Growth Mindset Psychoeducation for Modifiable Risk Factors for CMD
NCT03707522
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University of Nevada, Reno

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Part II Application – Social Behavioral/Education Research

Note the following:
1. A Part I Cover sheet is required for each project submitted in IRBNet; see **Locating the Cover Sheet**
2. See IRB policy for submission requirements for new projects for Full Committee Review or Expedited Review.

PI Responsibilities	
1. How will the PI ensure that all study personnel are informed about the research plan and their research-related duties?	X Routine meetings X Regular communication (e.g., email, phone) __ Other research staff training, describe:
Study Sites and Collaborating IRBS	
2. List/describe the study sites:	University of Nevada, Reno
3. Will this research be reviewed by other IRBs?	X No __ Yes[i] *(Consider contacting our office for assessment and coordination of single IRB review.)*
Selection of Research Participants	
4. How many participants (or records) will be enrolled?	500 Number of participants/records
5. What are the participant eligibility inclusion criteria? X Age, specify: 18-65 years old __ Gender, specify: __ Race/ethnicity, specify: X Language, specify: English __ Another country or specific culture[ii], specify: __ Veteran status, specify:	__ Adults with cognitive impairment[iii] __ PI's students, patients, or employees[iv] __ Economically/educationally disadvantaged persons[v] __ Socioeconomic factors, specify: __ Additional, describe:
6. What are the participant exclusion criteria?	__ N/A, no exclusion criteria Description: Under the age of 18, not fluent in English.
7. Justify exclusions based on age, gender, or race:	__ N/A, no such exclusions Justification: Minors will not be included as freshmen at orientation will likely not have a guardian present to provide informed consent. Non-English speakers will not be included in the study as translations of the material and measures are not available. Individuals over the age of 65 will not be included because risk factors for older adults may differ in important ways that would affect the content of the intervention material (e.g., Beekman, 1995)
8. Will the research involve researchers' clients, students, or employees; or persons who are educationally or economically disadvantaged (see IRB policy for inherently influential situations)?	X No __ Yes, specify and describe additional precautions to ensure participants are fully informed and agree voluntarily:

Recruitment Methods and Materials __ **Check here** if there are no processes/mechanisms to recruit participants; **skip** to next section.		
9. Who will recruit prospective participants?		__ Recruitment exclusively through SONA __ PI X Co-investigators __ Study coordinator __ Research assistants __ Third party, specify and describe the party's relationship to the study population: __ Other, specify:
10. Describe where, when, and how recruitment will take place:		__ N/A, recruitment exclusively through SONA Description of recruitment process: Participants will be recruited from freshmen orientation. Participants will be provided with a recruitment flyer in the binder provided by freshmen orientation programming staff. Research staff will also be present at orientation at a table with flyers to provide information about the study.
11. What recruitment materials will be used?[vi]	X Flyers/advertisements __ Emails/letters __ Scripts __ Slide or computer presentation	__ SONA post __ Social media, specify: __ List serves X Other, specify: Table set up at orientation, flyer in student orientation binders
Assessing Participants for Eligibility **Check here** if participants will NOT be assessed for eligibility; **skip** to next section.		
12. How will researchers confirm participants' eligibility for the research?		Participants will complete a set of demographic questions to ensure that they are between the ages of 18-65, fluent in English, and UNR college freshmen.
13. How will researchers inform participants about the process to assess eligibility?		Eligibility information will be included in the informed consent and study flyer.
14. What will happen to screening/eligibility data for individuals who are not eligible to participate?[vii]		Screening/eligibility data for individuals who are not eligible to participate will be destroyed after study recruitment is complete.
Recruitment Incentives/Payments X **Check here** if there are no recruitment incentives/payments; **skip** to next section.		
15. What types of recruitment incentives/payments will researchers give participants?[viii]		X Credit through SONA: .5 SONA credit for follow up __ Course credit; equivalent, alternative opportunities must be available __ Money or gift cards; specify amount: __ Raffle or drawing; specify value, and odds of winning: __ Other; specify and value:

16. When and how will researchers distribute incentives/payments?	X SONA credit awarded via standard procedures Description:
17. For all incentives/payments, explain why the amount or value is reasonable for the research:	X SONA credit, standard amounts Explanation:
18. Will participants be required to provide *Protected Personally Identifiable Information* (PPII) including social security numbers, to receive incentives/payments?[ix]	X No __ Yes, specify the PPII required for payment, to whom it will be provided, and how it will be protected during this process:
Informed Consent Methods/Procedures __ **Check here** if you do not plan to obtain informed consent from participants); **skip** to the next section. [x]	
19. Describe the process for obtaining legally effective informed consent from *each* participant (i.e., describe when, where, and how each recruit will be told about the research and agree to her/his participation).	__ N/A, research only involves children[xi] __ N/A, research only involves adults with impaired consent capacity and surrogate consent[xii] Description of informed consent process: All freshmen completing orientation receive a binder as part of orientation programming. This binder contains information and resources for freshmen students. This binder will contain a study flyer that contains a brief description of the study. Research staff will also be present at an information table at orientation. If participants are interested in learning more, they can choose to access the Qualtrics site through a survey link provided in the flyer. If they choose to access the Qualtrics survey link, they will be able to read the informed consent prior to agreeing to participate in the study.
20. Specify which researchers will obtain informed consent from participants:	X Via online or electronic information sheet __ PI __ Co-investigators __ Study coordinator __ Research assistants __ Other, specify:
21. How will researchers ensure consent is obtained in a language understandable to participants?	*Check all that apply:* X Consent materials reflect the expected literacy of the sample population X Participants speak English __ Researcher fluent in participants' language will interpret __ Person in community will interpret __ Professional interpreter will be present __ Consent materials translated in participants' language or short-form consent process used __ Other, specify:
22. How will researchers ensure individuals have sufficient opportunity to consider participation?	Participants will have as much time as they would like to review consent materials.

23. How will researchers protect participants from undue influence/coercion during the consent process?	No incentives will be offered for the first portion of the study taking place during orientation. Participation in the follow-up assessment will be compensated using SONA credits. Participants may decline to participate in the study and participate in another research study in order to obtain credits.
24. How will researchers assess each person's comprehension of the research?	X As recommended by the IRB __ Other, specify:
Documentation of Consent	
25. Will participants sign an IRB-approved consent form, as required at 45CFR46.117?	X N/A, minimal risk research that is NOT conducted/supported by a federal agency (including the VA); and does NOT involve incomplete disclosure or deception, or prisoners __ No, requesting IRB approval to waive requirement for documentation of consent[xiii] __ Yes, via short form consent documentation (for non-English-speaking participants) __ Yes
Research Costs	
26. Will participation result in out of pocket expenses (including costs for cell phones used in research), co-pays, 3rd party payer costs, or research-related injury costs?[xiv]	X No __ Yes, complete the following: What costs will participants or 3rd party cover? What costs will the researchers cover? What costs will the VA cover? What costs will the sponsor cover?
Study Design/Research Methods Describe in non-technical terms.	
27. What is the background information that supports this research? (Summarize previous work and provide references.)	The present study intends to determine the effect of psychoeducation on engagement with modifiable risk factors for depression and anxiety. While psychoeducation, and etiological beliefs about depression in particular, have been conceptualized as an important part of mental health literacy (MHL), little evidence exists to suggest what the content of psychoeducation should entail in order to improve the stated goals of MHL of recognition, management and prevention of common mental health problems such as anxiety and depression (Kelly, Jorm & Wright, 2007). As such, factors that increase both engagement with modifiable risk factors are key to the prevention of common mental disorders such as anxiety and depression. Risk factors are variables that if present increase likelihood of developing disorder. Modifiable

