

Appendix A

OHRP Flowcharts

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

September 24, 2004

Has HHS *prohibited* exemption of the human subjects research?
(All research involving prisoners, some research involving children.)
[Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

NO

Will the *only*** involvement of human subjects be in one or more of the following categories?

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is *not* exempt.

Research conducted in *established or commonly accepted* educational settings, involving *normal education practices*?

YES

Exemption 45 CFR 46.101(b)(1) may apply.

Go to Chart 3

AND/OR

Research involving the use of *educational tests, survey procedures, interview procedures, or observation of public behavior*?

YES

Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.

Go to Chart 4

AND/OR

Research involving collection or study of *existing data, documents, records, or pathological or diagnostic specimens*?

YES

Exemption 45 CFR 46.101(b)(4) may apply.

Go to Chart 5

AND/OR

Research studying, evaluating, or examining *public benefit or service programs*?

YES

Exemption 45 CFR 46.101(b)(5) may apply.

Go to Chart 6

AND/OR

Research involving *taste and food quality evaluation or consumer acceptance studies*?

YES

Exemption 45 CFR 46.101(b)(6) may apply.

Go to Chart 7

NO

YES

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.

Go to Chart 8

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

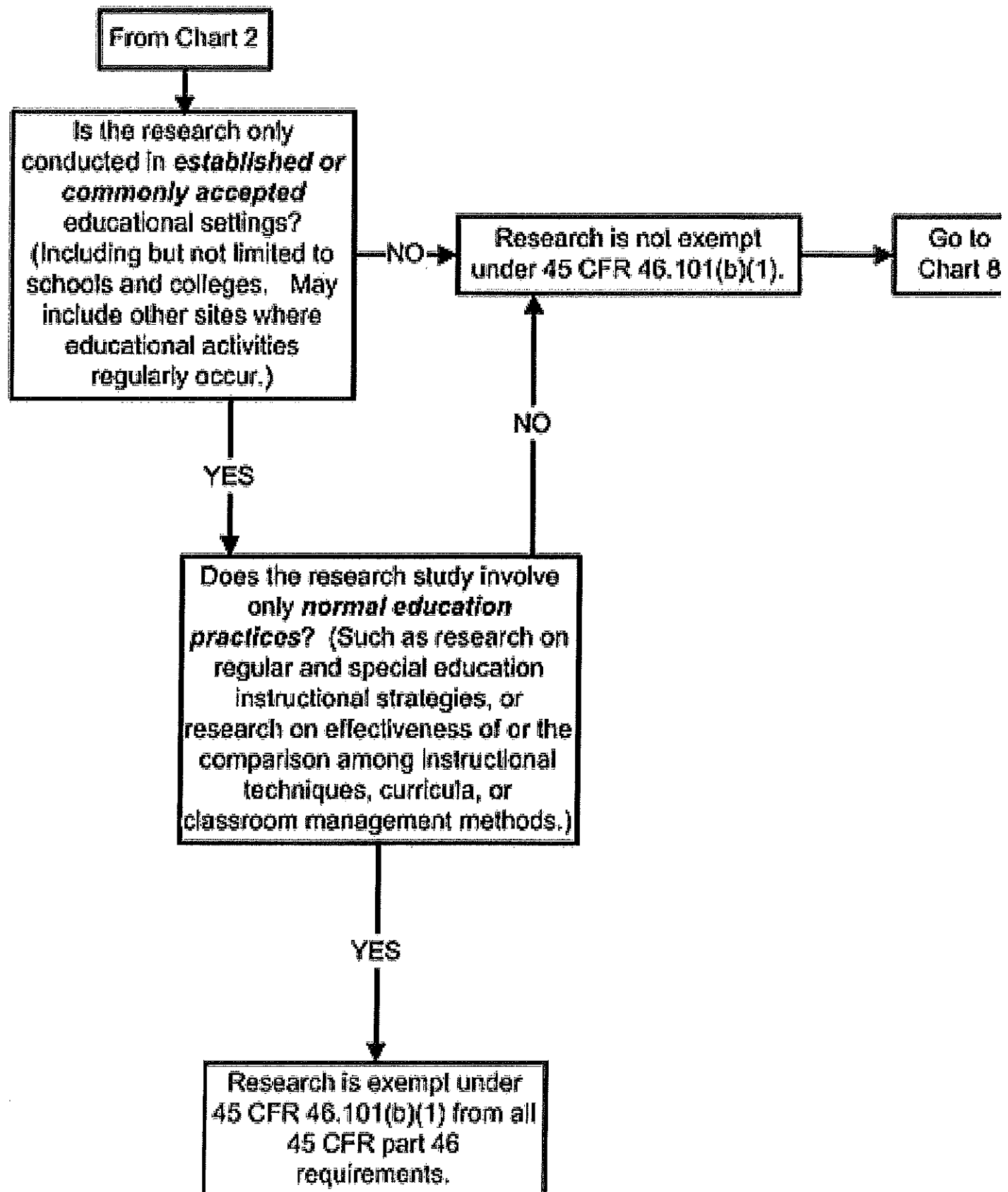


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

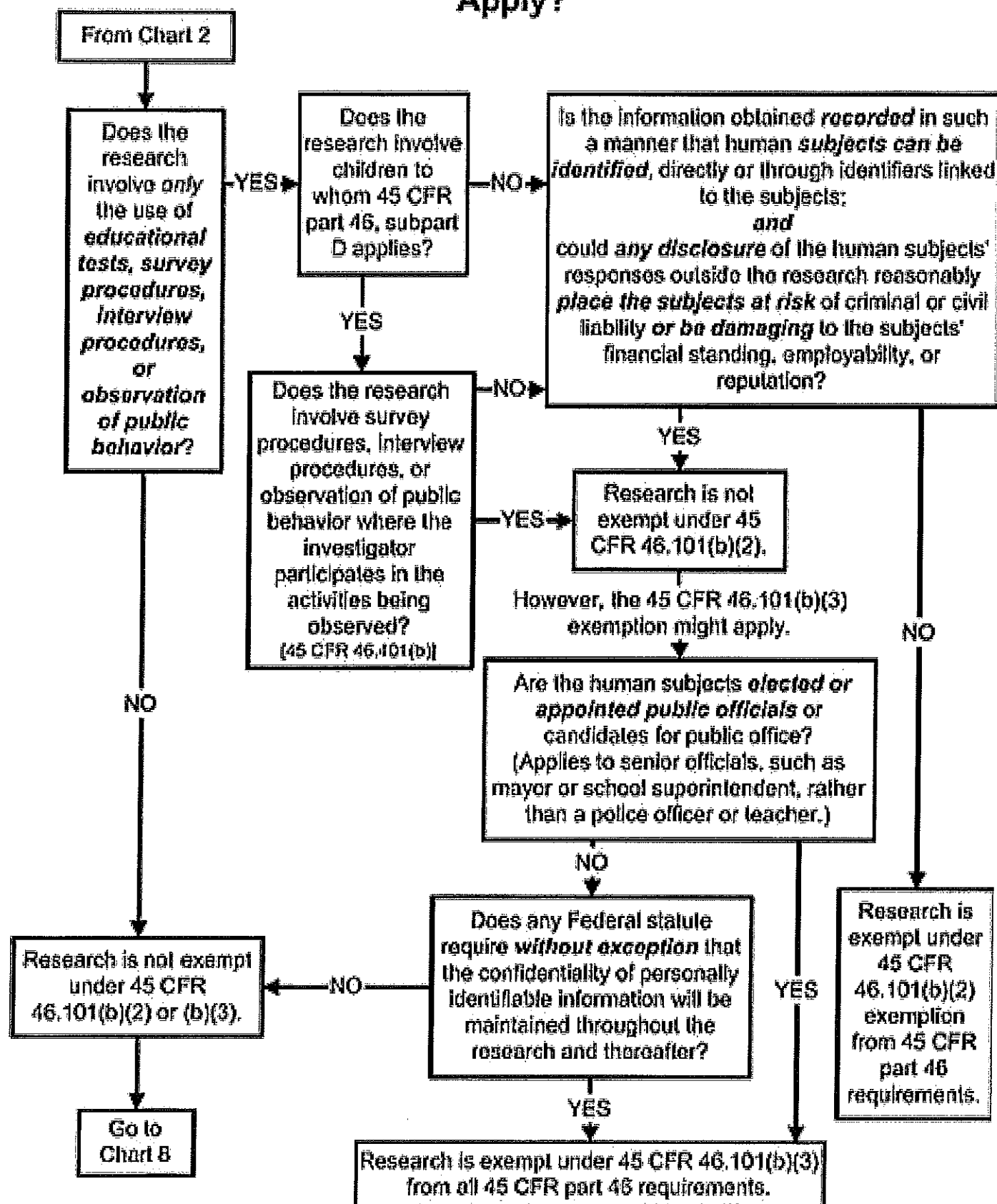


Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply

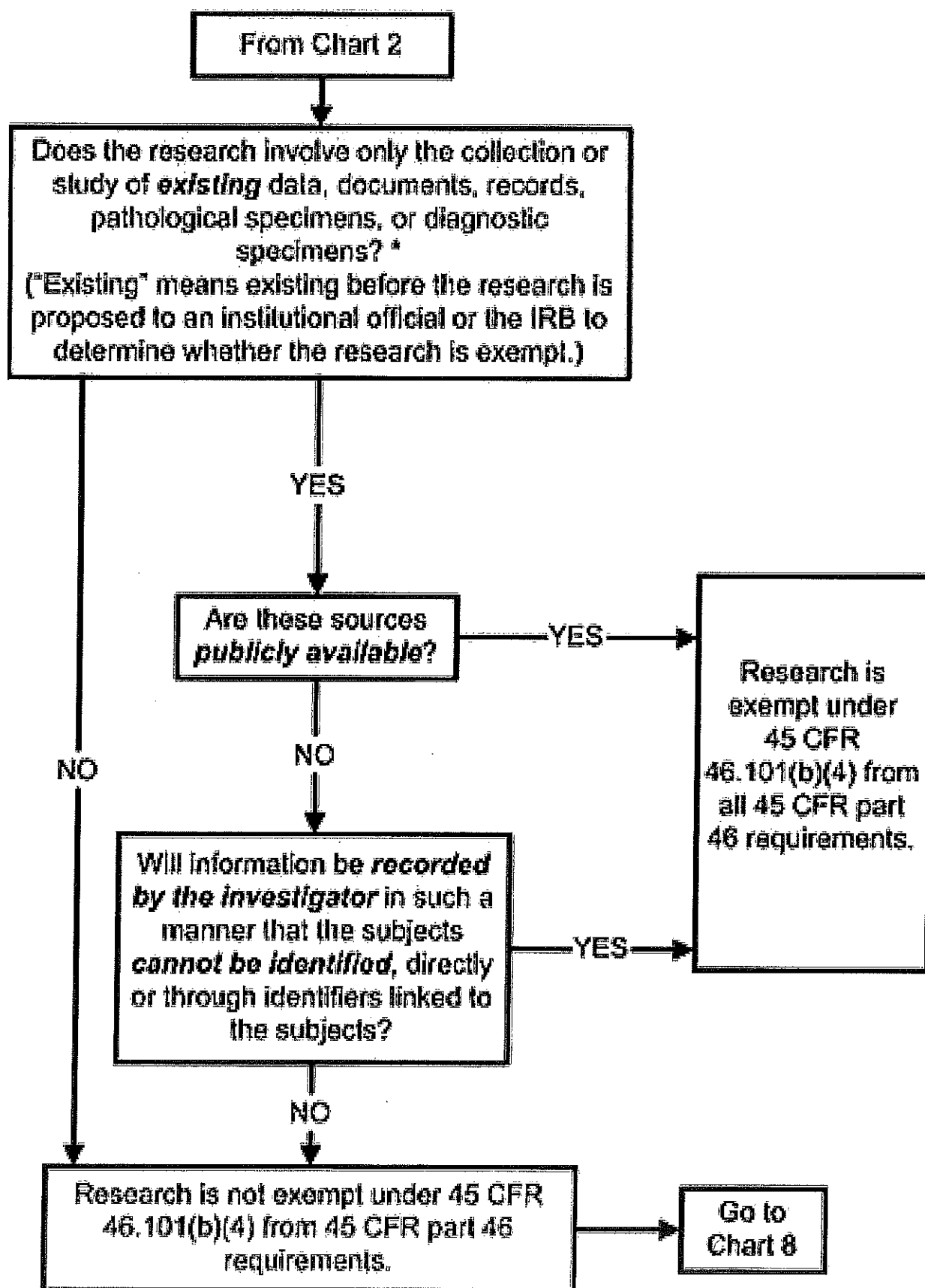


Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

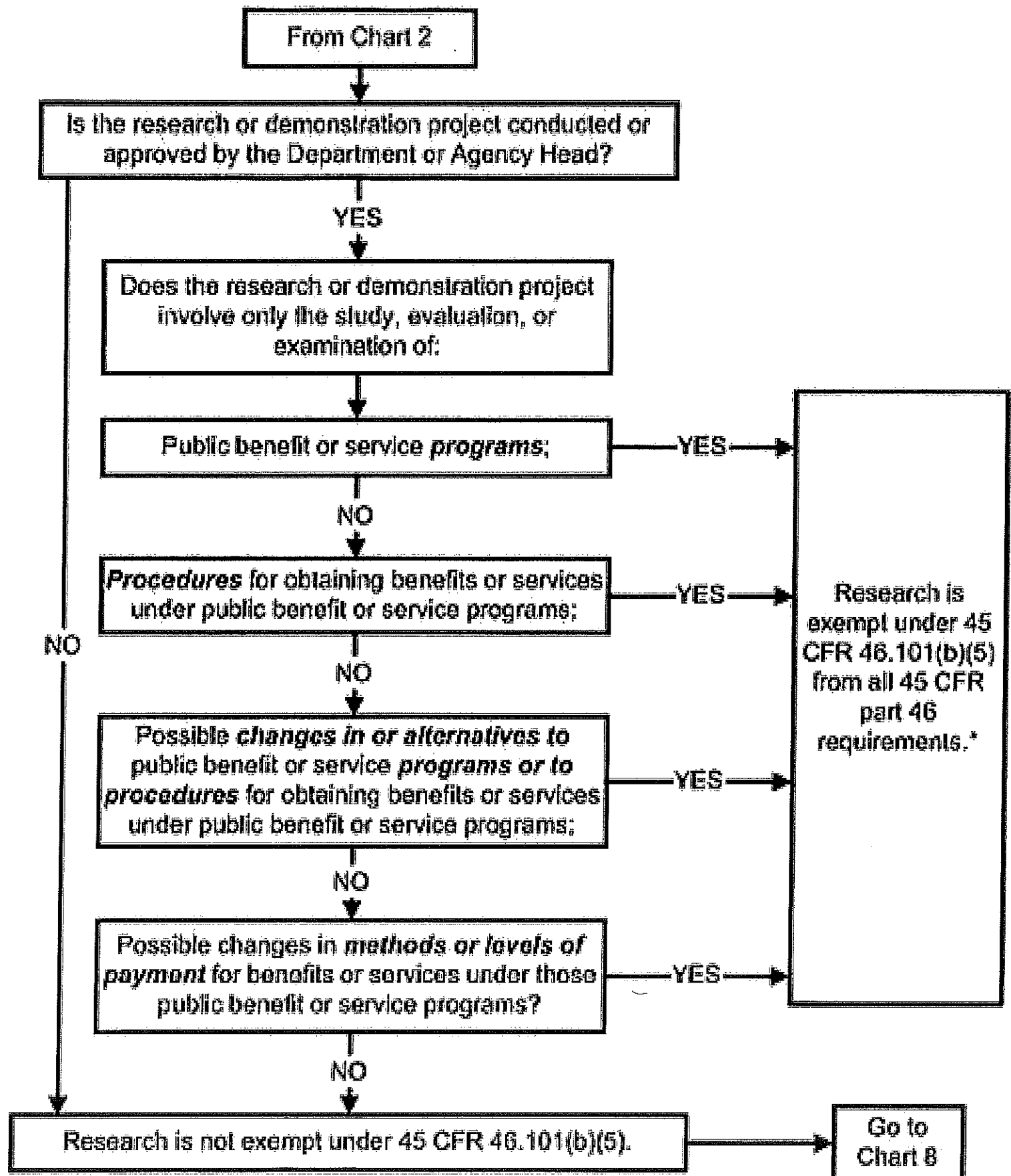


Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

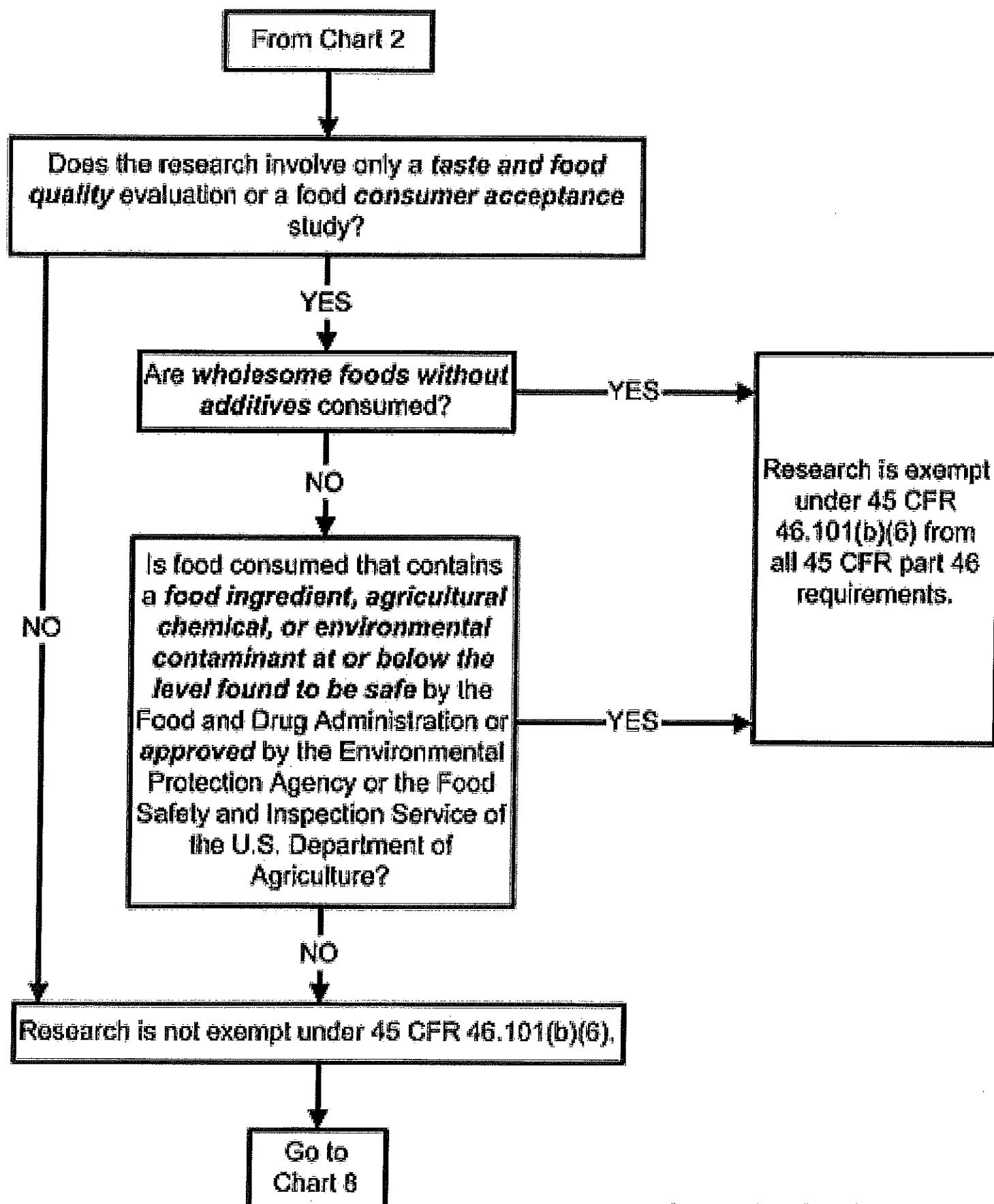


Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.

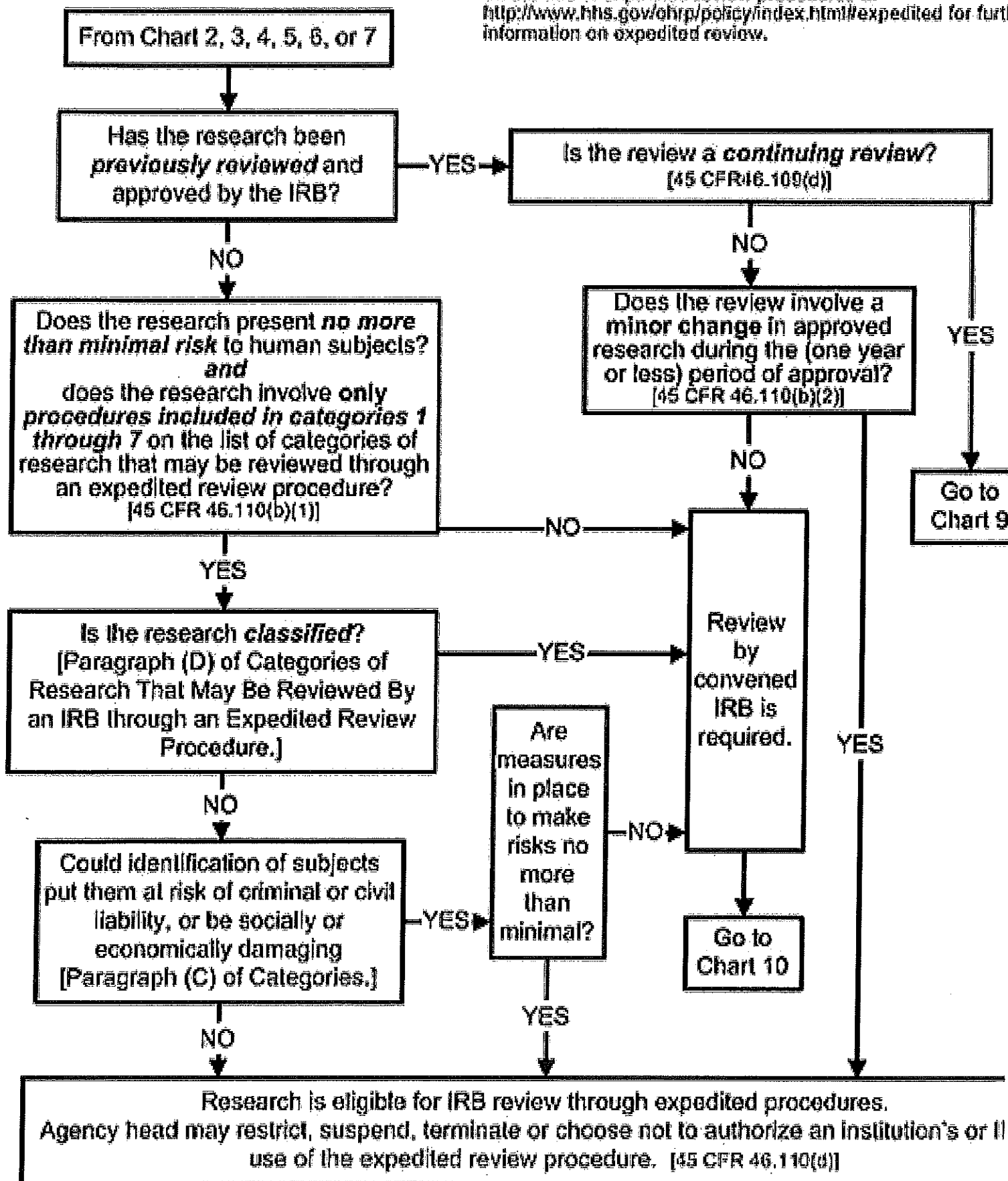


Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

* Note: See expedited review categories, OHRP guidance on the use of expedited review procedures and on continuing review at <http://www.hhs.gov/ohrp/policy/index.html#expedited> and <http://www.hhs.gov/ohrp/policy/index.html#continuing> for further information on expedited review.

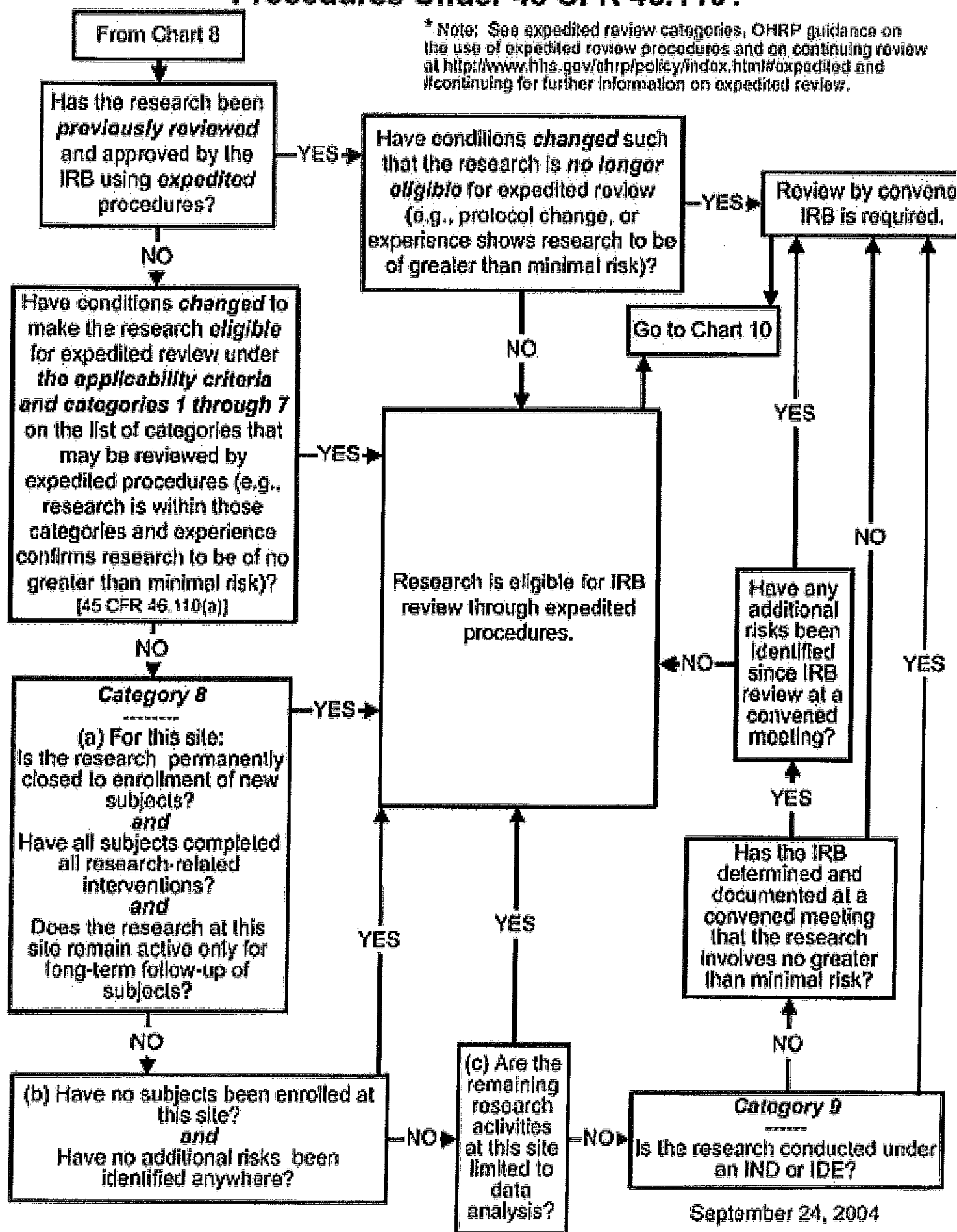


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

******(Note: If subjects include children to whom 45 CFR part 4 subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])

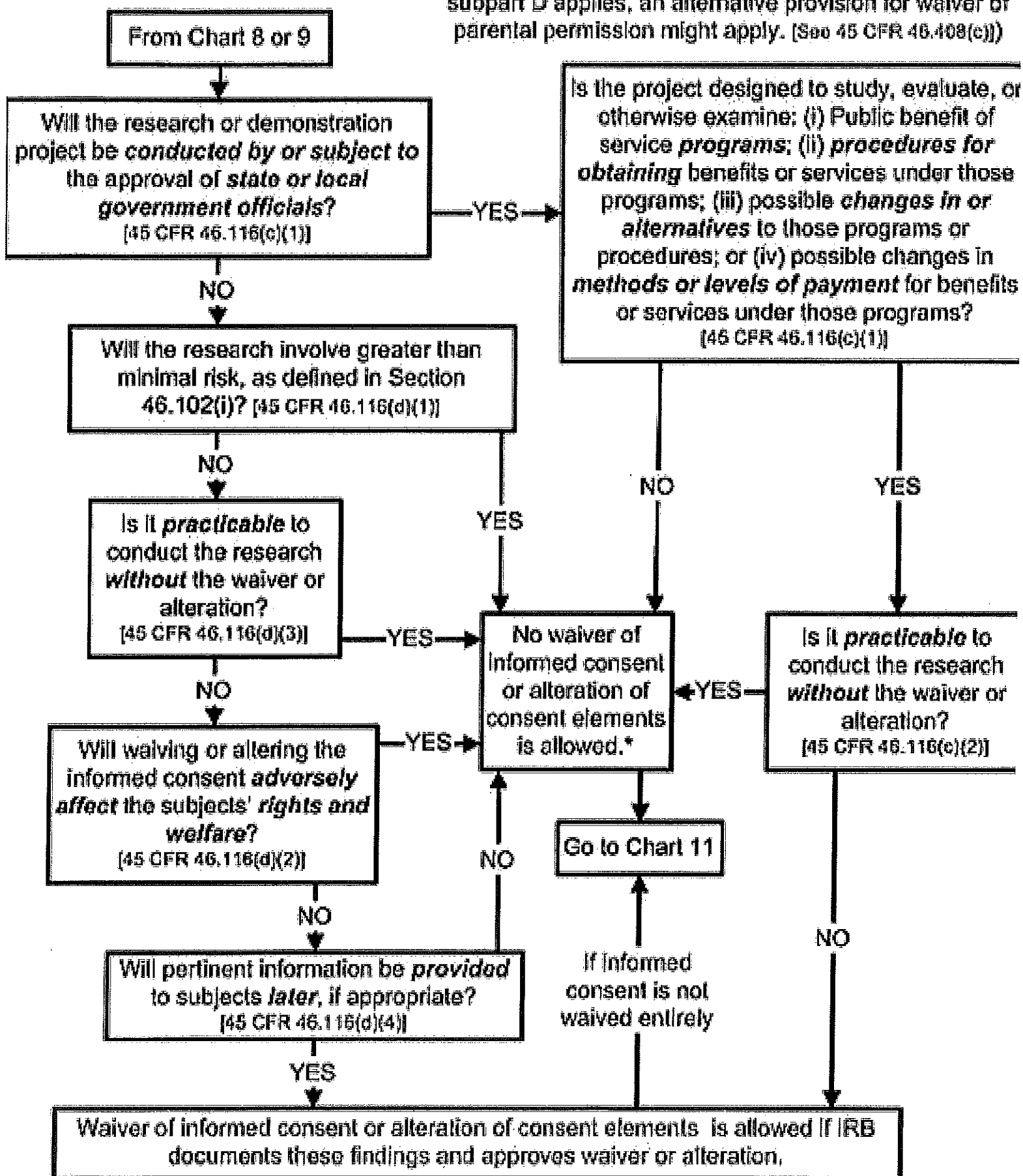
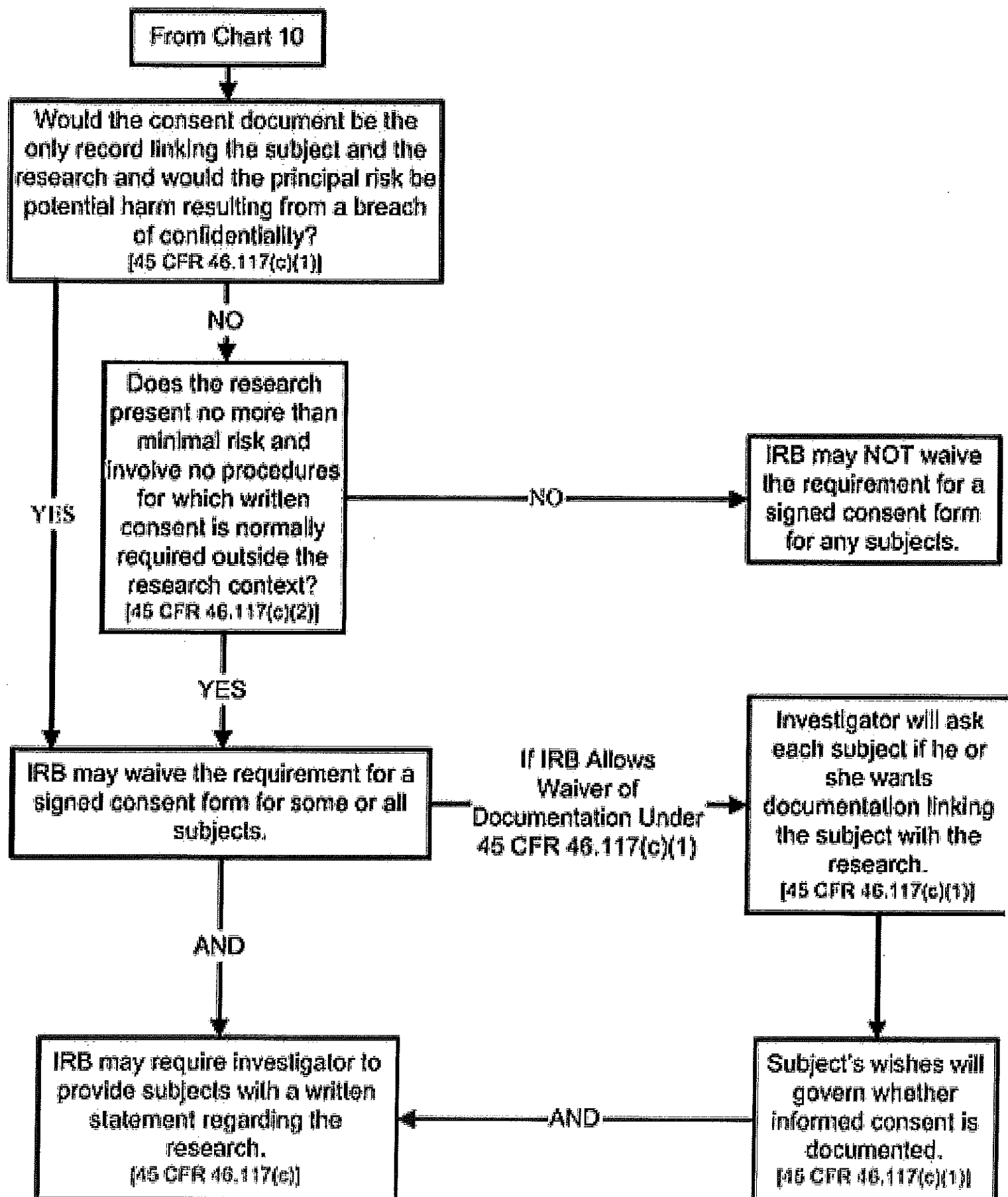


Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



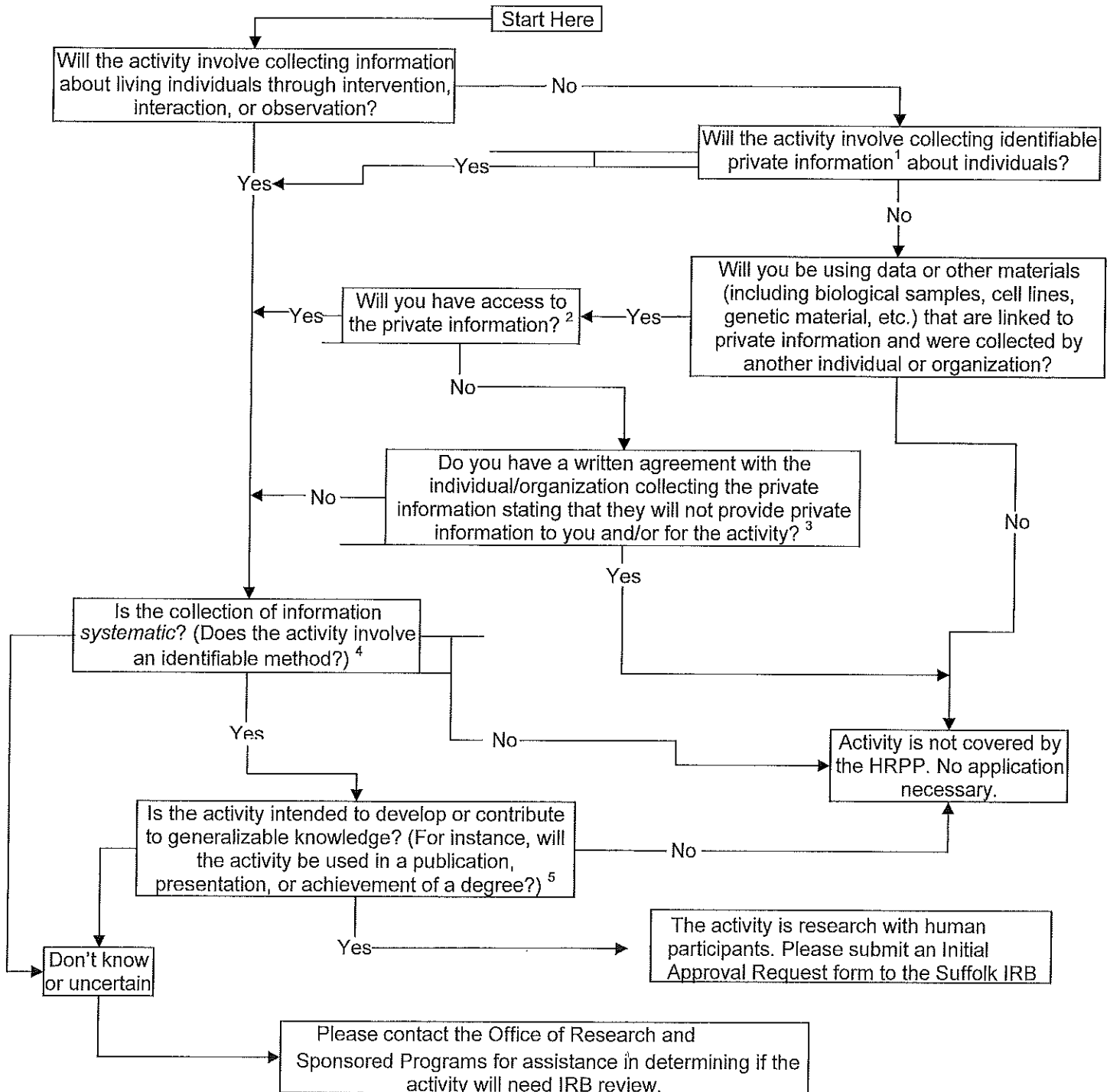
Appendix B

ORSP Flowchart with Guidance

Office of Research and Sponsored Programs

Is your activity covered under the Human Research Protection Program?

It is often very difficult to determine if an activity requires review and approval by the Institutional Review Board (IRB) without significant discussions with someone who has extensive knowledge about the regulations and institutional policies. To help faculty, students and staff with this decision, a decision tree has been designed to identify whether or not activities and/or projects fall under the purview of Suffolk University's Human Research Protection Program (HRPP). If you have any questions or need clarification on an issue, please contact the Office of Research and Sponsored Programs (ORSP) at (617-725-4140) or visit <http://www.suffolk.edu/explore/1407.php>



Office of Research and Sponsored Programs

¹ Identifiable private information is defined as:

- name
- address
- elements of dates related to an individual (e.g., birth date)
- email address
- numbers:
 - telephone
 - fax
 - social security
 - medical record
 - health beneficiary / health insurance
 - certificate or license numbers
 - vehicle
 - account numbers (e.g., credit card)
 - device identification numbers
 - serial numbers
 - any unique identifying numbers, characteristics, or codes (e.g., Global Positioning System (GPS) readings)
- Web URLs
- Internet Protocol (IP) addresses
- biometric identifiers (e.g., voice, fingerprints)
- full face photographs or comparable images

² Will the data you are receiving be coded or de-identified? If coded, at a minimum you still have access to private information.

³ A sample agreement is available from the ORSP, if you wish to use one for your activity.

⁴ Common research methods include interviews, surveys, questionnaires, observation, shadowing, case studies, etc. Some methods are clearly systematic, such as surveys and scripted interviews; others are less formally structured but may still qualify as systematic, such as emergent-design interviews and case studies. Additionally, some disciplines overlap in methodologies or “borrow” methods from other disciplines. For instance, researchers in linguistics or English studies may use ethnographic methods (such as case studies and emergent-design interviews) to examine people’s spoken or written communication practices. While the University encourages the interdisciplinary use of research methods, researchers must be aware that they are responsible for obtaining the necessary ethical review when using new or unfamiliar methods.

Another way of considering the question is to ask: Is there a written (or formulated or articulated) plan for the activity? Does that plan reflect the norms of an established discipline? If you are still unsure if your activity would be considered systematic, please contact the ORSP office for assistance.

⁵ The phrase generalizable knowledge also includes disseminating information through websites, newsletters, brochures, and other similar types of media. For instructors requiring human participant research exclusively as part of course activities, please submit a Research as Class Instruction form to the ORSP.

Appendix C

Full Board

And

Expedited Review

Application Materials

Human Subjects Research Application

For

Full Board

And

Expedited Reviews



FOR IRB USE ONLY -----

Type of Review: ☐ Full Committee ☐ Expedited
Category _____ applies

HUMAN SUBJECTS RESEARCH APPLICATION

Instructions and Important Information: Please complete this form and **submit a copy of the study protocol** and all supporting documentation, **to include verification of CITI or equivalent training for key personnel** for all new non-exempt human subject research. All questions must be answered completely in order to provide the Institutional Review Board with the necessary information to review your proposed research study. IRB approval without conditions **must** be obtained prior to beginning any non-exempt human subject research. The application should be written in layman's terms such that it can be understood by a non-scientist.

1. GENERAL INFORMATION:			
Protocol Title:			
Date:			
2. PRINCIPAL INVESTIGATOR:			
Name:		CITI Certified: <input type="checkbox"/> Yes Date:	
School/Department:			
Campus Mailing Address:		Telephone Number: () -	
E-mail Address:		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff	
3. CO-INVESTIGATOR: If additional space is needed, please add on a separate page.			
Name:		CITI Certified: <input type="checkbox"/> Yes Date:	
School/Department:			
Campus Mailing Address:		Telephone Number: () -	
E-mail Address:		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student	
Name:		CITI Certified: <input type="checkbox"/> Yes Date:	
School/Department:			
Campus Mailing Address:		Telephone Number: () -	
E-mail Address:		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student	
4. RESEARCH STAFF: If additional space is needed, please add on a separate page. All research staff must be CITI certified in the protection of human research subjects.			
Name		CITI Certified	
		<input type="checkbox"/> Yes Date:	
		<input type="checkbox"/> Yes Date:	
		<input type="checkbox"/> Yes Date:	
		<input type="checkbox"/> Yes Date:	
		<input type="checkbox"/> Yes Date:	
5. COLLABORATORS FROM OTHER INSTITUTIONS: If you will be conducting this study in collaboration with non-Suffolk investigators or in non-Suffolk facilities, please complete the section below. If the IRB from a collaborating institution has approved their participation in this research study, attach a copy of the IRB approval letter. <input type="checkbox"/> N/A			
Name	Affiliated Institution	IRB Approval	CITI Certified
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Pending	<input type="checkbox"/> Yes
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Pending	<input type="checkbox"/> Yes
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Pending	<input type="checkbox"/> Yes
Do the collaborating institutions hold a Federalwide Assurance (FWA)? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If yes, specify which institutions hold an FWA:			
If collaborator is employed by FWA affiliated institution, provide point of contact (name, email address and phone number) for that institution's IRB: Name: _____ Email: _____ Phone: _____			
Does the involvement of Suffolk University include the receipt of a sub-award from a collaborating institution? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Does any part of this research involve collaboration with an independent investigator? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If yes, please identify investigator:			

Is the involvement of a Suffolk University investigator limited to the evaluation of de-identified data? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, complete a <i>Human Subject Research Application for Exemption</i> in lieu of this form	
6. FUNDING SOURCES: If the study is funded, please provide a copy of the full grant, proposal and/or award <input type="checkbox"/> N/A	
<input type="checkbox"/> External Federal-Fund	Agency:
<input type="checkbox"/> External Non-Federal Fund	Source:
7. PURPOSE AND SCOPE: Please provide a brief summary of any relevant background information, study aims and its hypothesis. Please provide a rationale for the use of human subjects in meeting your study objectives.	
Duration: From: _____ To: _____	
Study Site(s): _____	
8. DECEPTION	
Does this study involve the use of deception? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, describe in detail how deception is to be used, include a plan for debriefing participants, and attach any debriefing scripts that will be used.	
9. DESCRIPTION OF STUDY POPULATION: Maximum number of subjects should take into account potential drops or withdrawals from the study. The maximum number indicated below cannot be exceeded unless a modification is submitted and approved by the IRB. Please note: the inclusion of any subjects under the age of 18 requires parental permission and child assent.	
Maximum Number of Subjects to be Enrolled: _____	Age Range: _____
Characteristics of Study Population: Please check all that apply.	
<input type="checkbox"/> Elderly	<input type="checkbox"/> Children (minors under the age of 18)
<input type="checkbox"/> Suffolk Students/Staff	<input type="checkbox"/> Educationally-Disadvantaged Persons
<input type="checkbox"/> Prisoners	<input type="checkbox"/> Economically Disadvantaged Persons
<input type="checkbox"/> Non-English Speaking	<input type="checkbox"/> Ethnic Minorities (exclusively)
<input type="checkbox"/> Cognitively Impaired	<input type="checkbox"/> Pregnant Women
<input type="checkbox"/> Fetuses /Neonates	<input type="checkbox"/> Other: _____
10. SELECTION OF SUBJECTS:	
Describe the inclusion/exclusion criteria and explain rationale for such. Describe how the selection of subjects is equitable. Explain rationale for using special populations such as children, pregnant women, prisoners, minorities or any vulnerable individuals and describe the additional safeguards that are in place to protect their rights and welfare. Provide rationale for concluding that the risks and benefits are fairly distributed among the population that stands to benefit from the research. If Suffolk University students are being exclusively recruited for the research study, provide sufficient rationale.	
11. RECRUITMENT TOOLS: Please provide copies for all marked.	
<input type="checkbox"/>	Flyers, Posters, Brochures
<input type="checkbox"/>	Study Advertisement (e.g., radio, television, online (Facebook, craigslist, private or public websites), newspaper, student newsletters, etc.)
<input type="checkbox"/>	Word of Mouth (e.g., participants referring other individuals to study)
<input type="checkbox"/>	In Person Recruitment (e.g., public events, meetings, open houses, school events, etc.)
<input type="checkbox"/>	Referrals (e.g., psychologist refer patients to study, teachers refer students to study, etc.)
<input type="checkbox"/>	Scripts (e.g., phone scripts, e-mail scripts, screening scripts, presentations, etc)
12. RECRUITMENT PROCESS: Describe in detail how subjects will be identified, method of initial contact and rationale for such method. If the recruitment process involves the recruitment of children who are being accessed through school or places where children participate in extracurricular activities, a letter of authorization must be obtained from the school principal, district superintendent, or administrative director or CEO of all applicable sites and included with the application. If Suffolk University students are involved in research as subjects, appropriate measures must be in place and addressed below to ensure potential coercion, undue influence, and exploitation is reduced or eliminated.	
13. INFORMED CONSENT/ASSENT/PARENTAL PERMISSION PROCEDURES: Provide copies as separate attachments for all marked.	
<input type="checkbox"/>	Written Informed Consent will be obtained
<input type="checkbox"/>	Waiver of Documentation of Informed Consent per §46.117(c) (Please complete appropriate form)
<input type="checkbox"/>	Informed Consent will be obtained via a short form written document per §46.117(b)(2)
<input type="checkbox"/>	Waiver of some of the elements of informed consent per §46.116(d) (Please complete appropriate form)
<input type="checkbox"/>	Waiver of informed consent per §46.116(d) (Please complete appropriate form)
<input type="checkbox"/>	Participants will be audio or video-taped (Please complete appropriate consent document)
14. INFORMED CONSENT OR ASSENT AND PARENTAL PERMISSION PROCESS: Describe consent or assent and/or parental permission procedures, including the circumstances under which consent/assent and/or parental permission will be sought and obtained, by whom it will be obtained, the nature of information to be provided to prospective subjects, and method of documentation. Include the Flesch-Kincaid Grade level test score of the document (for adults and children 14-17 years old, aim for a score between 7.0 and 8.0). For children 7-13 years old ensure the grade level is age-appropriate.	

<p>The Flesch-Kincaid Grade level test score of the adult informed consent document is:</p> <p>The Flesch-Kincaid Grade level test score of the child assent (if applicable) is (enter NA if not applicable):</p>														
<p>15. PROTECTED HEALTH INFORMATION: If collecting protected health information (PHI), describe the PHI being collected, the purpose for which it will be used, the entity from which the PHI will be collected and whether or not the entity is a HIPAA covered entity. If not applicable, insert NA below and skip item 16.</p>														
<p>16. METHOD OF COLLECTING PROTECTED HEALTH INFORMATION AND AUTHORIZATION: Check all that apply.</p> <p> <input type="checkbox"/> Prospective Chart Review <input type="checkbox"/> Retrospective Chart Review <input type="checkbox"/> Other: <input type="checkbox"/> Authorization to be obtained <input type="checkbox"/> Request Authorization Waiver (Please complete appropriate form) </p>														
<p>17. RESEARCH TOOLS: Please provide copies for all marked.</p> <p> <input type="checkbox"/> Surveys or Questionnaires (e.g. online surveys, mailed surveys, personal or medical history) <input type="checkbox"/> Measurement Instruments (e.g. psychological tests, IQ tests, diagnostic tools) <input type="checkbox"/> Interviews <input type="checkbox"/> In Person <input type="checkbox"/> Phone <input type="checkbox"/> Other: _____ Recorded: <input type="checkbox"/> Audio <input type="checkbox"/> Video <input type="checkbox"/> Focus Groups <input type="checkbox"/> In Person <input type="checkbox"/> Phone <input type="checkbox"/> Other: _____ Recorded: <input type="checkbox"/> Audio <input type="checkbox"/> Video <input type="checkbox"/> Record Review (e.g. chart review, public school records, medical records, agency records) <input type="checkbox"/> Other: _____ </p>														
<p>18. RESEARCH PROCEDURES: Briefly describe the study procedures that a research participant should expect to be involved in during the study. Define the type, frequency, duration of participation (e.g., what is done and when). When applicable, describe which procedures are experimental and which are routine.</p> <p>Will deception be used? <input type="checkbox"/> Yes <input type="checkbox"/> No If deception is used, describe how subjects will be deceived and include your plan for debriefing participants. Debriefing scripts are to be included as a separate attachment to the application.</p>														
<p>19. COMPENSATION METHOD: If participants will not be compensated check this box <input type="checkbox"/> N/A; skip to section 20.</p> <p>Amount/value of total compensation? _____ Type: <input type="checkbox"/> Gift Card <input type="checkbox"/> Cash <input type="checkbox"/> Drawing <input type="checkbox"/> Other: _____</p> <p>If students are participating in research will they receive course credit? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, describe criteria for awarding credit, i.e. amount of credit awarded and alternatives for receiving equivalent credit in lieu of participating in a study as a research subject. If credit is awarded in accordance with departmental policy, include the policy with your submission.</p> <p>Is compensation pro-rated? <input type="checkbox"/> Yes <input type="checkbox"/> No; If yes, describe in detail how it will be pro-rated (payment schedule and amounts): _____</p>														
<p>20. RISKS/DISCOMFORTS: Describe any known or potential risks and/or discomforts (physical, psychological, social, legal or other) and assess their likelihood, seriousness and potential reversibility. Describe procedures for protecting against these risks and assess their likely effectiveness. Describe any alternative procedures that may be available to subjects.</p>														
<p>21. BENEFITS: Describe any potential benefits to the individual subjects and/or to society in general that may be expected from the research. Describe the importance of knowledge that may reasonably be expected to result from the study. If no direct benefits are anticipated, please state so.</p>														
<p>22. RISK/BENEFIT ANALYSIS: Discuss why risks are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.</p>														
<p>23. RESEARCH DATA</p> <p>Will personally identifiable or protected health information be recorded? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If so, please check all that apply:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td><input type="checkbox"/> Names (First and Last)</td> <td><input type="checkbox"/> Date of Birth</td> <td><input type="checkbox"/> Telephone/Fax Number</td> </tr> <tr> <td><input type="checkbox"/> Email Address</td> <td><input type="checkbox"/> Social Security Number</td> <td><input type="checkbox"/> Student ID</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Street address, city, five digit zip code, county</td> <td><input type="checkbox"/> Internet IP Address</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> Other: _____</td> </tr> </table> <p>Will you be sharing any research data with any other investigator outside of Suffolk? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, with whom and for what purpose? _____</p> <p>Will the research data be coded? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, will a link between code and person's identifiable information be retained? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, for how long? _____</p>			<input type="checkbox"/> Names (First and Last)	<input type="checkbox"/> Date of Birth	<input type="checkbox"/> Telephone/Fax Number	<input type="checkbox"/> Email Address	<input type="checkbox"/> Social Security Number	<input type="checkbox"/> Student ID	<input type="checkbox"/> Street address, city, five digit zip code, county		<input type="checkbox"/> Internet IP Address	<input type="checkbox"/> Other: _____		
<input type="checkbox"/> Names (First and Last)	<input type="checkbox"/> Date of Birth	<input type="checkbox"/> Telephone/Fax Number												
<input type="checkbox"/> Email Address	<input type="checkbox"/> Social Security Number	<input type="checkbox"/> Student ID												
<input type="checkbox"/> Street address, city, five digit zip code, county		<input type="checkbox"/> Internet IP Address												
<input type="checkbox"/> Other: _____														
<p>24. DATA SECURITY AND MONITORING PLAN</p> <p><input type="checkbox"/> DSMP is attached.</p>														
<p>25. FINANCIAL AND OTHER CONFLICTS OF INTEREST DISCLOSURE</p> <p><input type="checkbox"/> The investigator and key study team personnel have no financial or other conflicts of interest related to this study.</p> <p><input type="checkbox"/> The investigator or other key study team personnel have conflicts of interest or potential conflicts of interest related to this study. (Identify specifically who on the study team has a conflict of interest. Identify the precise nature of the conflict(s) of interest to include financial conflicts of interest or other and how these conflicts will be managed. Conflicts of interest must be disclosed to research</p>														

