subjects who reported using that variety of deception. The percent of studies that each subject contaminated by use of each type of deception was calculated and the percentage of studies contaminated was averaged across subjects for each type of deception to derive the mean percentage of studies in which deception was used.

3. Results

3.1. Subject demographics

Of the 75 subjects who were interviewed, 14 were excluded from analysis because they did not meet the inclusionary criteria of participating in 2 or more health-related research studies in the past 12 months. Two subjects were excluded from analysis due to being extreme outliers in reported rate of study participation in the past 12 months (80 and 180 studies). Inclusion of these subjects would have inflated means and provided an over-estimate of the rate of study contamination that the “average” subject who admits to using deception may contribute. Demographic characteristics of subjects are shown in Table 1. The study sample was made up of 68% males and 32% females. Roughly half of subjects were between 46 and 60 years old (53%), with an average age of 54. Most subjects identified as white/Caucasian (46%) or black/African American (44%). Subject reports of the highest level of education completed were widely distributed, with 36% of subjects having received a high school diploma or equivalent and 25% having completed a Bachelor’s Degree. About half of the subjects (58%) were retired, unemployed, or unable to work due to permanent disability and almost three quarters (70%) reported an annual household income below US \$30,001.

Table 1
Subject demographics.

	n	%
Gender		
Male	40	68
Female	19	32
Hispanic/Latino		
Yes	1	2
No	58	98
Race		
White or Caucasian	27	46
Black or African American	26	44
American Indian or Alaska Native	1	2
Asian or Pacific Islander	1	2
Multi-racial	3	5
N/A	1	1
Age		
18–30	3	5
31–45	9	15
46–60	31	53
61–75	15	25
76+	1	2
Education		
Some schooling, no GED	1	2
High school graduate or GED	21	36
Some college credit, no degree	9	15
Associate degree	9	15
Bachelor's degree	15	25
Master's degree	3	5
N/A	1	2
Past 30 days employment		
Full-time, ≥ 35 h/week	5	8
Part-time, < 35 h/week	9	15
Employed, irregular or occasional jobs	4	7
Student	2	3
Military service	1	2
Retired	8	14
Unable to work, permanent disability	9	15
Temporarily unable to work, health issue	3	5
Unemployed	17	29
Homemaker	1	2
Annual household income		
US \$0-US \$15,000	27	46
US \$15,001-US \$30,000	14	24
US \$30,001-US \$45,000	9	15
US \$45,001-US \$60,000	2	3
US \$60,001-US \$75,000	1	2
US \$75,001-US \$90,000	3	5
US \$90,001-US \$105,000	1	2
N/A	2	3

3.2. Study participation history

Table 2 summarizes the subjects' experiences enrolling in different types of health-related studies. Subjects reported an average enrollment of 6 studies in the past 12 months with a range of 2–40 studies. On average, subjects had participated in 58 studies in their lifetime with a range of 2–1000 studies. Subjects reported earning an average of US \$1,024 in the past 12 months with a range of US\$0–14,000 and an average lifetime earnings of US\$6,764 with a range of US\$50–55,000. The types of studies subjects enrolled in within the past 12 months were widely distributed, with 42% of subjects enrolling in studies involving medication, 34% enrolling in studies that include talk therapy and 32% of subjects enrolling in studies that involved other types of therapy. The majority of subjects reported lifetime participation in a medication trial (76%) and roughly half reported participating in studies involving talk therapy (58%) or other forms of therapy (46%) in their lifetime. A small portion of subjects (15%) reported enrolling in overnight studies in the past 12 months, while about half of subjects (54%) had enrolled in an overnight study in their lifetime. Just under half of subjects (46%) reported lifetime enrollment in a study intended to treat a health condition that they actually had.

Table 2
Enrollment characteristics.