	risk factors are those variables that could be reasonably altered by the individual without outside intervention). For depression and anxiety, these include health behaviors such as drug and alcohol use, weight management, coping strategies, sleep, positive activities, physical activities and social support (Cairns et al., 2014; Zimmermann, Chong, Vechiu & Papa, 2017). Prevention is especially warranted for college students, because they are at a developmentally unique time of life before which 80% of individuals have not yet developed anxiety or depression. With respect to onset of depression, 20% of those with depression experience their first symptoms at age 19, meet criteria by age 25, 50% meet criteria by age 25, meet criteria by 38. Thus, college freshmen are at a key stage before which most individuals will have developed a disorder (Munoz, Mrazek & Haggerty, 1996). Growth mindset may be an important aspect of preventative psychoeducation. Dweck and colleagues' (1995) cognitive model of motivation has generated a significant body of work demonstrating that individuals have "implicit theories," related to the malleability of a trait, and that individuals set goals and behave with respect to that aspect. Thus, learned concepts about the mutability of a trait have consequences for future behavior, and persistence on challenging tasks in particular. Mueller and Dweck (1998) show that children who receive praise for intelligence are more likely to exhibit behaviors of entity theorists by choosing easier tasks and spending less time on challenging problems, whereas children praised for efforts are more likely to resemble incremental theorists by choosing mastery goals and working through difficult problems. Beliefs about the malleability of self-attributes are learned and apply to specific traits. For example, an individual may have learned that intelligence is fixed but that a personality trait such as hostility is flexible (Yeager & Dweck, 2012; Scott & Ghinea, 2014). With respect to mental health, research on malleability beliefs has been limited, but it does appear that engendering a "growth mindset," is effective for the reduction of mental health problems (Schleider & Weisz, 2016).

	Accordingly, beliefs about the malleability of emotions have been shown to predict depression outcomes in a sample of college students, with students endorsing beliefs in emotion malleability experiencing fewer symptoms of depression (Tamir et al., 2007). One possible mechanism through which this protective may occur is through the engagement with modifiable risk factors. Thus, research is needed to further demonstrate the effectiveness of growth mindset for the prevention of depression and anxiety, and to determine through what mechanism this intervention may be effective.
28. State the study purpose, research hypothesis, or research questions:	The present study aims to determine the effect of presenting psychoeducation emphasizing "growth-mindset," and information on modifiable risk factors on engagement with modifiable risk factors. We hypothesize that psychoeducation emphasizing that mental health is malleable will increase the participant's engagement with risk factors outlined in the intervention. Participants will randomly be assigned to complete one of four conditions: (1) Growth mindset + Modifiable risk factor information (2) Control + Modifiable risk factor information (3) Control + Growth mindset (4) Control + Control This design will allow assessment of the incremental effects of growth mindset and modifiable risk factor information as well as interactions between these conditions. We hypothesize that condition 1 will be associated with the greatest increase in engagement with modifiable risk factors for depression and anxiety followed by conditions 2-3 which will be associated with greater increases in engagement with modifiable risk factors than the control group (condition 4).
29. When appropriate (e.g., community-based participatory research, international research), how will you involve community members *as advisors* in the design/implementation of the research, and dissemination of results?	X N/A, not necessary/appropriate to involve community members Describe:

30. Check all research methods/procedures that apply to this research: X Psychological or behavioral interventions/treatments __ Educational activities/interventions __ Experimental-control group assignment __ Cross-over design __ Computerized simulations __ Equipment/devices[xv], specify: __ Ethnographic research	__ Needs assessment research __ Program evaluation research __ Observational research X Surveys, interviews, focus groups __ Collection of data from records __ Retrospective __ Prospective __ Other, specify:
31. Which of these methods/procedures are experimental (i.e., conducted to evaluate safety/efficacy or other outcomes)[xvi]?	The article containing psychoeducation related to the mental health will be experimentally manipulated. Participants will be randomly assigned to one of four conditions. (1) Growth mindset + Modifiable risk factor information (2) Control + Modifiable risk factor information (3) Control + Growth mindset (4) Control
32. Which of these methods/procedures are considered standard-of-care?	Neither procedure is considered usual care.
33. Who will provide the standard treatment or care referenced above?	X N/A, research does not include usual care/standard treatment __ Study team __ Participant's own health care provider __ Other, specify
34. Why is group assignment necessary, and how will participants be assigned to treatment/experimental or control groups?	__ N/A, research does not involve group assignment Justification/description: Group assignment is necessary to determine the differential effect of each article on task engagement and persistence. Participants will be randomly assigned to a condition using Qualtrics survey software.
35. What will participants experience or be asked to do when assigned to the treatment / experimental group *or* to the control group?	In all conditions, participants will be asked to read an article about mental health and complete a battery of questionnaires at Time 1. In both conditions, participants will complete a battery of questionnaires at Time 2 and Time 3.
36. Note the expected number/length of contacts/meetings, and time commitment for participation (include similar information in consent materials):	3 Expected number of contacts/meetings _____ Minutes/hours for each contact/meeting 30 minutes at Time 1 15 minutes at Time 2 15 minutes at Time 3 _____ Duration of participation (in weeks/months) for intervention 30 minutes for intervention

