How Do I Know That My Participant Is Who They Say They Are? Identifying And Preventing Fraud in Remote Trials

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Disclosures

Dr. Dahne is co-owner of Behavioral Activation Tech LLC.

Funding sources: NIDA, NIMH, NIMHD, NCI, HRSA, SCTA.

No other financial relationships or other relationships which could reasonably be considered a conflict of interest relevant to the content of this presentation.

A Few Brief Points Before We Begin

1. Definition: Providing false data that misrepresents critical information about eligibility criteria or study outcomes.
   - There are both bad and good reasons why fraud occurs.
   - Does intentionality matter?

2. Fraud is not unique to remote trials.

3. Because participants are not seen in person, remote trials *may* be more susceptible to fraud.
   - Important literature gap: Prevalence of fraud in remote vs. in person trials

4. Fraud mitigation strategies *may* decrease fraud prevalence.
   - Important literature gap: Effectiveness of different fraud mitigation strategies

Types of Fraud: Some Examples

- "Gaming the system"
  - Falsely gaining study entry either by providing untrue information or by repeatedly completing a study screening in an attempt to guess inclusion criteria

- Fraud of intention
  - Enroll in a study with no intention to follow study participation guidelines

- Multiple enrollments
  - One individual enrolls in a given study multiple times

- Loss of interest
  - Enroll in a study with the intention to participate fully, but over time lose interest and do not pay full attention to study procedures

Remote vs. In Person: How does Fraud Differ?

In Person Methods of Fraud Prevention	Type of Fraud Addressed	Can it Be Done Remotely?
Biochemical verification	Gaming the system	Yes, but perhaps more challenging, especially depending on the biospecimen needed (e.g., urine vs. a breath sample)
By virtue of attending in person, you know that the person is in the location they say they are in and the participant is the one completing study assessments	Gaming the system, multiple enrollments	Challenging. You could check IP address, but that can be masked.
ID verification to confirm name, address, and that the participant is a unique enrollee	Gaming the system, multiple enrollments	Yes (but concerns across both in person and remote for those that may not have ID)

Setting the Stage: Why Should We Care About Fraud?

"Destined to Succeed"

- Does not have the condition (e.g., does not have depression in a depression trial)
- Regardless of treatment allocation, participant **will** appear to respond
- 40% of participants (>1 research study per year) admit to exaggerating or feigning symptoms
- Increased risk when trials do not include biomarker confirmation
  - Biomarker confirmation may be more difficult in remote vs. in person trials

Devine et al., 2013; McCann et al., 2015; Slide credit: Dr. Rachel Tomko

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Who You Think You're Enrolling

Who You Actually Enroll

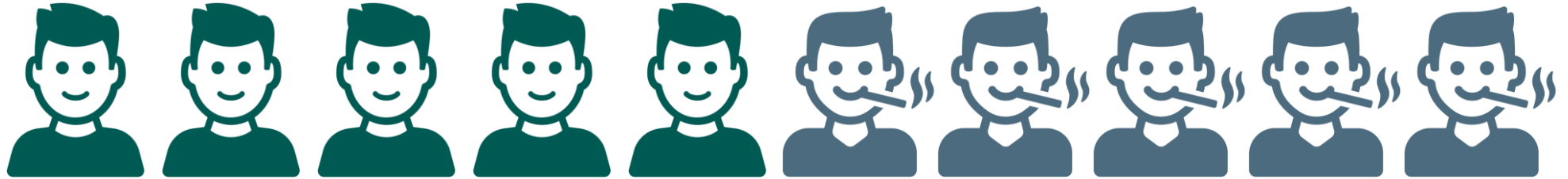Changing What's Possible | MUSC.edu

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Who You Think You're Enrolling

Who You Actually Enroll

Even if treatment does not truly work at all, 50% will appear to have quit, which is better than all first line FDA-approved pharmacotherapies for cessation.
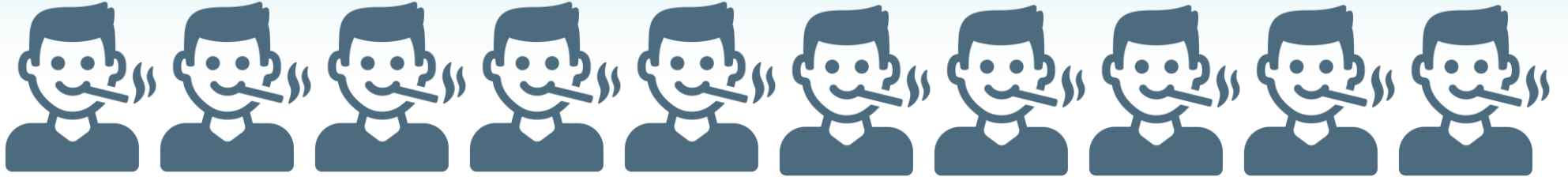
Ineffective treatments will appear efficacious and will be disseminated, negatively impacting public health.