participants in informed consent documents).

☐ This project includes an investigator or key personnel from another institution who will comply with his or her own institution's COI policies.

☐ This project involves an investigator or key personnel from another institution who will comply with Suffolk University COI policies (completed Suffolk University COI disclosure form attached).

26. *PRINCIPAL INVESTIGATOR'S CERTIFICATION (E-SIGNATURE)

I certify that the information contained in this application is true. I understand that IRB approval of this application must be received prior to beginning any subject recruitment. I also understand that the IRB must be notified in writing of any modifications made to the study subsequent to approval of this application. I acknowledge and accept my responsibility for protecting the rights and welfare of human research participants as discussed in the Common Rule (45 CFR 46) and Belmont Report. I certify that I will comply with all applicable regulations and directions of the Institutional Review Board, which may include:

1. Conducting this research study as approved by the IRB.
2. Complying with the requirements for the continuing review of research.
3. Submitting any changes to the protocol to the IRB for review and approval prior to implementation.
4. Monitoring and supervising investigators and research staff in the conduct of the research.
5. Maintaining accurate, current and complete records of all study materials including all IRB correspondence.
6. Complying with all state and federal laws as well as Suffolk University's institutional policies regarding the conduct of research with human subjects.
7. Promptly reporting adverse and unanticipated events related to the study to the IRB.
8. Filing a final report with the IRB upon completion of the study.

***E-SIGNATURES ARE *REQUIRED PRIOR TO SUBMISSION* from the following:**

Department Chair or Dean

Principle Investigator

Co-Investigator(s)

Faculty Advisor (for students only if different from PI)

Please contact the Office of Research and Sponsored Programs if you need assistance with setting up an account on www.irbnet.org.

Researcher

DATA AND SAFETY MONITORING PLAN

Instructions: Please complete this form if either:

- Required by a sponsor
- The protocol involves **non-exempt** human subjects research

1. GENERAL INFORMATION	
Protocol Title:	Date:
Principal Investigator:	
Phone:	Email:
Co-Investigator:	
2. DETERMINATION OF RISK	
<input type="checkbox"/>	The protocol is determined to be of minimal risk to subjects. (To satisfy the definition of minimal risk, the estimate of anticipated harms and discomforts of the research for the proposed study population may not be greater than an estimate of "the harms and discomforts ordinarily encountered in daily life or during the performance of routine medical and psychological examinations or tests", i.e. the anticipated harm or discomfort associated with the research is "acceptably-low.") Describe how you determined that the risk associated with this research is "acceptably low."
<input type="checkbox"/>	The research presents more than minimal risk of harm to subjects. Describe the risk of harm to subjects that may potentially be associated with this research (include any potential physical, psychological, financial, legal, or other risks).
3. INDIVIDUAL OR ENTITY RESPONSIBLE FOR THE OVERSIGHT OF THE DSMP. Check if the same as above <input type="checkbox"/>	
Responsible Person:	
Phone:	Email:
4. ACKNOWLEDGEMENT OF WHAT MUST BE MONITORED AND REPORTED	
a. Review of collected data to determine change in initial risk-benefit assessment (adverse events, unanticipated problems, subject withdrawals)	
b. External factors or relevant information that may impact the safety of study participants or ethics of the study such as pertinent scientific literature reports or results of related studies that may have an impact on the safety of study participants or ethical considerations related to the research study	
c. Study procedures designed to protect the privacy of the research subjects and the confidentiality of their research data	
<input type="checkbox"/>	I hereby acknowledge the data and safety monitoring requirements associated with this study and agree to promptly report to the IRB any adverse or unanticipated events related to this study. I understand that I am to submit to the IRB, data and safety monitoring reports concurrent with continuing review <input type="checkbox"/> annually <input type="checkbox"/> semi-annually <input type="checkbox"/> monthly
5. DETAILED DESCRIPTION OF PROCEDURES TO PROTECT PARTICIPANT PRIVACY AND CONFIDENTIALITY OF DATA COLLECTED. Describe procedures for protecting privacy and maintaining confidentiality including collection, storage and future use of data. If applicable, indicate whether codes will be used as a substitute for names and/or identifiable records and how the code list will be maintained separately from the research data. Describe in detail, specific measures that will be taken to prevent a breach of confidentiality. Describe who will have access to the research data, how long written records, tapes, or recordings will be maintained, where and in what manner they will be maintained and/or destroyed (the retention period for IRB records not containing protected health information is a minimum of three years; the retention period for protected health information is six years). In the event a professional association or other entity requires data be stored for a longer period of time, cite the reference; the investigator is responsible for adhering to the longer retention period.	

Sample

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

The following information describes the research study in which you are being asked to participate. You must be 18 years or older in order to participate. Please read the below information carefully and take whatever time is necessary to make your decision. If you have any questions about the study that you would like answered before you decide, please feel free to ask. You should feel fully informed before making your decision. If you decide that you would like to participate in this research study, you will be asked to sign this document and you will be given a copy.

TITLE OF RESEARCH STUDY:**PRINCIPAL INVESTIGATOR:** *[Name, department, institutional affiliation]***CO-INVESTIGATOR:** *[name, department, institutional affiliation]***PURPOSE OF RESEARCH:**

The purpose of this research study is to learn more about *[describe the purpose of the study in lay terms that will be understandable to the potential participants. For a general audience, readability should be at the sixth to eighth grade reading level]*. You are being invited to participate in this study because *[describe reasons for asking these individuals to participate]*.

RESEARCH PROCEDURES:

If you decide to volunteer for this research study, you will be asked to *[describe the step-by-step activities chronologically in which the participant will be involved during and after the study. The following items must be included in this section]:*

- *[The length of time a participant will be expected to commit (e.g., You will be asked to complete two interviews at two week intervals and each interview will last approximately 20 minutes).*
- *A description of the types of questions that will be asked; topics that will be covered; and data that will be collected through surveys, measures, questionnaires, school records, medical records, etc. (e.g., During the interview you will be asked about your experiences with depression and anxiety; The measures will ask about your responses to different levels of stress; The questionnaire will ask about your use of social networks, etc).*
- *A description of where and when the participants can expect to complete study procedures and with whom they will interact (e.g., For your first visit one week from today you will be asked to meet a research assistant at Suffolk University's Donahue Building).*
- *A description of any observations, audio or tape recordings that will be made (e.g., Your interview will be audiotaped and transcribed; Written notes will be taken during the interview). Participants should be made aware if agreement to audio or video-taping is a condition for participation. A separate consent to audio or videotape is to be used when only a segment of the research involves audio or video-taping.*

- *A clear definition of which procedures are being done as part of the research and which are standard procedures (e.g., The school sponsored writing workshop you are attending is not part of the research study. This research only seeks to collect information that results from the writing workshop and to analyze it to better understand whether this teaching method is effective).*
- *A clear explanation about the study design (e.g., You will be randomly assigned to a control group or an experimental group by [describe the randomization process]. Neither you nor the investigator can choose the group you will be in. You will have an equal chance of being placed in either group).*
- *Consider numbering the study procedures if they are extensive.]*

RISK AND/OR DISCOMFORTS:

There are no known risks. It is not expected that you will experience any risks and/or discomforts by participating in this research study that are any greater than those normally experienced in everyday life.

OR

There are some risks and/or discomforts that you may experience by participating in this study. These risks and/or discomforts may include *[Describe any risks or discomforts (e.g., boredom or traveling inconveniences and costs) that are reasonably foreseeable and are the result of the study procedures. This includes risks that may result in physical, psychological, legal, social or economic harm, as well as breach of privacy and confidentiality.*

If there is a possibility that unforeseeable risks exists this must be stated (e.g., There may be uncommon or unknown risks that are associated with this study. If you experience any adverse effects related to the study that were not anticipated or described in this form you should report these experiences to the investigators.)]

Describe the measures taken to minimize these risks and/or discomforts.

BENEFITS:

You may directly benefit from participating in this study. These benefits include *[Describe any reasonably expected direct benefits that the individual participants will receive. Compensation for participation is not considered a benefit.]*

OR

There are no direct benefits to you from being in this study. It is possible that others may benefit from this study by *[Describe how the general population may benefit (e.g. Educating faculty and staff at other colleges and universities on the best way to assist students suffering mental health issue may lead to improved mental health care; Your participation will help the investigators learn more about the effectiveness of this treatment model for treating depression in young adults).]*

For Research involving Suffolk Students Include: Your grades will not benefit as a result of your participation in this research study. It is possible that your professor will know if participate in this study;

however, there are safeguards in place to protect your confidentiality and to prevent your professor from knowing if you chose *not* to participate in this study. *[Describe what these safeguards may be]*

For Research involving Prisoners Include: Your housing, correctional program assignments or parole circumstances will not benefit from your participation in this study and you will not be punished or hurt in any way if you choose not to participate. Your release will not be impacted in any way from participating in this study.

ALTERNATIVES:

The alternative is not to participate in this study. *[Most studies will not have relevant alternatives to study procedures. However, there may be circumstance where this may apply in a social behavioral setting (e.g., Your alternative is to attend the school sponsored writing workshop without providing consent for the researchers to collect and record the information resulting from the workshop; There may be alternative methods for dealing with your depression or anxiety, for example, you can go to the Counseling Center at Suffolk University to receive the standard care for treating anxiety or depression.)]*

For Research with PSYCH 114 Students Include: You do not have to participate in this research study to receive the required research credits. There are alternative methods of obtaining such credits.

PRIVACY AND CONFIDENTIALITY:

Your privacy will be protected by *[Describe in detail how participant privacy will be protected (e.g., All interviews will be conducted in a private room, only you and the researchers will be present at all times; You will be asked not to use your real name during the focus group discussions; In describing real life events or experiences, you will be asked to refrain from using places or individuals' real names. Instead you can say my "mother", "father", "school" or "store").]*

The confidentiality *[or anonymity if applicable]* of the information obtained will be maintained by *[Describe in detail how participant confidentiality or anonymity will be protected. Describe the extent to which confidentiality of research records identifying the participant will be maintained and the limits of such confidentiality. Specifically, describe in detail:*

- *Where and how the records will be kept;*
- *Who will have access to these records;*
- *When identifying information is replaced by a code, how the linkage between two items will be maintained, for how long and by whom;*
- *If coding information, whether or not there is any likelihood that subjects can be re-identified simply by the combination of pieces of de-identified information collected (e.g., it is possible the combination of all the de-identified data such as age, country of origin, major in college, marital status, race, gender may allow someone to know the data pertains to a specific individual.)*
- *For online research, describe whether IP addresses or e-mails will be retained and the extent of online data security (e.g., Your data is collected via a secured encrypted network; The IP address tracking system has been disabled for the purpose of this research study; The online survey provider may keep your e-mail address for their records but will not disclose it to any third party.) If using a third party website, you may want to include a link to the websites privacy policy*

- *If a Certificate of Confidentiality is in place, describe the limits of the certificate's protection.*
- *If conducting video or audio recording, describe what will be done with the tapes, plans for storage during use and what will be done after transcription (e.g., The audio tapes will be transcribed and immediately destroyed; The video recordings will be downloaded into a password protected computer and deleted from the video camera).*
- *If conducting focus groups or group interviews, describe the measures taken, if any, to protect other's disclosure of private information (e.g., You will be asked to refrain from using yours or other's real names in talking about your experience. You will be asked to turn off your cell phone camera and refrain from taking pictures or audio and video recording. This will prevent others in the focus group from inadvertently disclosing private information.)]*

COMPENSATION:

You will not receive any money or other form of compensation for participating in this research study.

OR

To compensate you for your time and participation, you will receive *[Describe the monetary or other compensation provided to participants. Include such details as at whether compensation will be pro-rated in the event a subject withdraws from the study and how payments will be distributed. If additional private information is collected for the purpose of compensating participants, this must be clearly stated and a description of how this information will be protected must be included.]*

VOLUNTARY NATURE OF PARTICIPATION/ RIGHT TO WITHDRAW:

Participating in this research is voluntary. You have the right to refuse to participate. If you decide to participate, you may withdraw your consent at any time and any information collected from you will be destroyed. Your withdrawal will not result in any penalty or loss of benefits and/or services that you might be entitled to receive. The investigator may also determine that it is in your best interest to discontinue your participation at any time.

For Research Involving Suffolk Students: Your withdrawal or refusal to participate in this research study will not adversely affect your grade or standing at Suffolk University.

CONTACT INFORMATION:

If you have any questions about this study including the purpose, procedures, and/or risks and benefits you may contact *[Include the principal investigators phone number and e-mail address and mailing as well as that of any co-investigator who is assigned]*

If you have questions about your rights as a research participant or to report any concerns you may have please contact Suffolk University's Institutional Review Board (IRB) at (888) 634-4387.

CONSENT:

I have read the information in this document and I am aware of the risks and benefits involved. I have been given a chance to ask questions and enough time to decide whether to participate. By signing below I am voluntarily agreeing to participate in this research study.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

CONSENT TO AUDIOTAPING AND TRANSCRIPTION OF INTERVIEW

[Insert Study Title]

[Principal Investigator Name, Department]

[Co-Investigator Name, Department (if applicable)]

This study involves the audiotaping of your interview session with the study investigator. Neither your name nor any other identifying information will be associated with the audiotape or the transcript. Only the research team will have access to or listen to the tapes.

The tapes will be transcribed by the investigator or co-investigator and erased once the transcription is checked for accuracy. Transcripts of your interview may be reproduced in whole or in part for use in presentations or written products that result from this study. Neither your name nor any other identifying information (such as your voice) will be used in presentations or in written products resulting from the study.

Immediately following the interview, you will be given the opportunity to have the audiotape erased if you wish to withdraw consent to taping or participation in this study.

Indicate your agreement to each procedure by checking the appropriate box and signing below. If you do not agree to audio-taping, do not complete this document.

☐ I agree to having my interview audio-taped.

☐ I agree to having the audio-taped transcribed.

☐ I agree to the use of the written transcript in presentations and written products.

This consent for audio-taping is effective until *[insert date]*. On or before that date the tapes will be destroyed.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

WAIVER OF SOME OR ALL THE REQUIREMENTS OF INFORMED CONSENT

Instructions: Please complete this form if either:

- A waiver of documentation of informed consent is requested (complete Sections 1 and 2) or;
- A waiver of informed consent or a waiver of any required elements of informed consent is requested (complete Sections 1 and 3).