	_____ Duration of participation (in weeks/months) for long-term follow-up Follow up at Time 2 (one week following Time 1) Follow up at Time 3 (during Fall semester, 3-4 months following Time 1)
Data Collection and Analysis	
37. List the information/specimens that researchers will obtain for this research [xvii]:	Information collected will be data from the battery of questionnaires at Time 1, Time 2 and Time 3. At Time 1, participants will be provided with a participant ID number. Participants will provide their e-mail address at this time. Participant ID will be stored in a file with the participant's e-mail address for follow-up contact purposes.
38. How will research data be obtained?[xviii]	Research data will be obtained through Qualtrics survey software.
39. Identify each research instrument (e.g., diary, questionnaire, data collection log) and describe how its use relates to the study purpose[xix]:	*Demographic questions*. Participants will be asked their gender, age, marital status, race/ethnicity, level of education and treatment seeking history and intent. *Patient Health Questionnaire*. Severity of depression will be measured via the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer & Williams, 2001), a 9-item questionnaire associated containing one item for each symptom of MDD as specified by the DSM. The PHQ-9 score ≥10 has a sensitivity of 88% and a specificity of 88% for MDD. This measure has demonstrated good internal reliability (α=.86). *GAD-7.* Anxiety severity will be measured using the Generalized Anxiety Disorder 7-item scale (GAD-7; Spitzer, Kroenke, Williams & Lowe, 2006) is a common, brief measure of anxiety symptom severity (α=.92;). *ARM-CMD*. Mental health literacy will be assessed using the Awareness of Risks and Management of Common Mental disorders (ARM-CMD) measure developed to assess knowledge and attitudes related to the effective recognition, management and prevention of mental disorders (Zimmermann et al., in preparation). *SF-36- Physical and Mental Health Short Forms.* This measure includes sleep, social activity and health subscales. Sub-scales vary in response formats with

	items rated from either 1-6 or 1-5 (Tarlov et al., 1989). *Healthy diet questionnaire*. Healthy diet will be assessed using a 10-item yes/no scale total of 10 points for health eating behaviors. Higher scores indicates that the participant tries to eat more fiber, more fruit, more vegetables, more fish, less meat, less sweets and pastries, tries to avoid the intake of fat, the consumption of butter, removes fat from meat does not add sugar to drinks (Zazpe et al., 2011). *Substance Use Measure.* Alcohol and substance use will be assessed using a 3-item substance use measure including frequency of alcohol use, cigarette use and drug use (Lee et al., 2015) The internal reliability estimate is (α) .74. *Brief COPE*. Coping strategies will be assessed using the Brief COPE, a 28-item scale assessing various dimensions of healthy and unhealthy coping (B-COPE; Carver, 1997). *Ryff Purpose in life scale*. Purpose in life will be assessed using a 9-item scale (Ryff & Keyes, 1989). *Mental health immutability beliefs measure*. Immutability beliefs will be assessed after the manipulation is complete using a 4-item Likert scale from "strongly disagree," to "strongly agree." Items will be modified from the depression immutability beliefs questionnaire (Schroder et al., 2016) to refer to general mental health (e.g., "Your mental health is something about you that you cannot change very much.")
40. How will researchers analyze the data?[xx]	SPSS will be utilized to conduct a 4 factor between subjects ANOVA, to determine differences between groups in engagement with modifiable risk factors as well as to probe interactions between the effect of receiving the growth mindset education and information about modifiable risk factors.
41. Will this research include records of participants' voices or images?[xxi]	X No __ Yes, audio; describe and justify: __ Yes, video; describe and justify: __ Yes, photographs; describe and justify:

Research Risks	
42. Describe how risks will be minimized through use of sound research design:	X N/A, minimal risk research Description:
43. What precautions will researchers use to avoid unnecessarily exposing participants to risk?	*Check all that apply:* X N/A, minimal risk research __ Using recognized standard practices __ Ensuring researcher expertise/credentialing __ Researcher training __ Minimizing time required for procedures __ Using procedures that are already being performed (e.g., for education or treatment) __ Monitoring participants for adverse reactions __ Monitoring data for safety __ Other, specify:
44. List the discomforts and physical harms that might result from participation in this research; assess the probability, severity, and duration of each discomfort/harm:	No physical discomfort or harm is expected to result from participation in this study.
45. List the social, legal, financial, emotional, or familial harms might result from participation in this research; assess the probability, severity, and duration of each of these harms:	It is possible that emotional discomfort may result from reading about mental health. It is unlikely that this emotional discomfort will persist after the completion of the study.
46. Identify *secondary* and *incidental findings* (see Policy Manual Definitions) that are reasonably expected to result from this research. Explain the plans for whether the findings to participants or others will be disclosed:	X N/A, secondary/incidental findings not expected
47. How will participants be referred to psychological, or other services that may be required as a consequence of participation in the research?	__ N/A, need for referrals not anticipated Explanation: All participants will be provided with a list of contact information for on-campus psychological services including the Counseling Services Center, Psychological Services Center and Downing Clinic (see attached).
Safety Monitoring for Greater than Minimal Risk Research X **Check here** if this is minimal risk research and safety monitoring is not required; **skip** to next section.	
48. Describe the plan to monitor data for safety. Include: • Who will monitor the data for safety concerns? • What data will be reviewed? • How often will the monitoring occur? • How often will cumulative data be reviewed?	
49. Are there specific findings that would trigger an immediate suspension of the research?	__ No __ Yes, specify:

Research Benefits	
50. Are individual participants expected to benefit from being in this research?	X No: It is possible that the individual may benefit from learning more about mental health, but these benefits are not certain. __ Yes, specify:
51. What is the potential value of the knowledge to be gained from this research?	The knowledge gained from this research would be valuable in determining what should constitute core psychoeducation components of mental health literacy interventions in ways that serve to promote mental health through the increased engagement with modifiable risk factors to prevent anxiety and depression.
Protecting Participant Privacy	
52. Will *Protected Personally Identifiable Information* (PPII) be collected for this research (see Policy Manual Definitions)?	X No __ Yes, specify what PPII will be collected and why it is necessary to collect it:
53. How will researchers protect the privacy of prospective participants during initial contact, and interventions or interactions?	Data will be de-identified stored on a secure password protected computers that will only be available to the PI and study personnel.
54. What protections will be in place for investigators to access records generally considered private (e.g., education or personnel records)?	X N/A, records generally considered private will not be accessed for the research __ Compliance with FERPA (for education records) __ Other, describe:
55. Do any state laws for mandatory reporting apply to this research? (See IRB policy for applicable Nevada State Laws.)	X No __ Yes, specify and include in consent document:
56. For researching involving the collection of identifiable information that may have legal ramifications (e.g. illegal drug use, criminal activity), will a *Certificate of Confidentiality* be obtained (see IRB CoC policy)?	__ N/A, no such information will be collected X N/A, identifiers not collected or not maintained __ No, explain why not: __ Yes, upon receipt of the COC, **create** a new package, and **Add** the certificate.
Maintaining Data Confidentiality	
57. Identify the formats in which research records will be maintained by the PI:	__ Paper X Electronic __ Recorded media (e.g., audio/video, digital photos) __ Other, specify:
58. Where will research records be maintained by the PI?[xxii] (*Check all that apply.)*	
X Password-protected file on University/Affiliate server (e.g., UNRNAS) or secure VA network server __ In the UNR Med-hosted environment __ On an external cloud-based solution; **Add** *Business Associate Agreement* or ORD approval for VA research	__ In a locked file cabinet in the PI's office or lab __ In a locked or password-protected office or lab at the University, Affiliate site, or VASNHCS __ Off-site in a secure facility with password-protected access, **Add** *Business Associate Agreement* __ VA research only, off-site in another VA facility, specify:

__ On a password-protected stand-alone desktop/laptop computer (*must* be encrypted) __ On a password-protected Electronic Portable Device (*must* be encrypted)	__ VA research only, off-site in a secure non-VA facility with password-protected access, **Add** documentation of ORD approval __ Other location, specify:
59. Who will have access to research records? NOTE: It is understood the US DHHS, and UNR RI and IRB will have access.	*Check all that apply:* X Principal Investigator X Co-Investigators __ Research assistants __ Collaborating researchers, institutions or organizations, specify: __ Study sponsor __ VASNHCS or Affiliate Site Research Office __ Other federal agencies, specify: __ Other, specify:
60. How will researchers protect against unauthorized disclosure of identifiable information about participants?	__ N/A, data will be collected without identifiers __ Data will immediately be stripped of personal identifiers; no master code list X Data will be coded; master code list will be stored securely and separately __ Other, specify:
61. Will web-based applications be used to obtain, record, or store data (e.g., online survey administrator or sponsor-portal)?	__ No X Yes, identify the server/application[xxiii] Qualtrics
62. Will software provided by a 3rd party (e.g., sponsor) be used to record or transmit data?	X No __ Yes, identify the software and the source; summarize or **Add** data security policy:
63. Will mobile devices be used to collect or record data for this project?	X No __ Yes, with FIPS 140-2 encryption standard __ Yes, with other security measures, specify:
64. Will *identifiable* research records be transmitted or shipped to another location/institution?	X No __ Yes, describe how confidentiality will be maintained during transmission/shipping:
65. How long will the PI store *identifiable* records?	__ N/A, identifiers not collected or not kept __ N/A, data coded; master list will be destroyed before permanent storage X Until the study closes __ Years after study closure (note number): __ Indefinitely __ Other, specify:
66. What will happen to *identifiable* records after the storage period ends? (*Check all that apply.)*	
__ N/A, identifiable data not collected or not stored __ N/A, research data and records will be stored indefinitely (per VHA Records Control Schedule 10-1 when applicable) __ Paper/electronic records will be destroyed. __ Audiotapes/videotapes will be erased or destroyed	__ Coded data will be placed in an existing repository; master code list will be destroyed __ Coded data will be placed in an existing repository; master code list will be maintained by the repository __ Data along with PPII will be maintained by the PI for future research purposes

X The master code list will be destroyed; de-identified data will be maintained by the Investigator indefinitely	__ Other, describe:
Transferring Research Data to a Bank or Repository for Future Uses **X Check here if this is data will not be transferred to a bank or repository; skip to next section.**	
67. Will *identifiable* research data be transferred to a data bank or repository for future use? NOTE: Information about future uses *must* be in consent documents.	__ No __ Yes, name the bank/repository, justify the retention of identifiers, and describe future uses:
68. Specify the oversight mechanisms for future uses of identifiable data transferred to a bank/repository:	__ N/A, identifiable data will not be transferred to a bank/repository __ Existing repository has appropriate oversight mechanisms in accordance with VHA Handbook 1200.12. __ IRB of Record for the bank/repository is responsible for approval and oversight of research involving the records __ Other, specify:
Additional Requirements for VA Research X Check here if this is not VA research; skip to next section.	
69. Check the employment category that applies to the Principal Investigator:	__ VA employee, specify VA percentage of time in 8ths: _____ __ VA WOC (Without Compensation) __ VA-contracted personnel __ Other, specify:
70. How is this research relevant to Veterans?	
71. *If the research involves non-Veteran participants, d*escribe VA's coverage of costs resulting from research-related injury:	__ N/A, all participants will be Veterans Description:
72. Will a non-VA entity (other than as disclosed above) have access to *VA-Sensitive Information/Data* (as defined in VA Handbook 6500, Appendix A)?	__ No __ Yes, name the entities and *check* the type of agreement that will be in place, and **Add** a copy of the agreement: __ Data Use Agreement __ Cooperative Research and Development Agreement (CRADA) __ Other, specify:
Informed Consent Documents/Materials __ Check here if you request IRB approval to waive the requirement for informed consent and skip section.	
73. What materials will be used to inform participants about the research?[xxiv]	__ N/A, not obtaining consent __ Sponsor consent template, revised using *Consent Checklist* X Consent form or information sheet based on a *Consent Form Template* from IRBNet