Even if treatment does not truly work at all, 50% will appear to have quit, which is better than all first line FDA-approved pharmacotherapies for cessation.

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Setting the Stage: Why Should We Care About Fraud?

<u>"Destined to Fail"</u>

- Have condition, but have no intention of engaging in the trial or engaging in allocated treatment

- Regardless of treatment allocation, participant **<u>will not</u>** appear to respond
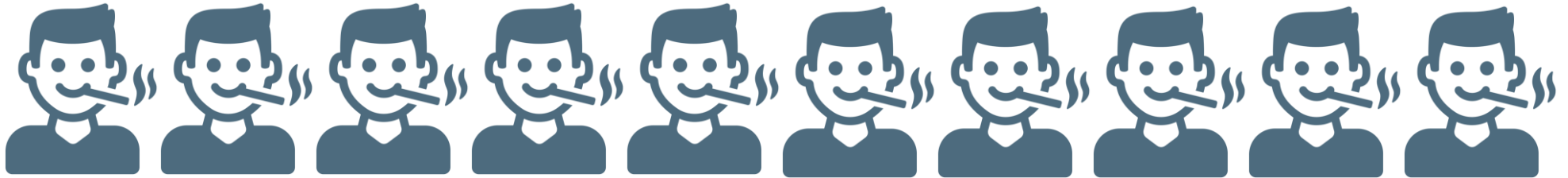
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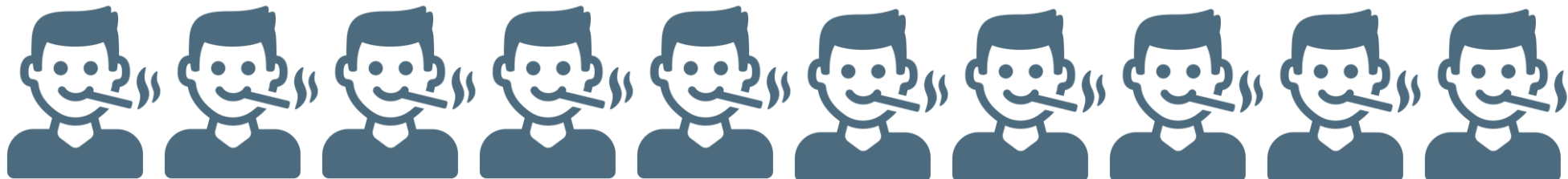
Even if treatment does truly work, 0% will appear to have quit.

Who You Think
You're Enrolling

Effective treatments will appear ineffective, also negatively impacting public health.

Even if treatment does truly work, 0% will appear to have quit.

Even for Non-Treatment and Non-Clinical Trials, Fraud is a Concern

- Enrolling participants that have no intention of completing study procedures
  - Need to enroll additional participants due to dropout, adding study costs and time

- Enrolling participants that have no intention of completing study procedures truthfully/honestly
  - Impacts the validity of results

- Enrolling participants that are not in the location that you are targeting
  - Affects results generalizability

Cheatblocker

- Focus is on identifying and preventing one form of fraud: repeatedly completing study screening in an attempt to falsely gain study entry

- A REDCap module that can be installed to your institution's instance of REDCap by your REDCap administrator and then deployed within any REDCap project

- Offers investigators flexibility in how they would like to define repeat entries
  - You can use any field or combination of fields in your dataset for defining duplicates

- Initial release February 2021, currently in use at 23 different REDCap institutions

REDCap Repo

Repository of External Modules

The REDCap Repo is a centralized repository of curated External Modules that can be downloaded and installed in REDCap by a REDCap administrator. External Modules are add-on packages of software that can extend REDCap's current functionality, as well as provide customizations and enhancements for REDCap's existing behavior and appearance, either at the system level or project level. The modules provided here were created and submitted by software developers at various REDCap institutions around the world.