Volume of participation	Mean	SD
Number of studies past 12 months	6	7
Number of studies lifetime	58	139
Reported earnings from studies past 12 months	US \$1,024	US \$2,047
Reported earnings from studies lifetime	US \$6,764	US \$10,190
Types of study enrolled (lifetime)	n	%
Study involving medication or vitamin	45	76
Study involving talk therapy or counseling	34	58
Study involving other forms of therapy	27	46
Study involving overnight inpatient stay	32	54
Study that improved a problem or health condition I have	27	46
Types of study enrollments (past 12 months)	n	%
Study involving medication or vitamin	25	42
Study involving talk therapy or counseling	20	34
Study involving other forms of therapy	19	32
Study involving overnight inpatient stay	9	15
Volume of types of studies enrolled (past 12 months)	Mean	SD
Study involving medication or vitamin	1	2
Study involving talk therapy or counseling	1	2
Study involving other forms of therapy	1	2
Study involving overnight inpatient stay	1	2

3.3. Overall frequency of deception by type

Table 3 summarizes the percent of subjects who reported using each category of deceptive behavior in the past 12 months and the mean percent of studies that subjects contaminated using each category. Among this sample of subjects who admit to using deception, the majority of subjects (83%) reported concealing some type of information in order to qualify for studies. On average, these subjects contaminated two-thirds (67%) of the studies they had participated in by concealing information. About half of subjects (55%) reported fabricating information in order to qualify for studies. These subjects contaminated approximately half (53%) of studies they participated in by fabricating information. Half of subjects (50%) reported falsifying study data following enrollment. These subjects contaminated 40% of studies they participated in by providing false data after enrollment.

3.4. Concealing information

Table 4 details the percent of subjects who reported using each form of concealment of personal information in order to qualify for studies within the past 12 months, as well as the mean percent of studies that subjects contaminated with each form. The most frequent types of information that subjects reported concealing were participation in

Table 3
Overall frequency of deception by type.

	Subjects reported using each type of deception in the past 12 months		Studies contaminated by each form of deception in the past 12 months	
	n	%	Mean # of studies	Mean % of studies
Concealing eligibility information	50	83	4	67
Fabricating eligibility information	33	55	3	53
Falsifying study data	30	50	2	40

Table 4
Concealing information.

Type of concealment in order to qualify	n	%	Mean # of studies	Mean % of studies
Health problems/conditions	29	48	3	57
Participation in another study	29	48	3	49
Use of other prescribed medicines	24	39	3	51
Recreational drug use	21	34	4	57
Mental health problems	18	30	4	58
Nicotine use	18	30	2	49
Alcohol use	9	15	5	54
Family history	9	15	3	42
Housing arrangements	4	7	2	36
Pending legal issues	2	3	2	62

another study (48%), existing health problems/conditions (48%), use of prescribed medications (39%) and recreational drug use (34%). A smaller portion of subjects reported concealing information regarding mental health problems (30%), nicotine use (30%), family history (15%), alcohol use (15%), housing arrangements (7%) and pending legal issues (3%). The mean percentage of studies that these subjects contaminated by use of at least one form of concealment was 67%, ranging from 36% to 62% depending upon type of information being concealed. Subjects contaminated 62% of studies by concealing pending legal issues, 58% of studies by concealing mental health problems, 57% of studies by concealing existing health problems/conditions, 57% of studies by concealing recreational drug use, 54% of studies by concealing alcohol use and 51% of studies by concealing use of prescribed medications. A considerable proportion of studies were also contaminated by concealment of nicotine use (49%), participation in another study (49%), family history (42%) and housing arrangements (36%).

3.5. Fabricating information

Table 5 details the percent of subjects who reported using each form of fabrication of information in order to qualify for studies within the past 12 months, as well as the mean percent of studies that subjects contaminated with each form. The most common types of fabrication of information that subjects had used were exaggerating symptoms of a health condition (31%), pretending to have a health condition to qualify for a study (26%), enrolling in a study in which one had no desire to benefit from treatment being offered (26%) and enrolling in a medication study with no intention of taking the medication (21%). A small proportion of subjects reported successfully changing identity data in order to enroll in a study multiple times (3%) and intentionally harming oneself/purposefully worsening their health condition in order to qualify for a study (2%). The mean percentage of studies that these subjects contaminated by use of at least one form of fabrication was

Table 5
Fabricating information.