1. GENERAL INFORMATION	
Protocol Title:	Date:
Principal Investigator:	
Phone:	Email:
Co-Investigator:	
2. WAIVER OF DOCUMENTATION OF INFORMED CONSENT: Please enter the rationale for why the marked criterion is met. Please note to waive this requirement at least one of the criterion <u>must</u> be met. N/A <input type="checkbox"/>	
<input type="checkbox"/>	The only record linking the subject to the research would be the consent document <u>and</u> the principal risk of the research would be a potential harm resulting from a breach of confidentiality. If this criterion is met, each subject must still be asked whether the subject wants to document consent and the subject's wishes must govern.
<input type="checkbox"/>	The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., diagnostic tests).
3. WAIVER OF INFORMED CONSENT If requesting a waiver of a required element of informed consent or the informed consent process altogether, please provide a rationale for each of the following criterion. Please note that a waiver can only be granted if <u>all</u> of the following criteria are met. N/A <input type="checkbox"/>	
(a)	The research involves no more than minimal risk to subjects
(b)	The waiver or alteration will not adversely affect the rights and welfare of the subjects
(c)	The research could not practicably be carried out without the waiver or alteration
(d)	Whenever appropriate, the subject will be provided with additional pertinent information after participation

HIPAA WAIVER AUTHORIZATION

Instructions: Please complete this form if:

- A HIPAA Waiver Authorization is requested (complete Sections 1 and 2). To qualify for a waiver, all of the conditions below must be met. A Waiver of Authorization does not imply that your research is exempt from HIPAA's Privacy Rule; it means only that you do not need a signed authorization from each research subject.

1. GENERAL INFORMATION	
Protocol Title:	Date:
Principal Investigator:	
Phone:	Email:
Co-Investigator:	
2. HIPAA WAIVER OF AUTHORIZATION. If requesting a waiver of authorization for the collection of private health information, please provide a rationale for each of the following criterion. Please note that a waiver can only be granted if <u>all</u> of the following criteria are met. N/A <input type="checkbox"/>	
(a) The research use of the health information does not present more than minimal risk to privacy	
(b) The research could not be done without the requested health information	
(c) It would not be practical to obtain signed authorizations from the research subjects	
(d) The specific elements of health information that are requested are not more than the minimum necessary to accomplish the goals of the study	

REVIEWER (AS NEEDED)**SUBPART D RESEARCH INVOLVING CHILDREN**

Protocol Number:	
Protocol Title:	
Principal Investigator:	Co-Investigator:
Please select which category best describes the study and complete the ASSENT and PARENTAL PERMISSION portions of the worksheet. If research does not fall within one of the listed categories → STOP , research may not include minors.	
<input type="checkbox"/> § 46.404 Research involving only minimal risk.	
<input type="checkbox"/> § 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects, if all of the following criteria is met. If NO on any criterion → STOP ; research may not include minors under this category.	
Yes <input type="checkbox"/> No <input type="checkbox"/>	The risk are justified by the anticipated benefits to the subjects;
Yes <input type="checkbox"/> No <input type="checkbox"/>	The relation of the anticipated benefit to the risk is at least as favorable to the subject as that presented by available alternatives approaches; AND
Yes <input type="checkbox"/> No <input type="checkbox"/>	Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians
<input type="checkbox"/> § 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individuals subjects, but likely to yield generalizable knowledge about the subject's disorder or conditions if all the following criteria is met. If NO on any criterion → STOP research may not include minors under this category.	
Yes <input type="checkbox"/> No <input type="checkbox"/>	The risk represents a minor increase over minimal risk
Yes <input type="checkbox"/> No <input type="checkbox"/>	The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations
Yes <input type="checkbox"/> No <input type="checkbox"/>	The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition
Yes <input type="checkbox"/> No <input type="checkbox"/>	Adequate provisions are made for soliciting assent of the children and permission of their parents or guardian.
<input type="checkbox"/> § 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children if all the following is met. If NO to any criterion → STOP ; research may not include minors under this category.	
Yes <input type="checkbox"/> No <input type="checkbox"/>	The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
Yes <input type="checkbox"/> No <input type="checkbox"/>	Research was submitted to the Secretary of DHHS for further review prior to being approved.
ASSENT <input type="checkbox"/> N/A . If assent will not be obtained → check N/A box and go to Assent Waiver section below.	
Yes <input type="checkbox"/> No <input type="checkbox"/>	Adequate provisions are made for soliciting and documenting the assent of children, when in the judgment of the IRB the children are capable of providing assent. If NO → STOP , research may not include minors
Yes <input type="checkbox"/> No <input type="checkbox"/>	The assent process takes into account the age, maturity and psychological state of the children involved. If NO → STOP , research may not include minors.
Yes <input type="checkbox"/> No <input type="checkbox"/>	The same assent process applies to all children involved in the research? If NO → please provide rationale below.
Please describe what assent process applies to which group of minors in the study.	
ASSENT WAIVER <input type="checkbox"/> N/A . If assent will be obtained → check N/A and complete assent section above. To waive assent one of the following must be met.	
<input type="checkbox"/>	The capability of some or all of the children is so limited that they cannot reasonably be consulted.
<input type="checkbox"/>	The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.
<input type="checkbox"/>	The research meets ALL the same conditions as those for waiver or alteration of informed consent in research involving adults
<input type="checkbox"/>	The research involves no more than minimal risks to subjects;
<input type="checkbox"/>	The waiver or alteration will not adversely affect the rights and welfare of the subjects;
<input type="checkbox"/>	The research could not be practicably carried out without the waiver or alteration; and
<input type="checkbox"/>	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Please provide rationale for your selection:	

PARENTAL PERMISSION <input type="checkbox"/> N/A. <i>If parental permission will not be obtained → check N/A box and go to Parental Permission Waiver section below. If NO on any of the criteria below → STOP, minors may not be involved in the research.</i>	
Yes <input type="checkbox"/> No <input type="checkbox"/>	Adequate provisions are made for soliciting the permission of each child's parents or guardian.
<input type="checkbox"/>	For research conducted under §46.404 or §46.405 listed in the first section of this worksheet → permission of at least one parent is obtained.
<input type="checkbox"/>	For research conducted under §46.406 or §46.407 listed in the first section of this worksheet → permission is obtained from both parents unless one parent is deceased, unknown, incompetent, or reasonably unavailable, or only one parent has legal responsibility for the care and custody of the child.
Yes <input type="checkbox"/> No <input type="checkbox"/>	Parental Permission will be documented.
PARENTAL PERMISSION WAIVER <input type="checkbox"/> N/A. <i>If parental permission will be obtained → check N/A box and go to Parental Permission section above. If NO on any of the criteria below → STOP, minors may not be involved in the research.</i>	
Yes <input type="checkbox"/> No <input type="checkbox"/>	The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children)
Yes <input type="checkbox"/> No <input type="checkbox"/>	An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted for such permission. <i>The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.</i>
Yes <input type="checkbox"/> No <input type="checkbox"/>	The waiver is consistent with federal, state, or local law
Yes <input type="checkbox"/> No <input type="checkbox"/>	The research meets ALL the same conditions as those for waiver or alteration of informed consent.
<input type="checkbox"/>	The research involves no more than minimal risks to subjects;
<input type="checkbox"/>	The waiver or alteration will not adversely affect the rights and welfare of the subjects;
<input type="checkbox"/>	The research could not be practicably carried out without the waiver or alteration; <u>and</u>
<input type="checkbox"/>	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Please provide rationale for your selection:	
Reviewer:	Date:

CHILDASSENT FORM
7-12 years old

Hi! My name is *[enter name of person obtaining assent]*. We are doing a research study about *[enter purpose of study]*. A research study is a way to learn more about people and how they think or behave. It is like an experiment.

We are asking you to be in this study because *[if possible, enter reason for participation e.g. you have a brother or sister who is sick or you are 7 yrs. old and go to the YMCA after school]*

If you decide take part in our study, you will be asked to *[enter procedures in simple terms, if there is more than one study procedures, include them as bullet items]*. The time it will take you do this is about *[enter length of time it should take to complete each activity and over what period of time]*.

Some of these steps may *[enter risks e.g. make you tired, sad, angry, anxious]*.

We do not know if being in this study will help you.

-or-

We think this study may benefit you. A benefit is when something good happens to you. We think the benefit(s) might be *[include a list of benefits]*. We may learn something that will help other children with *[insert topic of investigation or condition under investigation]* some day.

Taking part in this study is your choice. You do not have to be in this study if you do not want to. You can say okay now and change your mind later and no one will be mad at you. Even if the adults who care for you, like your mom and dad say yes, you can still say no.

All the information you share with us will be kept in a safe place. If we write a report about what we learned, we will not use your name. This way no one will know you were in the study.

We are happy to answer all the questions you have. Even if you do not have any questions now but have some later, you can still ask them. Just contact *[enter name of Principal Investigator or contact person for study]* at *[enter phone number and email]*.

If you have questions about what it means to be part of a research study, you can call (888) 634-4387.

If you sign your name below, it means you agree to take part in this research study.

(Sign your name here)

(Date)

(Signature of Person Obtaining Assent)

(Date)

CHILD ASSENT FORM
13 -17 years old

This form provides you important information about the research study you are being asked to participate in. Please read it carefully! When you are finished you should know what the research study is about, what you will be asked to do and what are the likely risks and benefits. If you agree to participate, you will be asked to sign this form. A copy of the form should be given to you.

[TITLE OF RESEARCH STUDY]**PURPOSE OF STUDY:**

We are conducting a research study about *[enter purpose of study in lay terms]*. A research study is a way for scientists to learn more about people and their behaviors. In order to do this, scientists need volunteers to participate in their research. You are being asked to volunteer because *[enter reason for participation]*

RESEARCH PROCEDURES:

If you decide to participate, you will be asked to *[enter procedures in simple terms, if there is more than one study procedure include them as bulleted items]*. It should take you *[enter length of participation and if several phases break them down]* to complete the study.

RISKS AND/OR DISCOMFORTS:

You should know that there is a possibility the study procedures may *[enter risks here e.g. make you angry, sad, nervous, uncomfortable etc.]* It is possible you may feel *[bored, inconvenienced, etc.]*

BENEFITS:

We do not know if this study will help you, personally.

-or-

We think this study may benefit you. A benefit is when something good happens to you as a result of your participation. We think these benefits might be *[enter benefits of study]*.

We may learn something that will help other teens with *[insert topic of investigator]* some day.

ALTERNATIVES:

You have the option to *[enter alternative procedure e.g. attend the school writing workshop without participating in the study.]*

You have the option of not participating in the study.

PRIVACY AND CONFIDENTIALITY:

The information that is collected in this research study will be kept private and confidential. This means that we will do our best to not let anyone see or hear the information you give to us while you participate

or after. We will protect your information by *[enter details of how participants' privacy and confidentiality will be protected]*.

COMPENSATION:

To compensate you for the time you spend in the research study, we will give you *[please describe any monetary or other compensation. Include details like when it will be disseminated and whether it is prorated.]*

-or-

You will not receive anything for participating in the study.

RIGHT TO WITHDRAW:

It is your choice to take part in this study. You do not have to be in this research study if you do not want to. You can say yes now and change your mind later. No one will be mad at you. Even if your parents give permission for you to participate, you can still say no. If we think it is best for you not to be in the research study, we may take you out of the study.

CONTACT INFORMATION:

We are happy to answer any questions you have about the study now or later. If you want to contact the researchers you may call *[enter name of PI or contact information for research assistant]*.

If you have any questions about your rights as a volunteer in this research study, you can call Suffolk University's Institutional Review Board. The IRB is a group of people who ensure the rights and welfare of research participants are protected. You can call or email them at (617) 557-2006 or irb@suffolk.edu.

PARTICIPANT CONSENT:

You can take your time in deciding if you want to participate. If you sign below it means you agree to participate. It also means that you have read this document, understand what it means and the researchers have answered all of your questions.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Assent

Date

Printed Name of Person Obtaining Assent

PARENTAL PERMISSION FORM

The following information describes the research study your son/daughter is being asked to participate in. Please read this form carefully as it provides important information about his/her participation. You have the right to take as much time as you need to make this decision and ask all the questions necessary to be fully informed about your son/daughter's participation. If you decide you want your son/daughter to participate, you will be asked to sign this form. A copy of this form will be provided to you for your records.

[TITLE OF RESEARCH STUDY]**PURPOSE OF STUDY:**

Your son/daughter is being asked to participate in a research study. The purpose of this study is to learn more about *[describe the purpose of the study in lay terms that will be understandable to the parents]*. Your son/daughter is invited to participate because *[describe reasons for asking the child to participate]*.

RESEARCH PROCEDURES:

If you decide you want your child to participate, he/she will be asked to *[describe step-by-step the activities that the parent can expect their child to endure before, during and after the study]*. You must include the following in your description:

- *The length of time the child is expected to commit e.g. your child will be asked to complete two interviews at 2-week intervals. Each interview will last approximately 20 minutes.*
- *Describe the types of questions that will be asked or topics that will be covered in all surveys, measures, questionnaires. Describe the type of data that will be collected from the child's school records, medical records, etc. For example, during the interview your son/daughter will be asked about his experience with being in the soccer team and his/her response to different levels of stress; your son/daughter will be asked about his use of social networking sites.*
- *Describe where and when the parents can expect their child to complete study procedures, whom they will interact with and whether the parents will be allowed to be present. For example, for visit one you will be asked to bring your child to Suffolk University in Boston. He/she will be with a research assistant who will help them complete the surveys and you will be asked to stay in the room.*
- *Describe if audio or video recordings will be made. If you are observing behaviors or taking notes during your interview, you must state so. For example, we will audio record our session with your son/daughter. While we talk to him/her we will be take note of how many times they look towards you for guidance. All audio recordings will be transcribed.*
- *Clearly define which procedures are being done as part of the research and which are non-research procedures. For example, the writing workshop your son/daughter is attending in school is not part of this research. This research is limited to collecting and analyzing the data that result from the workshop to better understand if this is an*

effective teaching method. We will collect your son/daughter's school records to see if their grades have improved as a result.

- *Provide information about the study design. For example, your son/daughter will be assigned by random to a control group or an experimental group. This is similar to a flip of a coin. It is up to chance and not the researchers which group your child is assigned to.*
- *If the study procedures are cumbersome, it may be helpful to number or bullet them.*

RISKS AND/OR DISCOMFORTS:

There are no anticipated risks and/or discomforts that your child should experience as a result of participating in this study.

-or-

There are some risks and/or discomforts your child may experience as result from his/her participation in this study. These risks and/or discomforts include *[Describe any risks or discomforts that are reasonably foreseeable and are a result of study procedures. This includes risks that result in physical, psychological, legal, social or economic harm. Breach of privacy and confidentiality should be considered a risk. Note: This section also includes discomforts. For example, boredom or traveling inconveniences and costs.*

Limit the risks to those that result from the research procedures and not risks children may encounter regardless of their participation. Describe measures you have taken to minimize these risks and/or discomforts.

If a possibility exists that there are risks which are unforeseeable, you must state so. For example, there may be uncommon or unknown risks that are associated with the study. If your son/daughter experience any risks not described in this form, you should report these to the researchers.

BENEFITS:

Your child may benefit from participating in this study. These benefits include *[Describe any expected benefits that the parent can expect their child to experience. Please be mindful not to overstate these benefits]*

-or-

Your child is not promised or guaranteed to benefit from taking part in this research study. It is possible that others may benefit from this study by *[Describe who in the general population may benefit and how. For example, educating faculty and staff at other colleges and universities on these new exercise programs may help the fight against childhood obesity.]*

-OR-

Your child will not benefit from taking part in this study.

ALTERNATIVES:

The alternative is to not allow your child to participate in this study. *[There are many studies that do not have alternative procedures. Some examples of an alternative procedure is that the child complete the standardized survey for diagnosing Autism or standard therapy for dealing with depression as supposed to the experimental used in your study. An alternative is a procedure that is already part of the standard of care for psychologists, sociologists or medical professionals and apply to the condition being studied in the research.]*

PRIVACY AND CONFIDENTIALITY:

Your child's privacy will be protected by *[Describe in detail how the child's privacy will be protected. For example, all interviews will be conducted in a private room with only the researchers and parent present.]*

The confidentiality of the information collected will be maintained by *[Describe in detail how the child's and in certain circumstances, the parent's confidentiality will be protected. Describe the extent to which the confidentiality of the records identifying the child and parents will be maintain and the limits of such confidentiality. Specifically,*

- *Where and how will the records be kept?*
- *Who will have access to the records?*
- *In cases the identifying information is replaced by a code, how the link between the code and private information will be maintained, by whom and for how long?*
- *If you are conducting online research, describe whether IP addresses or e-mails will be recorded and the extend of online data security e.g. your child's data is collected via a secured encrypted network, the IP address tracking system has been disabled or the online survey provider may keep your son's/daughter's email address for their records but will not disclose to any third party.*
 - *You may include a link to the provider's privacy policy.*
- *If you are using a Certificate of Confidentiality, describe the limits of the certificate's protection.*
- *Describe what, if any, information obtained from the child will be disclosed to the parent and under what circumstances.*
- *If you will use video or audio recordings, describe what will be done with the tapes or audio/video electronic files, include plans for storage and what will be done after transcription. For example, the audio recordings will be transcribed and immediately deleted; the video files will be downloaded to a password protected computer and deleted from the video camera.*
- *If you are conducting focus groups or group interviews, describe measures taken, if any, to protect other's disclosure of private information. For example, your son/daughter will be asked to refrain from using his/hers real name or the real names of others in talking about their experience. This measure is taken to minimize the inadvertent disclosure of private information by other children/teens in the group.*

- *If you are a mandated reporter per MA state law, describe the limits of confidentiality as mandated by the statute. If you are unsure whether you are a mandated reporter, please visit <http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter119/Section51a>*
- *If you are obtaining school records, please describe procedures for ensuring FERPA is followed. (see <http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>)*

COMPENSATION:

To compensate your child for his/her time, he/she will be given *[Describe any monetary or other compensation provided to each child. Include such details as whether the compensation is pro-rated in the even a child withdraws from the study before completion and how and when compensation will be distributed. If additional private information is needed to distribute compensation, you must describe what information will be collected and how it will be protected]*

-or-

Your son/daughter will not receive compensation for participating in this research study.