If you have created a module and wish to submit it to be listed in the REDCap Repo, please complete the Module Submission Survey. Updated versions must also be submitted via the survey. To learn more about the REDCap Repo module review process, you may download the Module Review Guidelines (PDF).

You may search below for available modules. If you got to this site directly, you will be able to view information about each module, but you will not be able to download modules from this page unless you arrived here from the REDCap application and are a REDCap administrator. If you have questions or are experiencing issues, please contact redcap@vumc.org.

Disclaimer: The modules listed in the REDCap Repo have gone through a process of testing, validation, and curation by the Vanderbilt REDCap Team with help from trusted individuals in the REDCap Consortium. It should not be assumed that all modules are bug-free or perfect, so please be aware that the entire risk as to the quality and performance of the module as it is used in your REDCap installation is borne by the REDCap administators who download and install the modules.

Show 10 ⬍ entries   cheatblocker

Module title and description	First Submitted	Most Recent Update	Downloads (Installs only - Excludes updates)	
CheatBlocker *(cheat_blocker_v1.0.4)* View on GitHub *Description:* This module is used to identify "cheaters" or "gamers" and prevents individuals from completing a study screener multiple times to gain study entrance. It can be used in two ways: 1) at the point of screening to automatically inform potential participants that they are ineligible for the study, or 2) to flag a record as a potential duplicate and then allow study staff to make the final decision to include or exclude the record. *Authors:* Andrew Cates (Medical University of South Carolina) , Sherly Roy Yesudhas , Johanna McGann , Sherly Roy Yesudhas , Johanna McGann , Sherly Roy Yesudhas , Johanna McGann	2021-02-25	2021-07-28	23	You must be a REDCap administrator logged in to REDCap to download modules.

Showing 1 to 1 of 1 entries (filtered from 213 total entries)

Previous   1   Next

📦 External Modules - Project Module Manager

External Modules are individual packages of software that can be downloaded and installed by a REDCap administrator. Modules can extend REDCap's current functionality, and can also provide customizations and enhancements for REDCap's existing behavior and appearance at the system level or project level.

As a user with Project Setup/Design privileges in this project, you can modify the configuration (if applicable) of any enabled module. Note: Only REDCap administrators are able to enable or disable modules.

DISCLAIMER: Please be aware that External Modules are not part of the REDCap software but instead are add-on packages that, in most cases, have been created by software developers at other REDCap institutions. Be aware that the entire risk as to the quality and performance of the module as it is used in your REDCap project is borne by you and your local REDCap administrator. If you experience any issues with a module, your REDCap administrator should contact the author of that particular module.

ℹ️ View available modules

Currently Enabled Modules

Search enabled modules

CheatBlocker - v1.0.3 `Discoverable`
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Configure
Disable

QuotaConfig - v1.0.4 `Discoverable`
This module allows the research team to specify an enrollment minimum for each demographic characteristic of interest for the study as a whole and/or for blocks of participants. If a demographic quota is filled, the module can either: 1) automatically inform potential participants at the point of screening that they are ineligible for the study or 2) allow study staff to delay the quota check until the time of enrollment.

Configure
Disable

📄 View Documentation (QuotaConfig & CheatBlocker Combined)

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[ℹ **View available modules**]

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[Configure]
[Disable]

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[Configure]
[Disable]

📄 View Documentation (QuotaConfig & CheatBlocker Combined)

SOPs for REDCap External Modules: CheatBlocker and QuotaConfig Combined

A. **Add the modules to your REDCap project:**
   1. Open your REDCap project that you want to use the modules in.
   2. In REDCap, underneath the "Applications" header on the left-hand sidebar, click "External Modules."
   3. Then, click the green button that says, "Enable a Module."
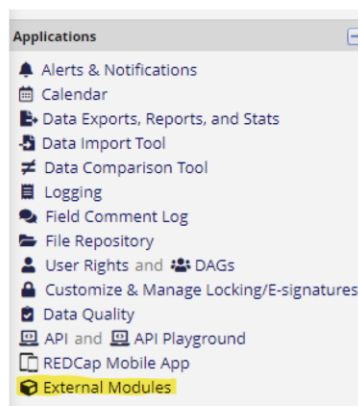
   4. Search for "CheatBlocker" and click the "Enable" button.
   5. Search for "QuotaConfig" and click the "Enable" button.