	__ Simplified info script, sheet, email, letter based on a *Consent Information Script/Sheet Template* from IRBNet __ Other, specify:
74. Will participants in *greater than minimal risk research* be provided with the DHHS required basic and additional elements of informed consent (as specified at 45CFR46.116)?	X N/A, minimal risk research __ N/A, under IRB-Flex for greater than minimal risk research, elements that do not apply to the research are excluded __ Yes[xxv] __ Other:
75. Will participants in *minimal risk research* that is conducted/supported by a federal agency, or that involves incomplete disclosure/deception or prisoners be provided with the DHHS required basic and additional elements of informed consent (as specified at 45CFR46.116)?	__ N/A, greater than minimal risk research (addressed above) X N/A, minimal risk research that does NOT involve federal funding, incomplete disclosure or deception, or prisoners __ N/A, PI requesting IRB approval for ***alteration*** of DHHS requirements for informed consent[xxvi] __ Yes, using a *Consent Form Template* from IRBNet to create the consent document
Obtain the electronic signature of Principal Investigator to confirm the following PI assurances:	
University/Affiliate Principal Investigator Assurance My electronic signature certifies that I have read/prepared the project documents and agree to comply with the PI responsibilities in the IRB Policy Manual and applicable Affiliate policies.	
Obtain the electronic signature of a Responsible Official (RO) or Affiliate Representative.	
University/Affiliate Responsible Official Assurance My electronic signature certifies that I have read the project documents, and agree to comply with the RO responsibilities in the IRB Policy Manual and applicable Affiliate policies.	

[i] **Add** copies of collaborating IRB decisions, as *Other*
[ii] **Add** form *Research*: *International*
[iii] **Add** form *Population: Persons with Cognitive Impairment*
[iv] **See** IRB policy for inherently influential recruitment situations
[v] **See** IRB policy for inherently influential recruitment situations
[vi] **Add** copies of all recruitment materials, as *Advertisements*.
[vii] **NOTE**: Data must be retained for VA research.
[viii] **Disclose** in consent materials, gift value and odds of winning.
[ix] **Disclose** in consent materials, requirement for participant to provide PPII to receive payment.
[x] **Add** form *Consent Waivers.*
[xi] **Add** form *Population: Children to describe child assent and parental permission*
[xii] **Add** form *Population: Persons with Cognitive Impairment*
[xiii] **Add** form *Consent Waivers.*
[xiv] **Disclose** costs to participants or 3rd-party payer in consent materials.
[xv] **For example**: Retinal scans, skin galvanometers,
[xvi] **NOTE**: All research components that are experimental must be identified as such in consent materials.
[xvii] **Include** information that will be obtained from existing records, from activities/procedures performed solely for the research, or from activities/procedures performed as part of standard treatment/educational practice.

[xviii] **Include** descriptions for obtaining data from existing records, prospectively from study procedures, or prospectively from procedures performed for standard treatment/educational practices.

[xix] **Add** non-standard instruments as *Questionnaire/Survey* or *Data Collection*, as applicable.

[xx] **For multi-site research specify** if site-specific data will be analyzed separately. If data will be pooled, indicate if participant identifiers will be maintained and describe how findings will be shared among cooperating PIs.

[xxi] **ONLY** for video or photographs, **Add** video/photo release form. (Release form not required for VA research.)

[xxii] **See** University IT Data Management on the web for information about electronic data management/storage solutions. Additional requirements apply to storage of identifiable information outside of the University. Investigators planning to store Identifiable data on a cloud-based solution or off-campus, *must* contact the University Chief Information Security Officer in the University IT office for requirements.

[xxiii] Add copies of the site's privacy/data security policies.

[xxiv] **Add** all consent materials.

[xxv] Use either the *Consent Checklist* to revise sponsor consent templates or a *Consent Form Template* from IRBNet to create a consent document.

[xxvi] **Add** form *Consent Waivers.*