RIGHT TO WITHDRAW:

Your child has the right to refuse to participate or can withdraw from the research study at anytime. Even if you give permission for your son/daughter to participate, it will ultimately be up to him/her to decide whether or not they would like to participate. Your child's withdrawal from the study will not result in any penalties or loss of benefits to which he/she is otherwise entitled. If the researchers feel it is in the best interest of your child, they may withdraw your son/daughter from the study.

[FOR RESEARCH IN SCHOOLS OR UNIVERSITIES: Your son's or daughter's withdrawal from the study will in no way adversely affect his/her grades or standing at ENTER NAME OF SCHOOL].

CONTACT INFORMATION:

If you have any questions about your child's participation in this study including the purpose, study procedures or risks and benefits you may contact *[Include principal investigator's phone, email and mailing address. Where applicable, you may include the research assistant's or co-investigator's contact information as well.]*

If you have questions about your child's rights as a research subject, you may contact Suffolk University's Institutional Review Board at (617) 557-2006 or irb@suffolk.edu.

PARENTAL PERMISSION:

I have read the information in this parental permission form including the risks and benefits associated with the study. All of my questions about my child's participation have been answered to my satisfaction and I have had the opportunity to consider whether or not to allow my son/daughter to participate. I understand I am entitled to receive a copy of this document for my own records.

Parent's Signature

Date

Printed Name of Parent

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

Appendix D

Exemption Request

Human Subjects Research Application Exemption

RESEARCHER



Suffolk University

Office of Research and
Sponsored Programs

INSTITUTIONAL REVIEW BOARD
73 Tremont St.
Boston, MA 02108
Phone: (617) 725-4169
Fax: (617) 725-4166
Email: irb@suffolk.edu

Protocol Number:

FOR IRB USE ONLY-----

☐ Meets Criteria for Exemption ☐ Does Not Meet Criteria for Exemption
under category _____

HUMAN SUBJECT RESEARCH APPLICATION EXEMPTION FROM CONTINUING REVIEW BY THE INSTITUTIONAL REVIEW BOARD

Instructions: Please complete this form with all appropriate signatures and attach a copy of the study protocol and all supporting documentation, to include verification of CITI training for key personnel for all new non-exempt human subject research. All the questions must be addressed in order to provide the Institutional Review Board with the necessary information to review your proposed research study. IRB approval must be obtained prior to beginning any non-exempt human subjects research. The application should be written in layman's terms such that it can be understood by a non-scientist.

1. GENERAL INFORMATION:			
Protocol Title:			
Date:			
2. PRINCIPAL INVESTIGATOR:			
Name:		CITI Certified: <input type="checkbox"/> Yes Date:	
School/Department:			
Campus Mailing Address:		Telephone Number: () - - -	
E-mail Address:		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/>	
3. CO-INVESTIGATOR: If additional space is needed, please add on a separate page.			
Name:		CITI Certified: <input type="checkbox"/> Yes Date:	
School/Department:			
Campus Mailing Address:		Telephone Number: () - - -	
E-mail Address:		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student	
4. RESEARCH STAFF: If additional space is needed, please add on a separate page.			
Name		CITI Certified	
		<input type="checkbox"/> Yes Date:	
		<input type="checkbox"/> Yes Date:	
		<input type="checkbox"/> Yes Date:	
5. COLLABORATORS: If you will be conducting this study in collaboration with non-Suffolk investigators or in non-Suffolk facilities, please complete the section below. If the IRB from a collaborating institution has approved their participation in this research study, attach a copy of the IRB approval letter. <input type="checkbox"/> N/A			
Name	Affiliated Institution	IRB Approval	CITI Certified
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Pending	<input type="checkbox"/> Yes
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Pending	<input type="checkbox"/> Yes
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Pending	<input type="checkbox"/> Yes
Do the collaborating institutions hold a Federalwide Assurance (FWA)? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If yes, specify which institutions hold an FWA:			
Does the involvement of Suffolk University include the receipt of a sub-award from a collaborating institution? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Does any part of this research involve collaboration with an independent (not with FWA institution or organization) investigator? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If yes, please identify investigator:			
Is the involvement of a Suffolk University investigator limited to the evaluation of archived de-identified data? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If yes, check Category 4 under Section 7 and complete Sections 8, 15, 16, 18, 23, 25 and 26 only.			
6. FUNDING SOURCES: If the study is funded, please provide a copy of the full grant, proposal and/or award. <input type="checkbox"/> N/A			
<input type="checkbox"/> External Federal-Funding		Agency:	

<input type="checkbox"/> External Non-Federal Funding	Source:
7. EXEMPTION CATEGORIES: The following categories of research are exempt from continuing review by the IRB. Check all that apply	
<input type="checkbox"/> Category 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as: <ul style="list-style-type: none"> research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 	
<input type="checkbox"/> Category 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: <ul style="list-style-type: none"> information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. <p>Note: this exemption does NOT apply to research involving children as subjects, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.</p>	
<input type="checkbox"/> Category 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that otherwise would not be exempt if: <ul style="list-style-type: none"> the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. 	
<input type="checkbox"/> Category 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.	
<input type="checkbox"/> Category 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: <ul style="list-style-type: none"> public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. 	
<input type="checkbox"/> Category 6. Taste and food quality evaluation and consumer acceptance studies if: <ul style="list-style-type: none"> wholesome foods without additives are consumed or a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. 	
8. PURPOSE AND SCOPE: Please provide a brief summary of any relevant background information, study aims and its hypothesis. Please provide a rationale for the use of human subjects in meeting your study objectives.	
Duration: From: To:	
Study Site(s):	
9. DESCRIPTION OF STUDY POPULATION	
Total Number of Subjects:	Age Range:
Characteristics of Study Population: Please check all that apply.	
<input type="checkbox"/> Elderly	<input type="checkbox"/> Children
<input type="checkbox"/> Suffolk Students/Staff	<input type="checkbox"/> Educationally-Disadvantaged Persons
<input type="checkbox"/> Non-English Speaking	<input type="checkbox"/> Economically Disadvantaged Persons
<input type="checkbox"/> Ethnic Minorities (exclusively)	<input type="checkbox"/> Pregnant Women
<input type="checkbox"/> Fetuses/Neonates	<input type="checkbox"/> Other:
10. SELECTION OF SUBJECTS: Describe the inclusion/exclusion criteria and explain rationale for such. Explain rationale for using special populations such as children, pregnant women, minorities or any vulnerable individuals and describe the additional safeguards that are in place to protect their rights and welfare. Provide rationale for concluding that the risks and benefits are fairly distributed among the population that stands to benefit from the research. If Suffolk University students are involved in research as subjects appropriate measures must be in place to ensure the age requirement for informed consent (age 18 or older) is met. If not, parental permission must be sought for their participation.	
11. RECRUITMENT TOOLS: Please provide copies for all marked.	

<input type="checkbox"/>	Flyers, Posters, Brochures												
<input type="checkbox"/>	Study Advertisement (e.g., radio, television, online (Facebook, craigslist, private or public websites), newspaper, student newsletters, etc.)												
<input type="checkbox"/>	Word of Mouth (e.g., participants referring other individuals to study)												
<input type="checkbox"/>	In Person Recruitment (e.g., public events, meetings, open houses, school events, etc.)												
<input type="checkbox"/>	Referrals (e.g., psychologist refer patients to study, teachers refer students to study, etc.)												
<input type="checkbox"/>	Scripts (e.g., phone scripts, e-mail scripts, screening scripts, presentations, etc)												
12. RECRUITMENT PROCESS: Describe in detail how subjects will be identified, method of initial contact and rationale for such method. If the recruitment process involves the recruitment of children who are being accessed through school or places where children participate in extracurricular activities, a letter of authorization must be obtained from the school principal, district superintendent, or administrative director or CEO of all applicable sites and included with the application.													
13. INFORMED CONSENT/ASSENT/PARENTAL PERMISSION PROCEDURES: Provide copies as separate attachments for all marked.													
<input type="checkbox"/>	Written Informed Consent will be obtained												
<input type="checkbox"/>	Waiver of Documentation of Informed Consent per §46.117(c) (Please complete appropriate form)												
<input type="checkbox"/>	Informed Consent will be obtained via a short form written document per §46.117(b)(2)												
<input type="checkbox"/>	Waiver of some of the elements of informed consent per §46.116(d) (Please complete appropriate form)												
<input type="checkbox"/>	Waiver of informed consent per §46.116(d) (Please complete appropriate form)												
14. INFORMED CONSENT OR ASSENT AND PARENTAL PERMISSION PROCESS: Describe consent/assent and/or parental permission procedures to be followed, including the circumstances under which consent/assent and/or parental permission will be sought and obtained, the nature of information to be provided to prospective subjects, and method of documentation.													
15. PROTECTED HEALTH INFORMATION: If collecting protected health information (PHI), describe the PHI being collected, the purpose for which it will be used, the entity from which the PHI will be collected and whether or not the entity is a HIPAA covered entity. If not applicable, insert NA below and skip item 15.													
16. METHOD OF COLLECTING PROTECTED HEALTH INFORMATION AND AUTHORIZATION: Check all that apply.													
<input type="checkbox"/>	Prospective Chart Review	<input type="checkbox"/>	Retrospective Chart Review	<input type="checkbox"/>	Other:								
<input type="checkbox"/>	Authorization to be obtained	<input type="checkbox"/>	Request Authorization Waiver (Please complete appropriate form)										
17. RESEARCH TOOLS: Please provide copies for all marked.													
<input type="checkbox"/>	Surveys or Questionnaires (e.g. online surveys, mailed surveys, personal or medical history)												
<input type="checkbox"/>	Measurement Instruments (e.g. psychological tests, IQ tests, diagnostic tools)												
<input type="checkbox"/>	Interviews	<input type="checkbox"/>	In Person	<input type="checkbox"/>	Phone	<input type="checkbox"/>	Other:	<input type="checkbox"/>	Recorded:	<input type="checkbox"/>	Audio	<input type="checkbox"/>	Video
<input type="checkbox"/>	Focus Groups	<input type="checkbox"/>	In Person	<input type="checkbox"/>	Phone	<input type="checkbox"/>	Other:	<input type="checkbox"/>	Recorded:	<input type="checkbox"/>	Audio	<input type="checkbox"/>	Video
<input type="checkbox"/>	Record Review (e.g. chart review, public school records, medical records, agency records)												
<input type="checkbox"/>	Other:												
18. RESEARCH PROCEDURES: Describe the study procedures that a research participant should expect during the protocol. Define the type, frequency, duration of participation (e.g., what is done and when). When applicable, describe which procedures are experimental and which are routine. Does the study involve the use of deception? <input type="checkbox"/> Yes <input type="checkbox"/> No If deception is to be used, the study does not meet criteria for exemption.													
19. COMPENSATION METHOD: If participants will not be compensated check this box <input type="checkbox"/> N/A; skip to section 20.													
Amount/value of total compensation?			Type: <input type="checkbox"/> Gift Card; <input type="checkbox"/> Cash; <input type="checkbox"/> Raffle; <input type="checkbox"/> Other:										
If students are participating in research will they receive course credit? <input type="checkbox"/> Yes <input type="checkbox"/> No													
If yes, describe criteria for awarding credit, i.e. amount of credit awarded and alternatives for receiving equivalent credit in lieu of participating in a study as a research subject.													
Is compensation pro-rated? <input type="checkbox"/> Yes <input type="checkbox"/> No; If yes, how:													
20. RISKS/DISCOMFORTS: Describe any known or potential risks and/or discomforts (physical, psychological, social, legal or other) and assess their likelihood, seriousness and potential reversibility. Describe procedures for protecting against these risks and assess their likely effectiveness. Describe any alternative procedures that may be available to subjects including the choice not to participate.													
21. BENEFITS: Describe any potential benefits to the individual subjects and/or to society in general that may be expected from the research. Describe the importance of knowledge that may reasonably be expected to result from the study. If no direct benefits are anticipated, please state so.													
22. RISK/BENEFIT ANALYSIS: Discuss why risks are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.													
23. RESEARCH DATA													

Will personally identifiable or protected health information be recorded? <input type="checkbox"/> Yes <input type="checkbox"/> No		
If so, please check all that apply:		
<input type="checkbox"/> Names (First and Last)	<input type="checkbox"/> Date of Birth	<input type="checkbox"/> Telephone/Fax Number
<input type="checkbox"/> Email Address	<input type="checkbox"/> Social Security Number	<input type="checkbox"/> Student ID
<input type="checkbox"/> Street address, city, five digit zip code, county	<input type="checkbox"/> Internet IP Address	<input type="checkbox"/> Other:
Will you be sharing any research data with anyone outside of Suffolk? <input type="checkbox"/> Yes <input type="checkbox"/> No		
If yes, with whom and for what purpose?		
Will the research data be coded? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
If yes, will a link between code and person's identifiable information be retained? <input type="checkbox"/> Yes <input type="checkbox"/> No		
If yes, for how long?		
24. PRIVACY AND CONFIDENTIALITY: Describe procedures for protecting privacy and maintaining confidentiality including procedures for collection, storage and future use of data. Describe whether codes will substitute names and/or identifiable records, who will have access to study data, whether database will be password-protected or encrypted for online data collection. Describe how long written records, tapes, or recordings will be maintained and in what manner they will be kept or destroyed (the retention period for IRB records not containing protected health information is a minimum of three years; the retention period for protected health information is six years).		
25. FINANCIAL CONFLICTS OF INTEREST DISCLOSURE		
<input type="checkbox"/> The investigator and key study team personnel have no financial or other conflicts of interest related to this study.		
<input type="checkbox"/> The investigator or other key study team personnel have conflicts of interest or potential conflicts of interest related to this study. (Identify specifically who on the study team has a conflict of interest. Identify the precise nature of the conflict(s) of interest to include financial conflicts of interest or other and how these conflicts will be eliminated or managed. Conflicts of interest must be disclosed to participants during the informed consent process.)		
<input type="checkbox"/> This project includes an investigator or key personnel from another institution who will comply with his or her own institution's COI policies.		
<input type="checkbox"/> This project involves an investigator or key personnel from another institution who will comply with Suffolk University COI policies (completed Suffolk University COI disclosure form attached).		
26. *PRINCIPAL INVESTIGATOR'S CERTIFICATION (E-SIGNATURE)		
<p>I certify that the information contained in this application is true. I understand that IRB approval of this application must be received prior to beginning any subject recruitment. I also understand that the IRB must be notified in writing of any modifications made to the study subsequent to approval of this application. I acknowledge and accept my responsibility for protecting the rights and welfare of human research participants as discussed in the Common Rule (45 CFR 46) and Belmont Report. I certify that I will comply with all applicable regulations and directions of the Institutional Review Board, which may include:</p> <ol style="list-style-type: none"> 1. Conducting this research study as approved by the IRB. 2. Submitting any changes to the protocol to the IRB for review and approval prior to implementation. 3. Monitoring and supervising research staff in the conduct of the research. 4. Maintaining accurate, current and complete records of all study materials including all IRB correspondence. 5. Complying with all state and federal laws as well as Suffolk University's institutional policies regarding the conduct of research with human subjects. 6. Promptly reporting adverse and unanticipated events related to the study to the IRB. 		

***E-SIGNATURES ARE REQUIRED PRIOR TO SUBMISSION from the following:**

Department Chair or Dean

Principle Investigator

Co-Investigator(s) (if applicable)

Faculty Advisor (for students only if different from PI)

Please contact the Office of Research and Sponsored Programs if you need assistance with setting up an account on www.irbnet.org.

Appendix E

OHRP Informed Consent Guidance

Office for Human Research Protections (OHRP)

§46.116 Informed Consent Checklist - Basic and Additional Elements

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- **Research, Rights or Injury:** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional Elements as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
 - Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
 - Any additional costs to the subject that may result from participation in the research
-

- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study

§46.117 Documentation of Informed Consent Checklist

- Except as provided in paragraph "c" of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Written

The consent form may be either of the following:

1. A **written consent** document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

Done Orally

2. A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Waiver of Requirement for Signed Form

- An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

1. That the only record linking the subject and the research would be the consent document, and the **principal risk** would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent

§ 46.116 - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- C: 1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- C: 2. The research could not practicably be carried out without the waiver or alteration.
- D: 1. The research involves no more than minimal risk to the subjects;
- D: 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- D: 3. The research could not practicably be carried out without the waiver or alteration; and
- D: 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Special Requirements - 45 CFR 46 Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research

Assent/Waiver

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances, in which consent may be waived in accord with §46.116 of Subpart A.

Parents

- The IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405.
- Where research is covered by §46.406 and §46.407, and permission is to be obtained from

parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

- If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

Content last reviewed on July 8, 2014.