B. **Add the variables to your project that will be used to customize the modules:**
   1. On the left -hand sidebar in the External Modules section, click "QuotaConfig & CheatBlocker Data Dictionary" to

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📄 View Documentation (QuotaConfig & CheatBlocker Combined)

[Configure]
[Disable]

Configure Module: CheatBlocker ✕

Project: New iCo Study Screener

Settings	Values
Popup title: * must provide value	Eligibility
Acceptance Message: * must provide value	Thank you for your interest in this study. Please click "continue" to proceed to the screening survey so we may determine your eligibility for participation.
Rejection Message: * must provide value	Thank you for your interest but it looks like you're not eligible for this study at this time. You may close your browser at this time.
Eligibility message: * must provide value	You may be eligible for this study. Please click continue to proceed to the screening survey to determine further eligibility.
Potential duplicate message: * must provide value	We may need more information from you in order to review your record. Please click submit to proceed to the rest of the screening survey.
Automatic Duplicate Check: * must provide value	☑

Compare Dates By:	6
Time Period:	Months ▾

1.Criteria: [+] [–]

Field: * must provide value	first_name - First Name ▾	[+] [–]
Field: * must provide value	last_name - Last Name ▾	[+] [–]

2.Criteria: [+] [–]

| Field:
* must provide value | email - E-mail ▾ | [+] |

3.Criteria: [+] [–]

| Field:
* must provide value | telephone - Phone numb ▾ | [+] |

Cancel   Save

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You can select whether you would like duplicate entries to be automatically rejected (box checked) or if you would like all records to be manually reviewed.

Configure Module: CheatBlocker ✕

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Automatic Duplicate Check: * must provide value	☑

Compare Dates By: `6`

Time Period: **Months** ▼

1.Criteria: [+] [-]

Field:
 * must provide value — **first_name - First Name** ▼   [+] [-]

Field:
 * must provide value — **last_name - Last Name** ▼   [+] [-]

2.Criteria: [+] [-]

Field:
 * must provide value — **email - E-mail** ▼   [+]

3.Criteria: [+] [-]

Field:
 * must provide value — **telephone - Phone numb** ▼   [+]

[Cancel] [Save]

Data from 3 Studies Using Cheatblocker

	STARS	COast	VapeX
Total Screenings Completed	468	464	166
Original Duplicates (#, %)	36 (8%)	25 (5%)	21 (13%)
Duplicate Entries (#, %)	64 (14%)	50 (11%)	36 (22%)
Total Duplicates (#, %)	100 (21%)	75 (16%)	57 (34%)
Range (duplicates per original)	1-33	1-5	1-6
Duplicated fields			
First name, last name, e-mail, and phone number	48	62	27
E-mail and phone number	8	3	6
First name, last name, and phone number	2	6	1
First name, last name	2	0	0
First name, last name, e-mail	1	0	0
Phone number	3	3	1
E-mail	0	1	1

Something was changed between entries

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Additional Strategies for Fraud Prevention

Commentary

Recognizing and Preventing Participant Deception in Online Nicotine and Tobacco Research Studies: Suggested Tactics and a Call to Action

Jaimee L. Heffner PhD[1], Noreen L. Watson PhD[1], Jennifer Dahne PhD[2,3], Ivana Croghan PhD[4,5], Megan M. Kelly PhD[6,7], Jennifer B. McClure PhD[8], Matthew Bars MS[9], Johannes Thrul PhD[10,11,12], Eric Meier MS[13]