Type of false information given in order to qualify	n	%	Mean # of studies	Mean % of studies
Exaggerated symptoms of a health condition	19	31	2	45
Pretended to have a health condition	16	26	2	39
Enrolled in a study in which one had no desire to benefit from the treatment being offered	16	26	2	31
Enrolled in a medication study in which one had no intention of taking the medication	13	21	2	36
Successfully changed identity data in order to enroll multiple times in a study that does not use an identity registry	2	3	1	22
Intentionally harmed oneself/purposefully worsened condition	1	2	1	10

Table 6
Falsifying study data.

Type of false information given after enrollment	n	%	Mean # of studies	Mean % of studies
Provided false information about symptoms of a health condition	22	36	2	42
Falsely reported to researchers that one was taking the study medication regularly	17	28	2	32
Threw away study medication to give researchers the appearance that one was taking it	15	25	2	32
Recorded false data on a medication diary card to give researchers the appearance that one was taking it	13	21	1	24
Falsely reported improvement of a health condition	12	20	2	38

53%, ranging from 10% to 45% depending upon type of information being fabricated. Subjects contaminated 45% of studies by exaggerating their health condition to qualify, 39% of studies by pretending to have a health condition to qualify, 36% of studies by enrolling with no intention of taking the study medication, 31% of studies by enrolling with no intention of benefitting from the treatment, 22% of studies by changing identity data in order to enroll in a study multiple times, and 10% of studies by intentionally harming themselves in order to qualify for a study.

3.6. Falsifying study data

Table 6 details the percent of subjects who reported falsifying data after being enrolled in a study, as well as the mean percent of studies that subjects reported contaminating by falsifying data after enrollment. The most common types of data that subjects reported falsifying after study enrollment were providing false information about symptoms of a health condition (36%), falsely reporting taking the study medication regularly (28%), throwing away study medication to give researchers the appearance that one was taking it (25%), recording false data on medication diary card to give researchers the appearance that one was taking it (21%), and falsely reporting improvement of a health condition (20%). The mean percentage of studies that these subjects contaminated by use of at least one form of falsifying study data after enrollment was 40%, ranging from 24% to 42% depending upon type of information being falsified. Subjects reported contaminating 42% of studies by providing false information about symptoms of a health condition, 38% of studies by giving false reports of improvement of health condition, 32% of studies by falsely reporting study medication compliance, 32% of studies by disposing of study medication to give researchers the appearance of compliance, and 24% of studies by recording false data on a medication diary card to give researchers the appearance of compliance.

4. Conclusions

It is clear from published data over the past 10 years that there is a segment of the research participant population that utilizes deception to gain entry into studies and provides false data once enrolled. Efforts to characterize the scope of the problem have revealed percentages of subjects enrolled in a particular study or group of studies who employ deception. In one of the few studies that directly assessed the extent deceptive behavior among a sample of "experienced research subjects," Devine and colleagues [4] found the 75% of "experienced subjects" had used some form of concealment in order to gain entry into studies. The present study indicates that people who use concealment contaminate an average of 67% of the studies they take part in during a 12-month period. Devine et al. [4] found that 33% of "experienced subjects" have fabricated information during screening or participation in a trial

and the present study finds that people who use fabrication contaminate an average of 53% of studies they take part in. Although the independence of these two studies/samples does present some limitations for interpretation, it is clear that fabrication strategies used by a high percent of subjects and at a high rate across the studies they take part in. Given that our analytic approach included removing two subjects who were extreme outliers in the number of studies that they had completed in the past 12 months (80 studies and 120 studies), these estimates of study contamination may underestimate the true extent of the problem given there is a small proportion of the deceptive subject population that engage in a high number of studies each year [1].

One particularly troubling pattern of deception to emerge from the present study is related to McCann et al.'s modeling of subjects who pretend to have a health condition to qualify for enrollment and then falsify reports of the condition improving [10]. This modeling of subjects who are "destined to succeed" shows that sample size more than doubles when as little as 10% of a sample is comprised of this variety of deceptive subjects. Devine et al. [4] found that 14% of "experienced subjects" pretend to have a health condition in order to qualify for a study and the present study indicates that these people contaminate an average of 39% of the studies they take part in. The present study also revealed that 20% of subjects who admit to using deception have fraudulently reported improvement of health symptoms and do this in approximately 38% of the studies they take part in. This finding underscores the importance of screening strategies that include strong methods for verification of the disease being studied. Whenever possible, researchers should use objective measures to verify that the disease being studied is present. When no objective measure can be used to confirm a disease (e.g., anxiety, pain, addiction), medical record review may provide corroborating data that can be used to minimize the risk of enrolling subjects who are "destined to succeed."

Another finding that is particularly worrisome is the high reported rate of subjects falsifying study data after being enrolled in a study. One quarter of subjects in the present study admitted to throwing away study medication to give the appearance of compliance and they reported contaminating 32% of the studies they took part in in the past 12 months by faking medication compliance. Similar results were found for falsifying medication diary card entries and self-reports of pill compliance to researchers. Given the effect that falsified adherence data has on sample size requirements [11], the present study provides strong evidence that we need effective methods to assess medication adherence that protect study data from being contaminated by deceptive subjects. Indirect methods of verifying medication compliance (e.g., pill diaries, self-report) are exceptionally vulnerable to contamination by deceptive practices. Emerging technologies such as digital pills [12] and artificial intelligence apps that witness pill taking [13] may seem like expensive design features, but the cost of null findings due to subject deception may be far greater.

Researchers have proposed a number of strategies for mitigating the risk of enrolling deceptive subjects including use of recruitment strategies, screening strategies, objective testing measures, required medical record review and subject identity registries [14–17]. Given the findings in the present study that deceptive subjects contaminate a high percentage of the studies they participate in, it is clear that widespread adoption of research registries would have a valuable impact in combating deceptive subject enrollment. Specifically, including research registries in study design could be used to limit the number of studies that any subject can take part in within a specified time period and, therefore, limit the potential number of studies a deceptive subject is able to contaminate with fraudulent data. Research registries may also provide protections against deceptive subject enrollment by identification of disallowed health conditions based on prior study enrollment, duplicate enrollment, concurrent study enrollment, enrollment with a fraudulent identity and washout period violations. No single strategy is likely to provide complete protection from enrolling deceptive subjects. Some study designs are inherently less vulnerable to deception than

others due to design features including 1) direct observation of medication taking, 2) objective measurement of the primary outcome, 3) objective testing or observation of the qualifying health condition, 4) verification of health status by review of an existing electronic medical record, and 5) verified identity. The importance of designing studies to prevent deceptive subjects from enrolling may also be impacted by study factors that increase the overall vulnerability to deceptive subjects (e.g., studies with a high rate of reimbursement, studies with no potential for direct benefit, and studies with medication that has a high risk of diversion).

Although this study provides evidence that deceptive subjects contaminate a high percentage of studies that they take part in, a larger sample that is more geographically diverse may provide more accurate and generalizable data regarding the scope of deception in research. Regional differences in how subjects use deception may be related to the local culture of research volunteers or related to the deception detection strategies employed by large regional research centers. It is also plausible that economic factors such the regional poverty level or the reimbursement levels of studies could influence subjects' drive to employ deception for the sake of compensation. Conclusions about the demographic characteristics of people who admit to using deception may be limited by the potential for sampling bias in the present study and lack of a comparison group comprised of people who do not use deception. In a prior study of experienced subjects we found that people who use deception were younger and more likely to be male than people who denied lifetime use of deception [4]. The overrepresentation of black/African American subjects in the present study may be explained by Boston Medical Center's geographic proximity to neighborhoods with high percentages of such residents compared to the general Boston population. The findings of this study may have also been impacted by sampling bias as some subjects who use deception could be reluctant to admit this behavior or volunteer for a study that is designed to understand this behavior. Finally, it is also possible that some subjects in this study used deception. The study was designed to minimize deception through collection of anonymized data. Subjects were reminded during the interview that data would not be traceable to any individual and that no linking key between subject identity and study data was created.

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References

- [1] R. Abadie, *The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects*, Duke University Press, Durham NC, 2010, <https://doi.org/10.1215/9780822393245>.
- [2] R. Dresser, Subversive subjects: rule-breaking and deception in clinical trials, *J. Law Med. Ethics* 41 (4) (2013) 829–840, <https://doi.org/10.1111/jlme.12093>.
- [3] T.M. Shiovitz, M.E. Zarrow, A.M. Shiovitz, et al., Failure rate and "professional subjects" in clinical trials of major depressive disorder, *J. Clin. Psychiatr.* 72 (9) (2011) 1284, <https://doi.org/10.4088/JCP.11lr07229>.

- [4] E.G. Devine, M.E. Waters, M. Putnam, et al., Concealment and fabrication by experienced research subjects, *Clin. Trials* 10 (6) (2013) 1–14, <https://doi.org/10.1177/1740774513492917>.
- [5] T. Shiovitz, B. Steinmiller, C. Steinmetz, R. Perez, et al., The patient in your Alzheimer's Disease study may be in another: duplication and deception in clinical trials of Alzheimer's Disease, *J. Prev. Alzheimers Dis.* 7 (1) (2020) 43–46, <https://doi.org/10.14283/jpad.2020.3>.
- [6] Q.A. Karim, A.B. Kharsany, K. Naidoo, et al., Co-enrollment in multiple HIV prevention trials – experiences from the CAPRISA trial, *Contemp. Clin. Trials* 32 (3) (2011) 333–339, <https://doi.org/10.1016/j.cct.2011.01.005>.
- [7] T.M. Shiovitz, C.S. Wilcox, A. Shawkat, CNS sites cooperate to detect duplicate subjects with a clinical trial subject registry, *Innov. Clin. Neurosci.* 10 (2) (2013) 17–21. PMID: PMC3615509.
- [8] A. Paveltic, M. Pao, Safety, science, or both? Deceptive healthy volunteers: psychiatric conditions uncovered by objective methods of screening, *Psychosomatics* 58 (6) (2017) 657–663, <https://doi.org/10.1016/j.psym.2017.05.001>.
- [9] D. Boyar, N.M. Goldfarb, Preventing overlapping enrollment in clinical studies, *J. Clin. Res. Best Pract.* 6 (4) (2010). https://www.researchgate.net/profile/Norman_Goldfarb/publication/242771963_Preventing_Overlapping_Enrollment_in_Clinical_Studies/links/0046353c557b282387000000/Preventing-Overlapping-Enrollment-in-Clinical-Studies.pdf.
- [10] D.J. McCann, N.M. Petry, A. Bresell, et al., Medication nonadherence, “professional subjects,” and apparent placebo responders: overlapping challenges for medications development, *J. Clin. Psychopharmacol.* 35 (5) (2015) 566–573, <https://doi.org/10.1097/JCP.0000000000000372>.
- [11] T.M. Shiovitz, E.E. Bain, D.J. McCann, et al., Mitigating the effects of nonadherence in clinical trials, *J. Clin. Pharmacol.* 56 (9) (2016) 1151–1164, <https://doi.org/10.1002/jcph.689>.
- [12] R.S. Plowman, T. Peters-Strickland, G.M. Savage, Digital medicines: clinical review on the safety of tablets with sensors, *Expert Opin. Drug Saf.* 17 (9) (2018) 849–852, <https://doi.org/10.1080/14740338.2018.1508447>.
- [13] E.E. Bain, L. Shafner, D.P. Walling, et al., Use of a novel artificial intelligence platform on mobile devices to assess dosing compliance in a phase 2 clinical trial in subjects with Schizophrenia, *JMI2R Mhealth Uhealth* 5 (2) (2017) e18, <https://doi.org/10.2196/mhealth.7030>.
- [14] D.B. Resnik, G. Koski, A national registry for healthy volunteers in phase 1 clinical trials, *J. Am. Med. Assoc.* 305 (12) (2011) 1236–1237, <https://doi.org/10.1001/jama.2011.354>.
- [15] E.G. Devine, K.R. Peebles, V. Martini, Strategies to exclude subjects who conceal and fabricate information when enrolling in clinical trials, *Contemp. Clin. Trials Commun.* 5 (2017) 67–71, <https://doi.org/10.1016/j.conctc.2016.12.005>.
- [16] M.E. McCaul, G.S. Wand, Detecting deception in our research participants: are your participants who you think they are? *Alcohol Clin. Exp. Res.* 42 (2) (2017) 230–237, <https://doi.org/10.1111/acer.13556>.
- [17] D.B. Resnik, D.J. McCann, Deception by research participants, *N. Engl. J. Med.* 373 (2015) 1192–1193, <https://doi.org/10.1056/NEJMp1506985>.