Appendix F

IRB Related Review Flow Charts

Chart1: Processing New Protocols (part1)

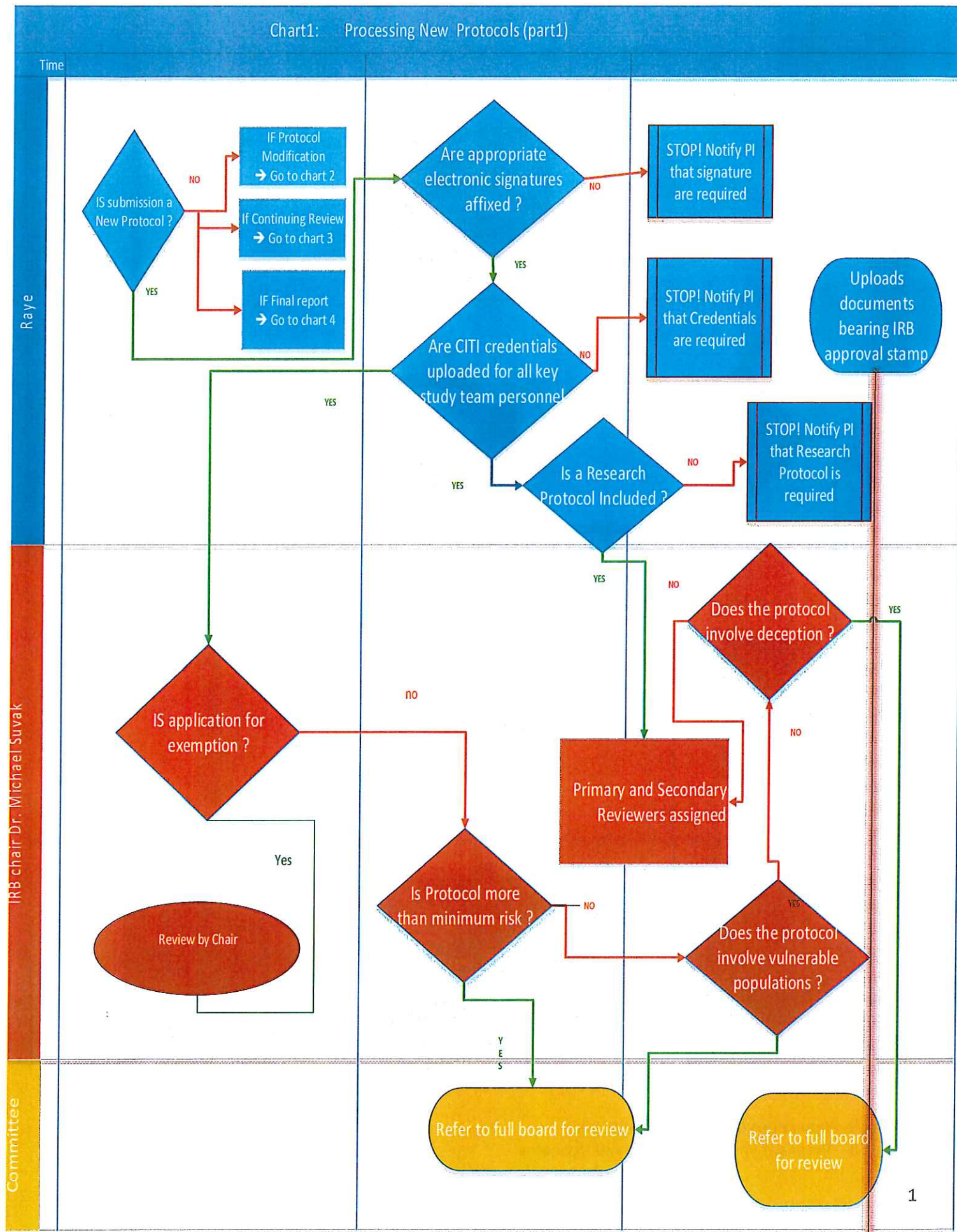


Chart1: Processing New Protocols (part2)

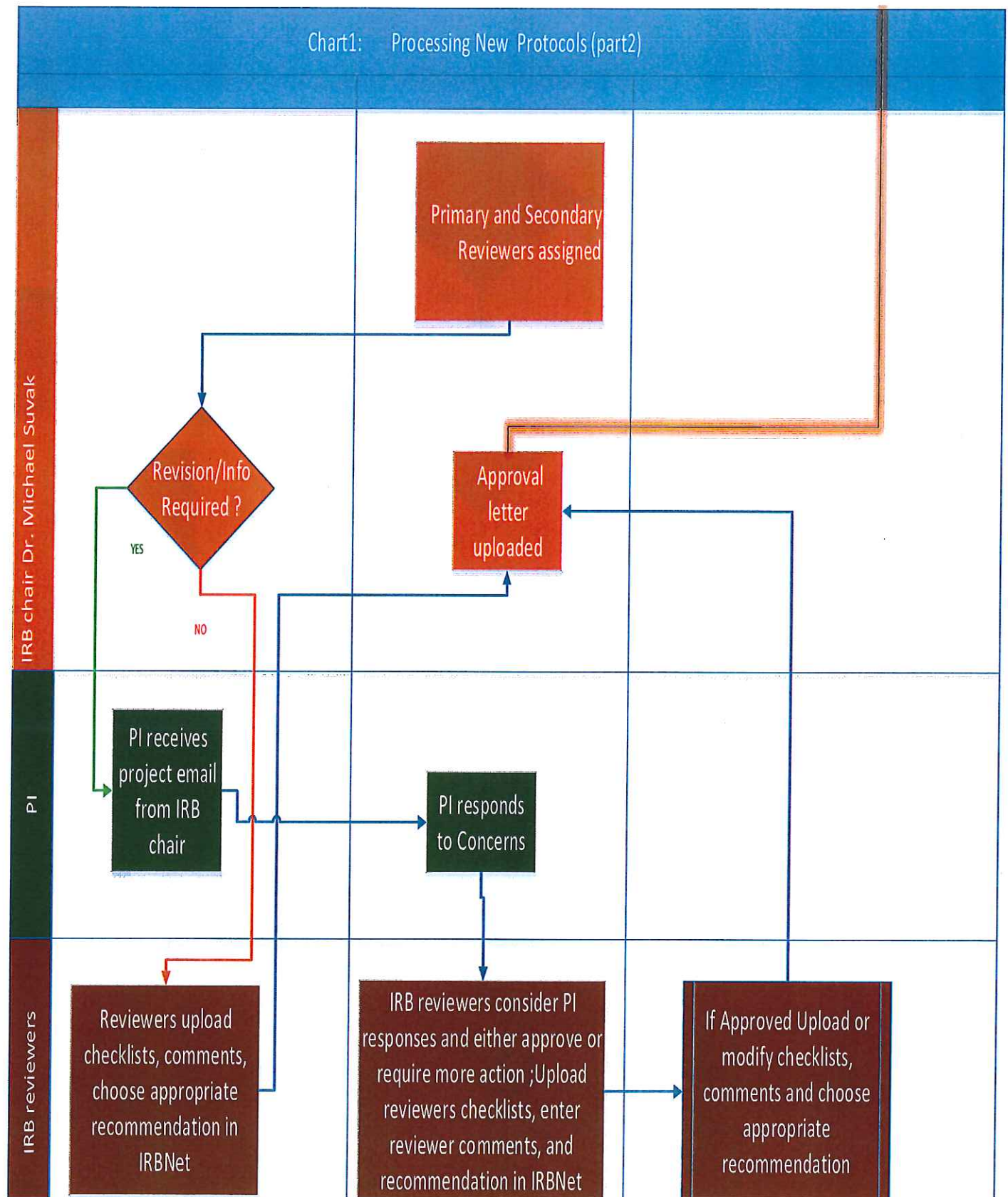
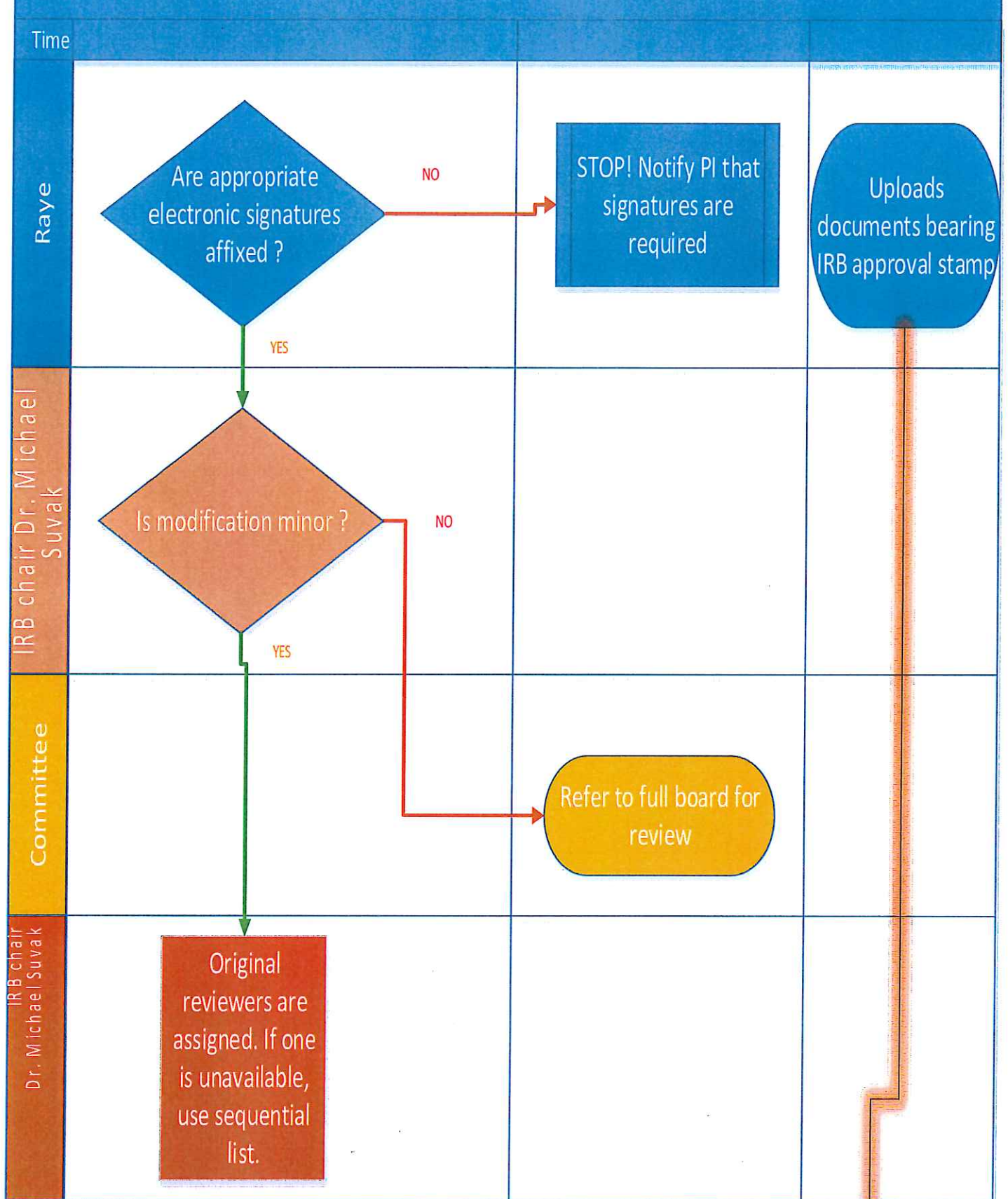


Chart 1 Footnotes:

Vulnerable Populations defined in the 45CFR46
Subpart B – Pregnant Women, Fetuses, and Neonates

Subpart C – Prisoners
Subpart D – Children

Chart 2 : Processing Protocol Modifications (part1)



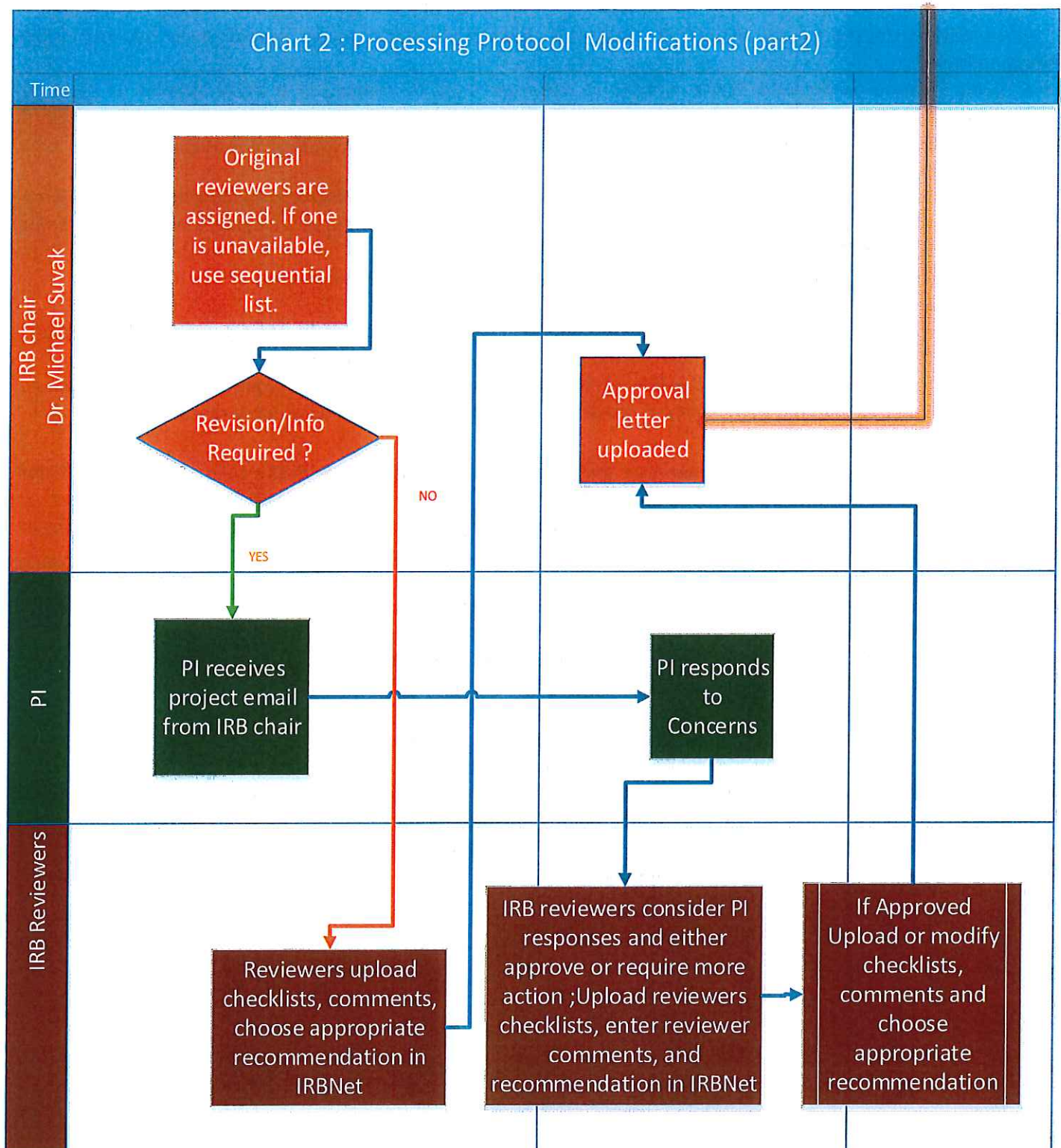


Chart 2 Footnotes

Minor Modifications

Level of Approval: Expedited

Definition: Minor changes have no substantive effect upon an approved protocol or reduce the risk to the subject

Examples of minor changes are:

- Changes in research personnel that do not alter the competence of the research team to conduct the research
- Scientific and/or therapeutic changes that leave the research population at the same or lower risk than risk(s) already approved
- A minor increase or decrease in the number of participants (<25% change) or a >25% increase in the # of participants to be enrolled, but the # of participants to be "treated" remains the same. (e.g. - increase in # consented due to a higher than expected rate of screen failures) or a larger % increase in # of subjects which does not affect the statistical plan.
- Changes in research procedures that have a minor impact on risks of harm and which remain within the expedited criteria, addition of a clinic visit that involves no new procedures, or addition of a questionnaire that does not introduce new subject matter.
- An increase in the number of study visits for the purpose of increased safety monitoring
- Minimal changes in remuneration
- Changes to improve the clarity of statements, enhance comprehension or to correct typographical errors, updating to current template, without altering the content or intent of the statement
- Clarification of discrepancies within the IRB review materials (protocol cover sheet, protocol, consent) such as numbers of subjects, number and identity of research sites, timing, nature, and duration of research procedures.

Major Modifications

A major modification is defined as a change that materially affects an assessment of the risks and benefits of the study. For example a change that increases risks to subjects, alters the informed consent process whereby a waiver is requested, requests a change in inclusion criteria whereby a vulnerable population is added, or substantially changes the specific aims or design of the study.

Level of Approval: Full Board

Examples of major changes that are considered to increase the risk to the subject:

- Knowledge of a new risk which might affect the risk/ benefit ratio (For example, if a risk that is serious, life-threatening, or could potentially result in permanent disability). The addition of these sorts of risk might affect the IRB's view of the risk/benefit ratio and should therefore be reviewed by the full board.
- Increasing the length of time a subject is exposed to experimental aspects of the study.
- Changing the originally targeted population to include a more at-risk population (example: previous exclusion for those with renal failure are now allowed to enroll, or adding children or pregnant women to the study.)
- Adding additional procedures where the risk of the additional procedure is greater than minimal risk.
- Adding an element that may breach the confidentiality of the subject such as tissue banking or genetic testing.
- An increase >25% in the # of participants to be "treated" which affects the statistical plan for the study.
 - Requesting surrogate assent for a full board study.