Method	Functions	Considerations
Avoid advertising full eligibility criteria	Prevent individuals from being able to answer screening questions in ways known to make them eligible	Less targeted recruitment can result in a higher number of individuals ineligible at screening, which has potential recruitment time and cost implications
Have individuals complete entire screening survey before informing them of eligibility, and do not provide reasons for ineligibility	Deter ineligible individuals from re-taking screening survey and changing responses to meet eligibility criteria	Increases respondent burden, may increase staff burden if any part of screening procedures are conducted by staff
Specify in informed consent that individuals with suspicious responses will be contacted to determine eligibility	Deter individuals from providing false information by informing them that data will be monitored	(1) Important to have an a-priori plan for what circumstances would warrant contact vs. deeming an individual ineligible without contact (2) Requires staff time to follow up on suspicious responses
Avoid advertising compensation type and amount	Deter efforts to fraudulently enter study for financial gain	May decrease interest in participation among eligible participants
Provide compensation via mail	(1) Ensure individuals are eligible based on geographic location (2) Make it more difficult for participants to collect multiple incentives	(1) Incentives may be lost in the mail, and confirmation of receipt has additional cost (2) Adds staff time and mailing costs
Provide lottery-based compensation	Deter efforts to fraudulently enter study for financial gain if incentive is not guaranteed	(1) May decrease interest in participation among eligible individuals (2) Some IRBs may not allow lottery-based incentives
Check IP address for duplicate entries within and across studies and compare location to general eligibility criteria	(1) Detect repeat attempts at study entry (2) Detect efforts to join the study from geographic locations that would make the person ineligible	Not always accurate as an indicator of repeat attempts or location at study entry, especially if survey is completed on smartphones, VPNs, campus-based networks, etc.
Require CAPTCHA/reCAPTCHA verification to access surveys	Detect bots	CAPTCHA methods can be circumvented by advanced bots
Place cookies in browsers when survey is accessed	Prevent a person from attempting the same survey multiple times in the same browser	(1) Can be circumvented if individuals delete cookies (2) May create privacy concerns (e.g., if others check participants' cookies)
Use separate survey URLs for each source of advertisement	(1) Know if response was made before or after study advertisement was removed (2) Know if response rate to s[urvey] link is reasonable given its placement	
Prevent survey URL from being indexed by an Internet search engine	Prevents unintended, broad accessibility of survey	
Monitor time stamps for time to complete survey/page	Surveys or survey pages completed too quickly may in[dicate] a bot or inattentive human respondent	
Include survey item with directions for how to respond (e.g., "select option A below")	(1) Detect bots (2) Serve as an attention che[ck]	…fatigue, clicking/touching the wrong button, etc.; missing multiple attention check items is more indicative of deception
Include embedded hidden/"honeypot" questions that are not visible to human respondents	Detect bots	Less useful with the advent of more sophisticated bots
Assess name, phone number, email address, mailing address for duplication within and across studies	(1) Detect attempts of study entry from individuals who were previously deemed ineligible (2) Prevent same person from participating in multiple studies, if desired	Can be circumvented by creation of multiple identities for repeat study entry
Check for virtual phone numbers using verification text messages	Prevent an individual from enrolling multiple times using different virtual phone numbers, which can be easily obtained. A text message can be sent for mobile number verification. Some text services indicate whether the receiving number is virtual.	Legitimate participants may use a virtual phone number, thus action on this check alone is not recommended.
Assess for suspicious email addresses, including addresses that are similar within study	(1) Deter individuals from creating multiple entries for purposes of study entry (2) Detect bots	Difficult to automate, requires manual review
Search online for survey URL to ensure that it only exists where intended	Prevent link to survey from being shared online in a way that increases fraudulent responses (e.g, in an online forum for sharing paid survey opportunities)	Requires manual check
	…surveys (2) Detect "straightlining" (e.g., choosing the first response option for every question)	…without manual review
Search for participant's information in an internal or external database of potentially deceptive research participants	Exclude participants who have a history of engaging in deception in other research studies	IRB approval is typically necessary to create and maintain such a database within a lab or institution or to use an external paid database search for this purpose
Require participants to confirm e-mail address and/or phone number before enrollment	(1) Verify that participant is human (2) Verify that email/phone number is working and checked regularly	Requires manual review
Ask participants to confirm demographic characteristics in a separate survey sent via email	Helps ensure consistency of responses over time to items that should not change	Requires manual review
Require participants to provide a photo of identification card before enrolling	Verify identity and demographics including age, sex, country/state of residence, current mailing address	(1) Could deter participation from eligible participants (2) Requires manual review
Include phone or video calls	(1) Deter fraudulent and non-serious participants (2) Verify that participant is human	Depending on size of study, this could be burdensome for study staff
Observed biochemical verification of tobacco use status	(1) Ensure that individuals are active tobacco users prior to enrollment, verify self-report of abstinence following intervention (2) Observation of sampling can reduce likelihood of deception	(1) Depending on size of study and associated budget, this may not be feasible (2) May also deter eligible individuals from participating

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Use separate survey URLs for each source of advertisement	(1)Know if response was made before or after study advertisement was removed (2)Know if response rate to survey link is reasonable given its placement	May require merging of survey datasets following data collection, depending on how this is implemented
Prevent survey URL from being indexed by an Internet search engine	Prevents unintended, broad accessibility of survey	Limits reach of study recruitment materials
Monitor time stamps for time to complete survey/page	Surveys or survey pages completed too quickly may indicate a bot or inattentive human respondent	Time cutoff for completing a survey too quicky should be set conservatively to avoid misclassifying fast readers/responders as deceptive respondents
Include survey item with directions for how to respond (e.g., "select option A below")	(1)Detect bots (2)Serve as an attention check	It's possible for eligible individuals to miss individual attention check items due to fatigue, clicking/touching the wrong button, etc.; missing multiple attention check items is more indicative of deception
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Assess name, phone number, email address, mailing address for duplication within and across studies	(1)Detect attempts of study entry from individuals who were previously deemed ineligible (2)Prevent same person from participating in multiple studies, if desired	Can be circumvented by creation of multiple identities for repeat study entry
Check for virtual phone numbers using verification text messages	Prevent an individual from enrolling multiple times using different virtual phone numbers, which can be easily obtained. A text message can be sent for mobile number verification. Some text services indicate whether the receiving number is virtual.	Legitimate participants may use a virtual phone number, thus action on this check alone is not recommended.
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Search online for survey URL to ensure that it only exists where intended	Prevent link to survey from being shared online in a way that increases fraudulent responses (e.g, in an online forum for sharing paid survey opportunities)	Requires manual check
Ask "insider knowledge" questions to verify eligibility criteria (e.g., for location-based eligibility, ask for zip code or other knowledge of location during a phone/video call)	Ensure that the individual is part of the target population	(1)Depending on the questions and how they are administered (e.g., web survey vs. on a call/video that requires immediate response), individuals may be able to look up the correct answer(s) (2)Often requires manual evaluation of response accuracy
Require responses to open-ended questions	Blank, nonsensical, or duplicate responses across surveys may be indicative of bots	(1)Failure to answer appropriately does not prove presence of a bot (2)Requires manual review of responses
Review pattern of survey responses	(1)Detect inconsistent responses between the same/similar questions within or across eligibility and study surveys (2)Detect "straightlining" (e.g., choosing the first response option for every question)	Can be at least partly automated, but some patterns are more difficult to detect without manual review
Search for participant's information in an internal or external database of potentially deceptive research participants	Exclude participants who have a history of engaging in deception in other research studies	IRB approval is typically necessary to create and maintain such a database within a lab or institution or to use an external paid database search for this purpose
Require participants to confirm e-mail address and/or phone number before enrollment	(1)Verify that participant is human (2)Verify that email/phone number is working and checked regularly	Requires manual review
Ask participants to confirm demographic characteristics in a separate survey sent via email	Helps ensure consistency of responses over time to items that should not change	Requires manual review
Require participants to provide a photo of identification card before enrolling	Verify identity and demographics including age, sex, country/state of residence, current mailing address	(1)Could deter participation from eligible participants (2)Requires manual review
Include phone or video calls	(1)Deter fraudulent and non-serious participants (2)Verify that participant is human	Depending on size of study, this could be burdensome for study staff
Observed biochemical verification of tobacco use status	(1) Ensure that individuals are active tobacco users prior to enrollment, verify self-report of abstinence following intervention (2) Observation of sampling can reduce likelihood of deception	(1)Depending on size of study and associated budget, this may not be feasible (2)May also deter eligible individuals from participating

Future Thinking

- What fraud prevention strategies work best, in what contexts (studies), and for which participants (types of fraud)?
  - What fields are the best to use for detecting fraud?

- Means of committing fraud keep advancing (masking IP addresses, sharing inclusion criteria online) and our methods of detection need to advance at a faster pace.

- Studies should include in their protocols plans for preventing and addressing fraud and publish those plans (clinicaltrials.gov, manuscripts) along with outcomes related to fraud detection.

- There are good reasons why participants may provide fraudulent responses (marginalized groups, sensitive clinical topics). How do we address fraud in those circumstances?

Acknowledgements

Funding

- MUSC CTSA
- NIDA K23 DA045766
- SCTA
- HRSA U66RH31458
- NIMH R41 MH108219
- NIMH R42 MH108219
- NCI R21 CA241842
- ACS IRG

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"OK, but if we work *together*... Whammo! Depth perception!"

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