Chart3: Processing Continuing Review (part1)

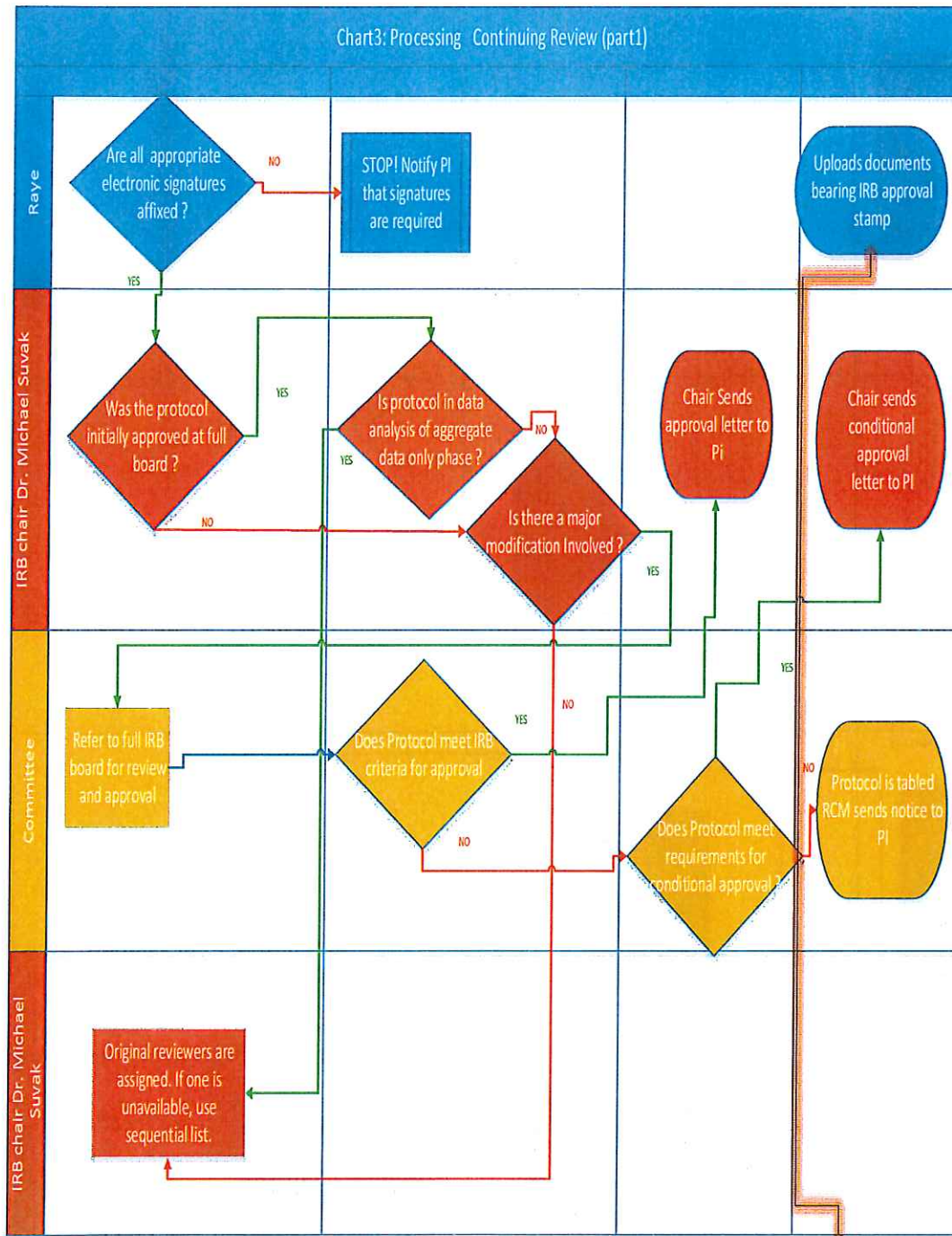


Chart3: Processing Continuing Review (part2)

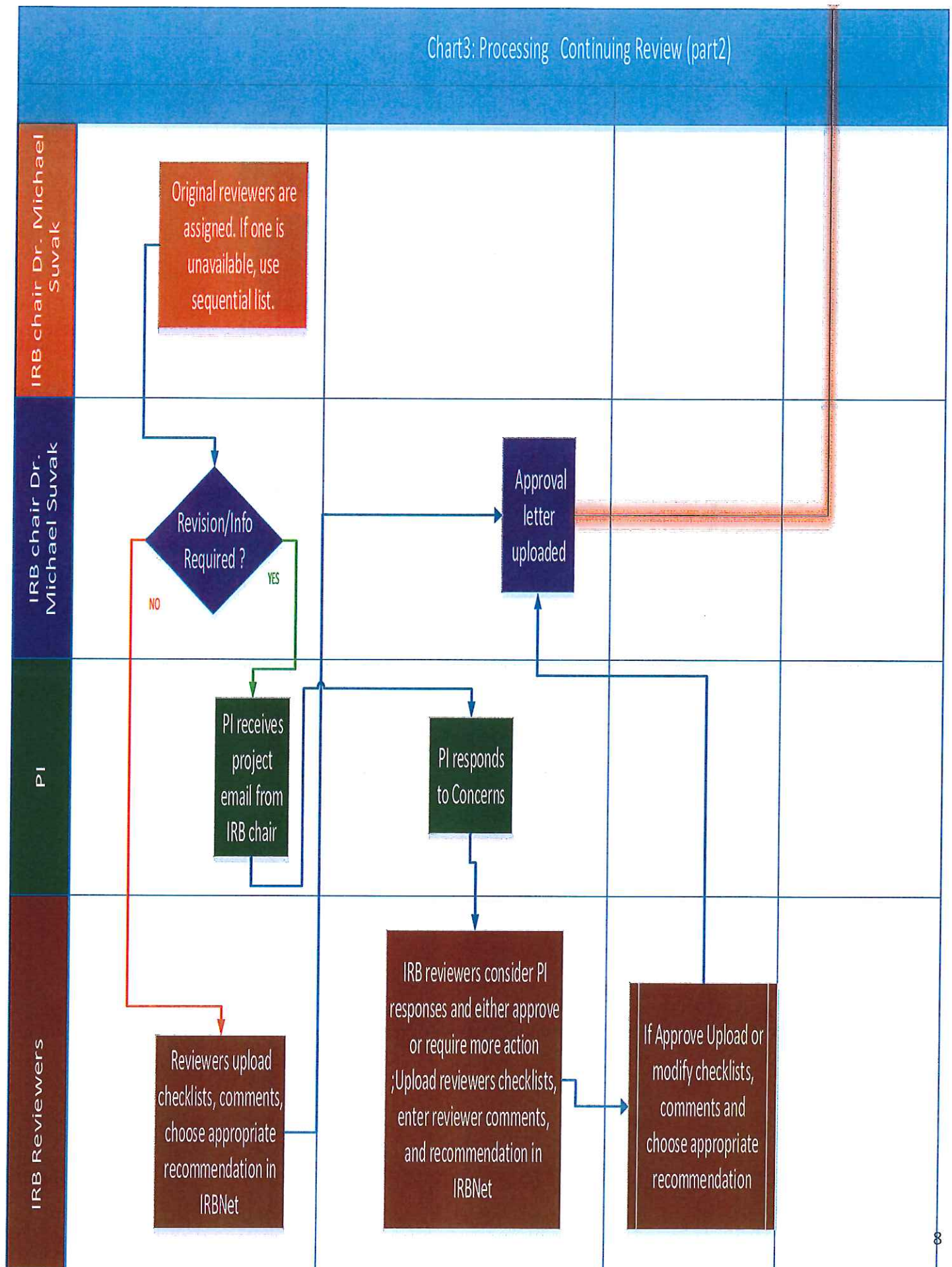
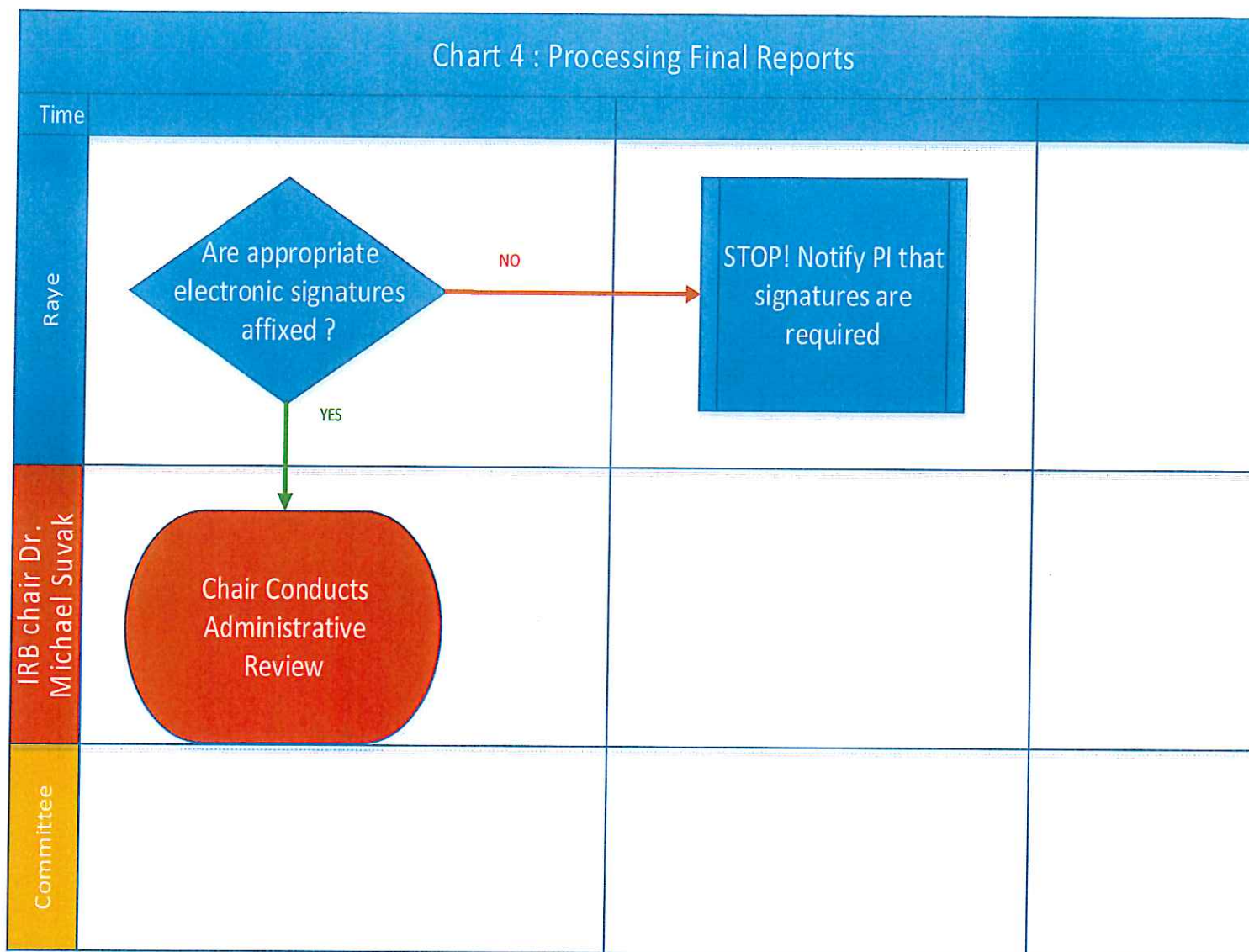


Chart 4 : Processing Final Reports



Appendix G

IRB Reviewer Forms

CRITERIA FOR IRB APPROVAL OF RESEARCH WITH HUMAN SUBJECTS

Protocol Number:	
Protocol Title:	
Principal Investigator:	Co-Investigator:
§46.111 Criteria for IRB Approval of Research. (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied. NOTE: If any of the responses is "NO" the study cannot be approved	
<input type="checkbox"/> Yes <input type="checkbox"/> No	(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
Protocol Specific Comments:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
Protocol Specific Comments:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
Protocol Specific Comments:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Waived	(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116. <i>If waived, please complete waiver worksheet.</i>
Protocol Specific Comments:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Waived	(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117. <i>If waived, please complete waiver worksheet.</i>
Protocol Specific Comments:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
Protocol Specific Comments:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
Protocol Specific Comments:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	§46.111(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as Suffolk University students, children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
Protocol Specific Comments:	
Reviewer:	Date:

EXPEDITED REVIEW RESEARCH CATEGORIES CHECKLIST

Protocol Number:	
Protocol Title:	
Principal Investigator:	Co-Investigator:
§46.110(b)(1) An IRB may use the expedited review procedure to review research if it determines the following:	
1. Does the research present <u>no more than</u> minimal risk to subjects? If YES → <i>continue</i> . If NO → STOP ; cannot be reviewed via expedited review.	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Can the identification of subjects and/or their responses <u>reasonably</u> place them at risk of criminal or civil liability or damage the subject's financial standing, employability, insurability, reputation, or be stigmatizing? If YES → 2.1. If NO → skip to 3.	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.1 Will reasonable and appropriate protections be implemented so that the risk of invasion of privacy and breach of confidentiality are <u>no greater than</u> minimal? If YES → <i>continue</i> . If NO → STOP ; cannot be reviewed via expedited review.	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Is the research classified? If NO → <i>continue</i> . If YES → STOP ; cannot be reviewed via expedited review.	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Does the research involve only procedures listed in one or more of the following categories? If YES → <i>check applicable categories</i> . If NO → STOP ; the research <u>cannot</u> be approved via expedited review	<input type="checkbox"/> Yes <input type="checkbox"/> No
Categories (1) through (7) pertain to both initial and continuing review.	
<input type="checkbox"/> 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which an investigational device exemption application (21 CFR Part 812) is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.	
<input type="checkbox"/> 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week	
<input type="checkbox"/> 3. Prospective collection of biological specimens for research purposes by noninvasive means.	
<input type="checkbox"/> 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)	
<input type="checkbox"/> 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)	
<input type="checkbox"/> 6. Collection of data from voice, video, digital, or image recordings made for research purposes.	
<input type="checkbox"/> 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.	
<input type="checkbox"/> 8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.	
<input type="checkbox"/> 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.	
<input type="checkbox"/> Approve	<input type="checkbox"/> Recommend for Full Committee Review; please provide rationale in space provided below.
viewer:	Date:

45 CFR 46.116 GENERAL REQUIREMENTS FOR INFORMED CONSENT

Protocol Number:

Protocol Title:

PI:

Co-PI:

§46.116 General Requirements of Informed Consent Investigators may not involve a human being as a subject in research unless:

☐ Yes ☐ No Investigator will obtain the **legally effective** informed consent of each prospective subject or subject's legally authorized representative (LAR).

Comments:

☐ Yes ☐ No Investigator will seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and the possibility of coercion or undue influence is minimized.

Comments:

☐ Yes ☐ No The information that is given to the subject or the representative is in **language understandable** to the subject or the representative.

Comments:

☐ Yes ☐ No Informed consent, whether oral or written, **does not include language** through which the subject or the representative is made to **waive or appear to waive any of the subject's legal rights**, or **release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence**.

Comments:

46.116 (a) Basic Elements of informed Consent. In seeking informed consent the following information shall be provided to each subject. If you answer "NO" and such element is not appropriately waived under §46.116(d) then the informed consent form is not approvable.

- | | |
|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (1) A statement that the study involves research |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (2) An explanation of the purposes of the research |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (3) The expected duration of the subject's participation |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (4) A description of the procedures to be followed |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (5) Identification of any procedures which are experimental |
| <input type="checkbox"/> N/A | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (6) A description of any reasonably foreseeable risks or discomforts to the subject |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (7) A description of any benefits to the subject or to others which may reasonably be expected from the research |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |
| <input type="checkbox"/> N/A | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (9) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (10) For research involving more than minimal risk , an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further info may be obtained |
| <input type="checkbox"/> N/A | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (11) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (12) A statement that participation is voluntary |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (13) Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | (14) The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. |

§46.116 (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject. *If you answer "NO" it means the element is required but was not met by the informed consent document.*

<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable ;
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	(3) Any additional costs to the subject that may result from participation in the research;
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject ; AND
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	(6) The approximate number of subjects involved in the study.

Reviewer:

Date:

Appendix H

Exempt Research Checklist

REVIEWER

EXEMPT RESEARCH CHECKLIST

Protocol Number:

Protocol Title:

Principal Investigator:

Co-Investigator:

§ 46.101(b) Unless otherwise required by department or agency heads, research with human subjects is exempt if:

1. Does the research involve only procedures listed in one or more of the following categories? If YES → continue. If NO → STOP; the research is not exempt from IRB review. ☐ Yes ☐ No
 - ☐ (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - ☐ (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 - ☐ (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
 - ☐ (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - ☐ (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
 - ☐ (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture
2. Is this a minimal risk study? If YES → continue. If NO → STOP this research is not exempt from IRB review. ☐ Yes ☐ No
3. Does the research involve prisoners? If NO → continue. If YES → STOP this research is not be exempt from IRB review ☐ Yes ☐ No
4. Does the research involve minors? If NO → skip sections 4(a)(b) and (c); If YES → go to 4(a) ☐ Yes ☐ No
 - 4(a) Will research involve survey or interview procedures? If NO → proceed to 4(b). If YES → STOP, the research is not exempt from IRB review. ☐ Yes ☐ No
 - 4(b) Will the research involve observations of public behavior? If NO → skip 4(c). If YES → go to 4(c) ☐ Yes ☐ No
 - 4(c) Will the investigator(s) participate in the activities being observed? If NO → continue; If YES → STOP, research is not exempt from IRB review. ☐ Yes ☐ No

Provide Protocol Specific Comments:

Reviewer:

Date:

