Appendix 6:

Human Subject Determination checklist

and

Other OHRP Checklists

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Human Subject Regulations Decision Charts

Human Subject Regulations Decision Charts

September 24, 2004

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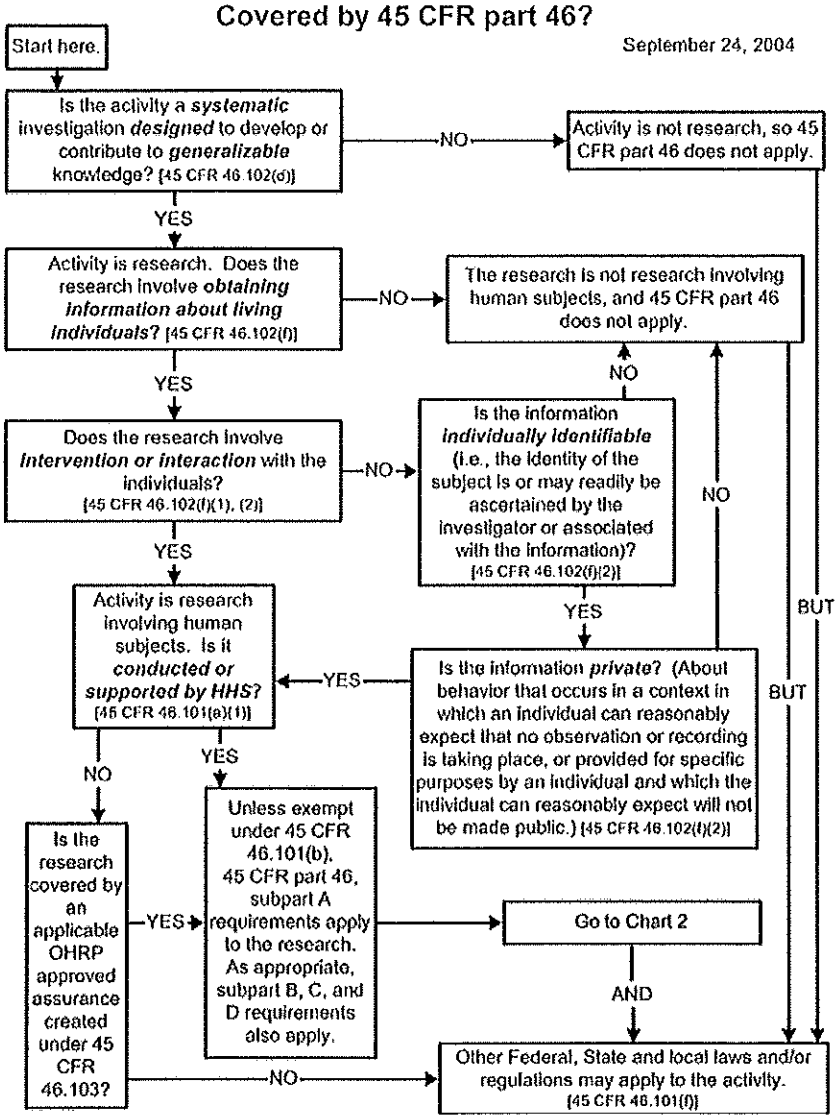

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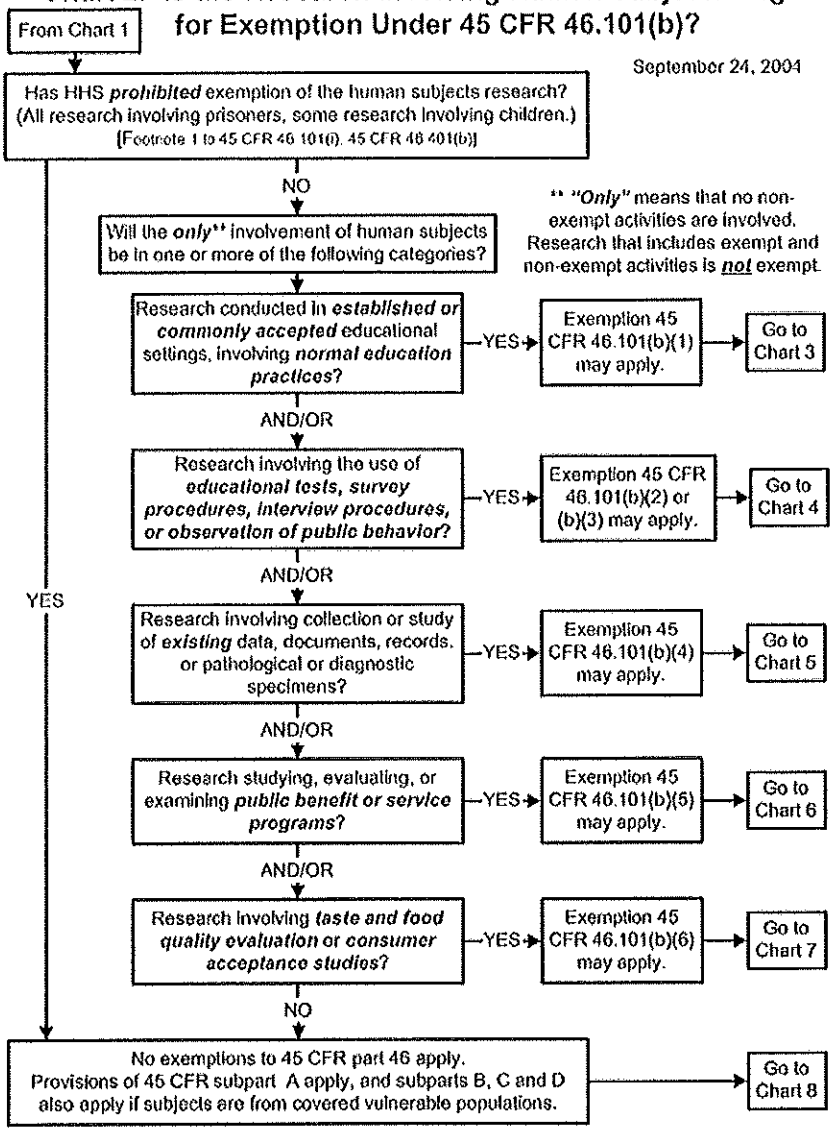

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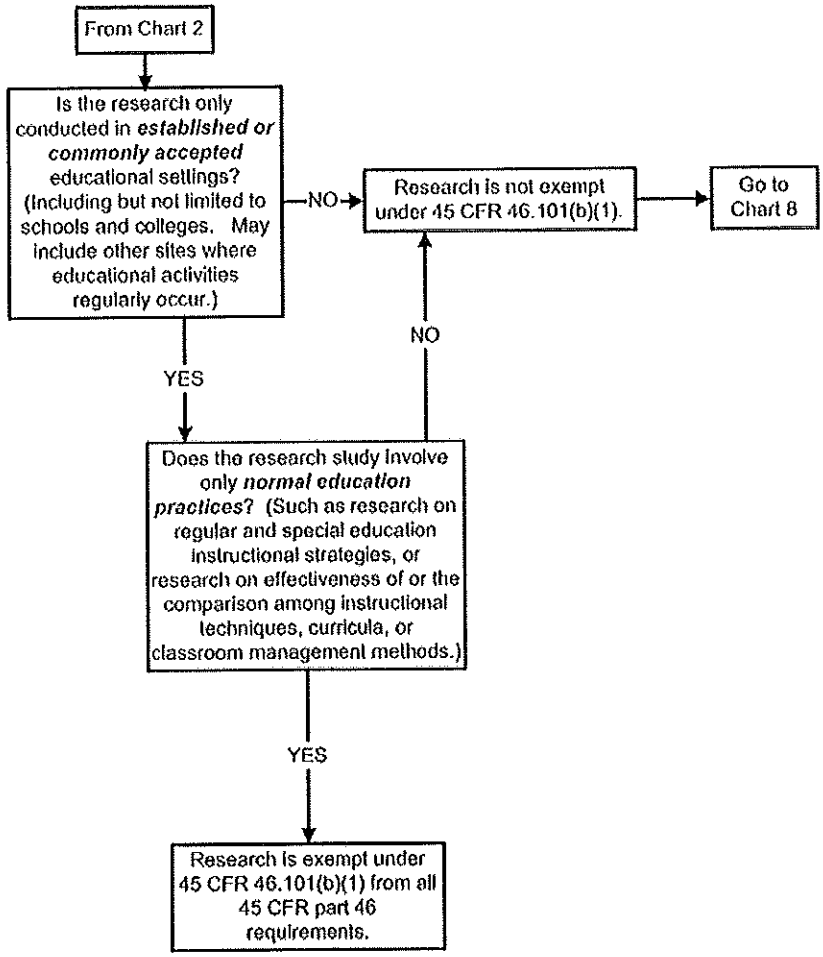

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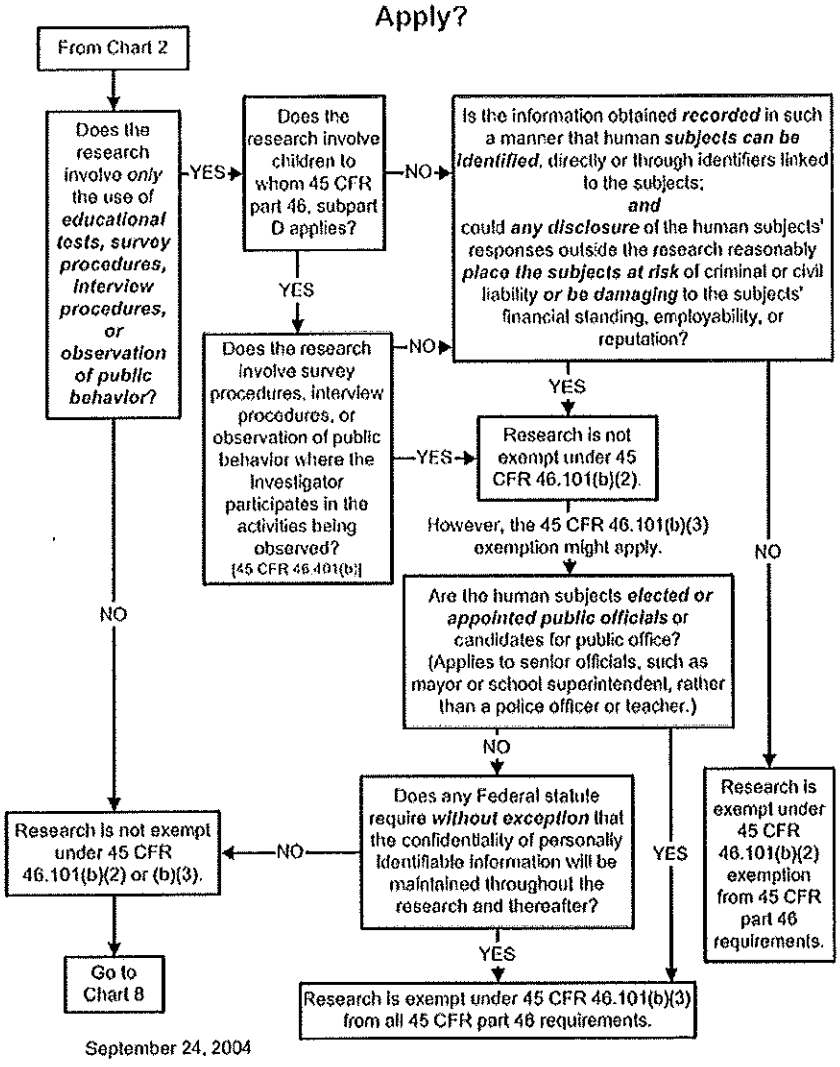

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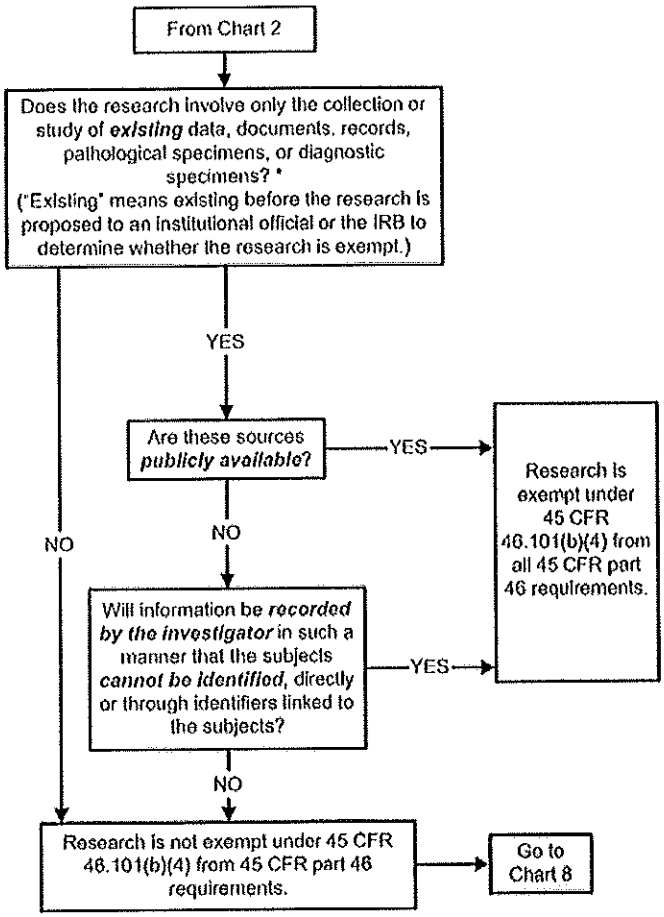

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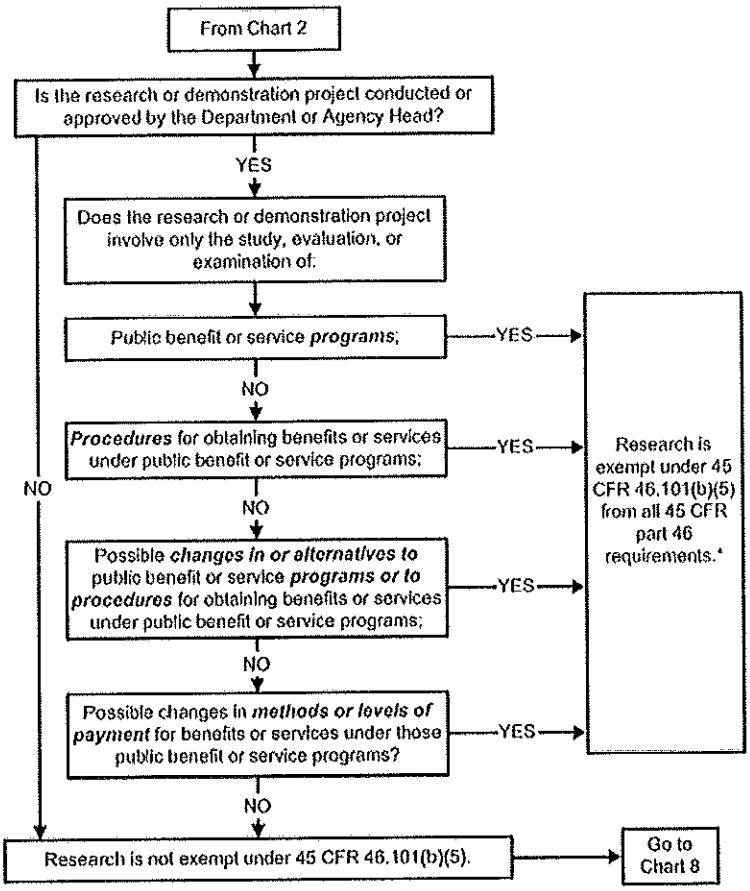

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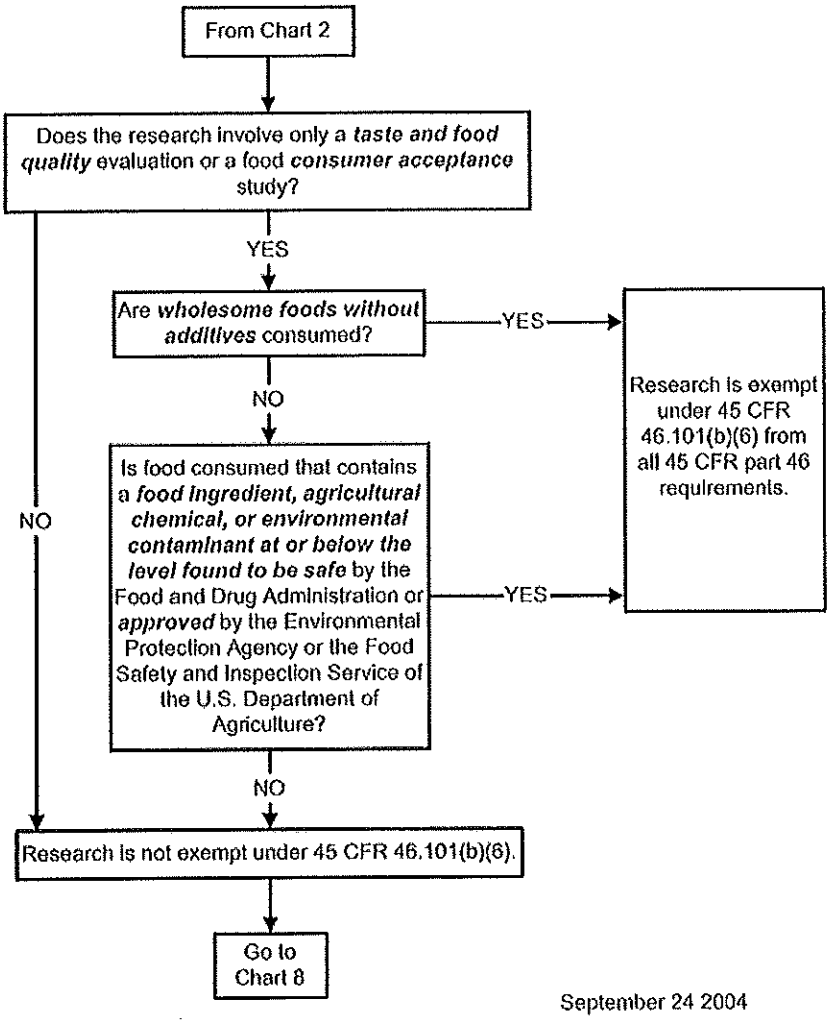

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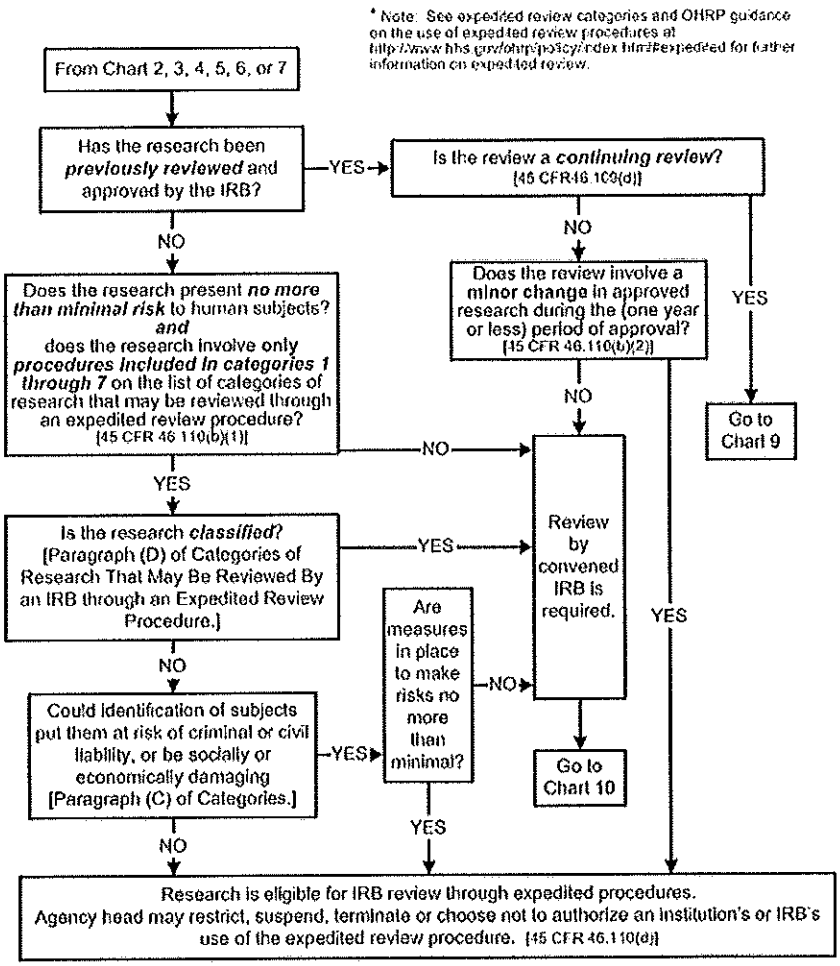
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*



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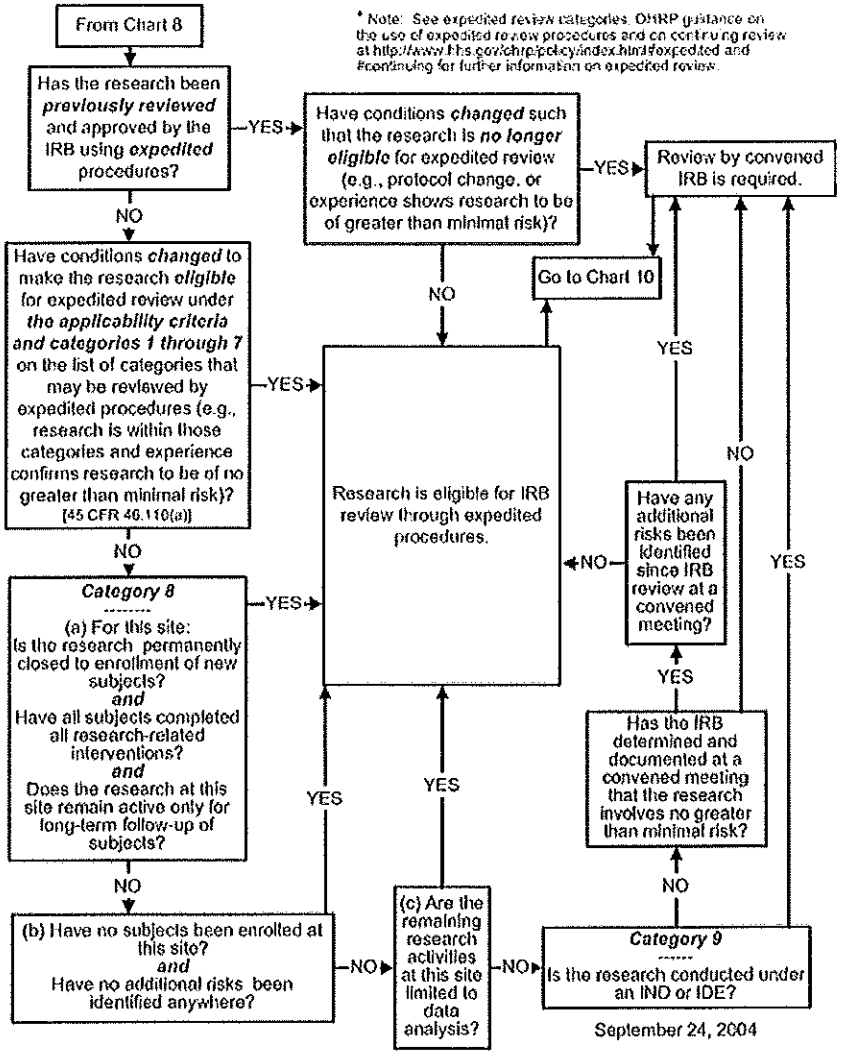

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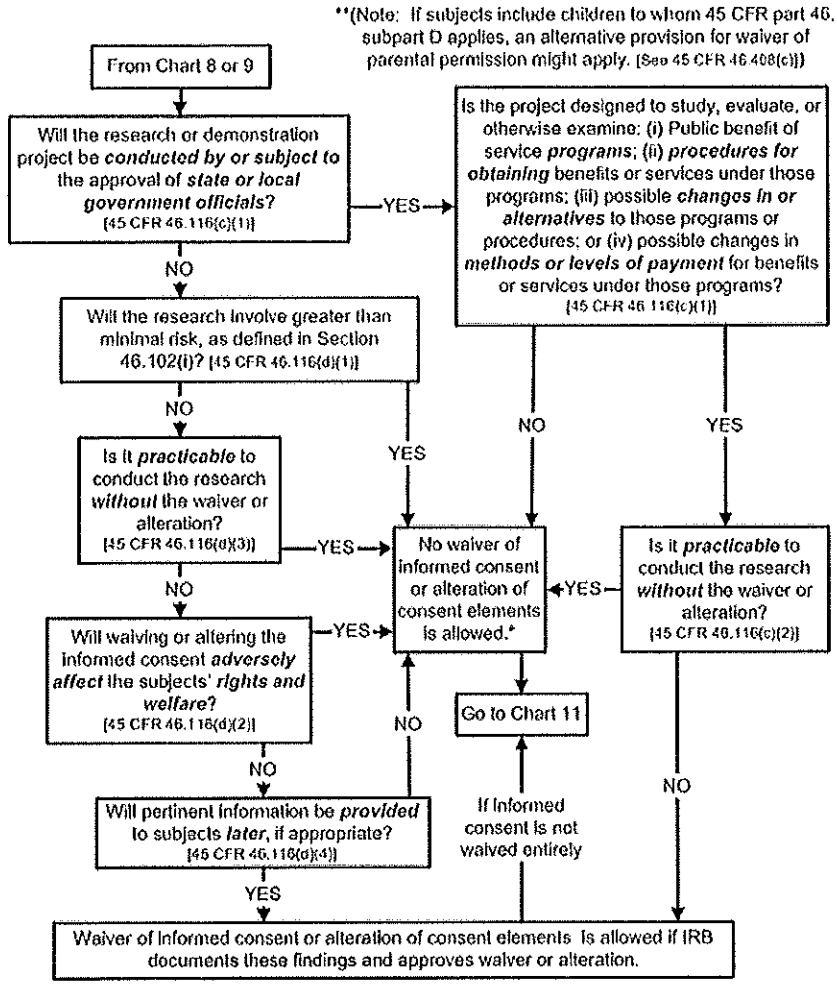

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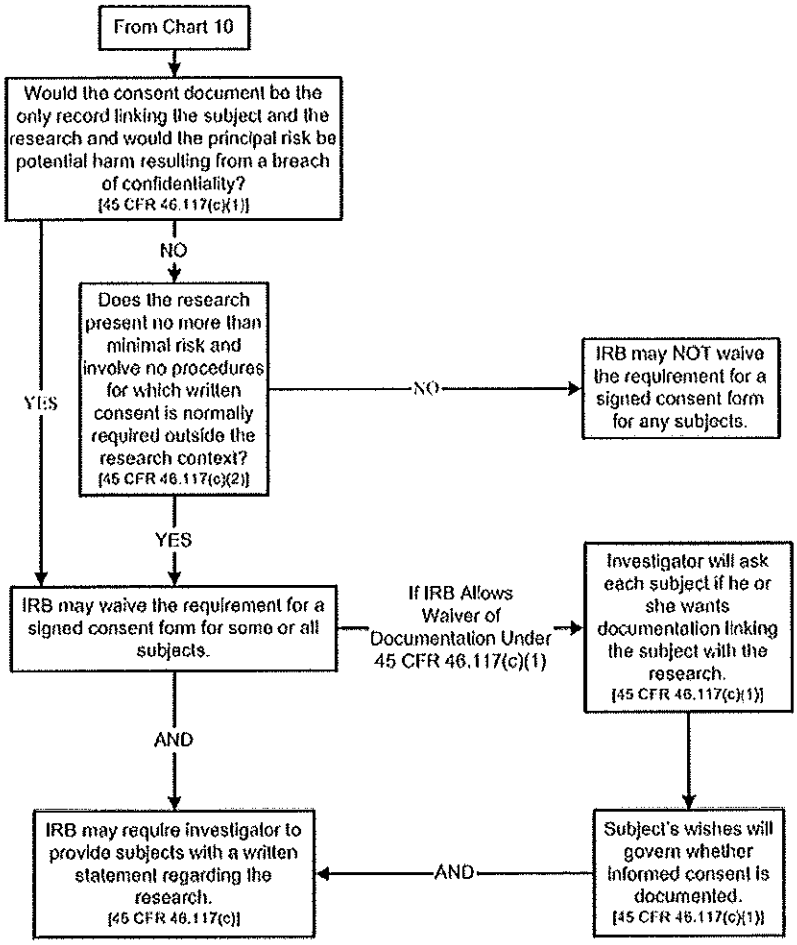

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Human Subject Regulations Decision Charts

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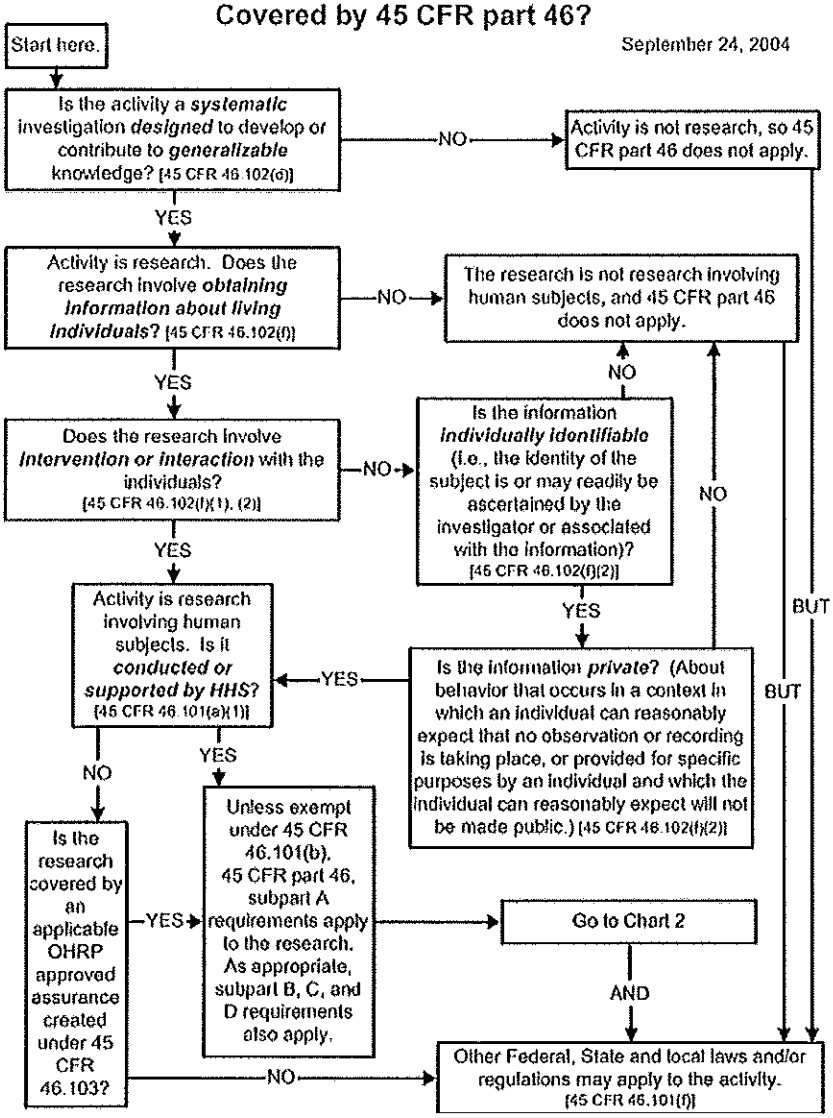

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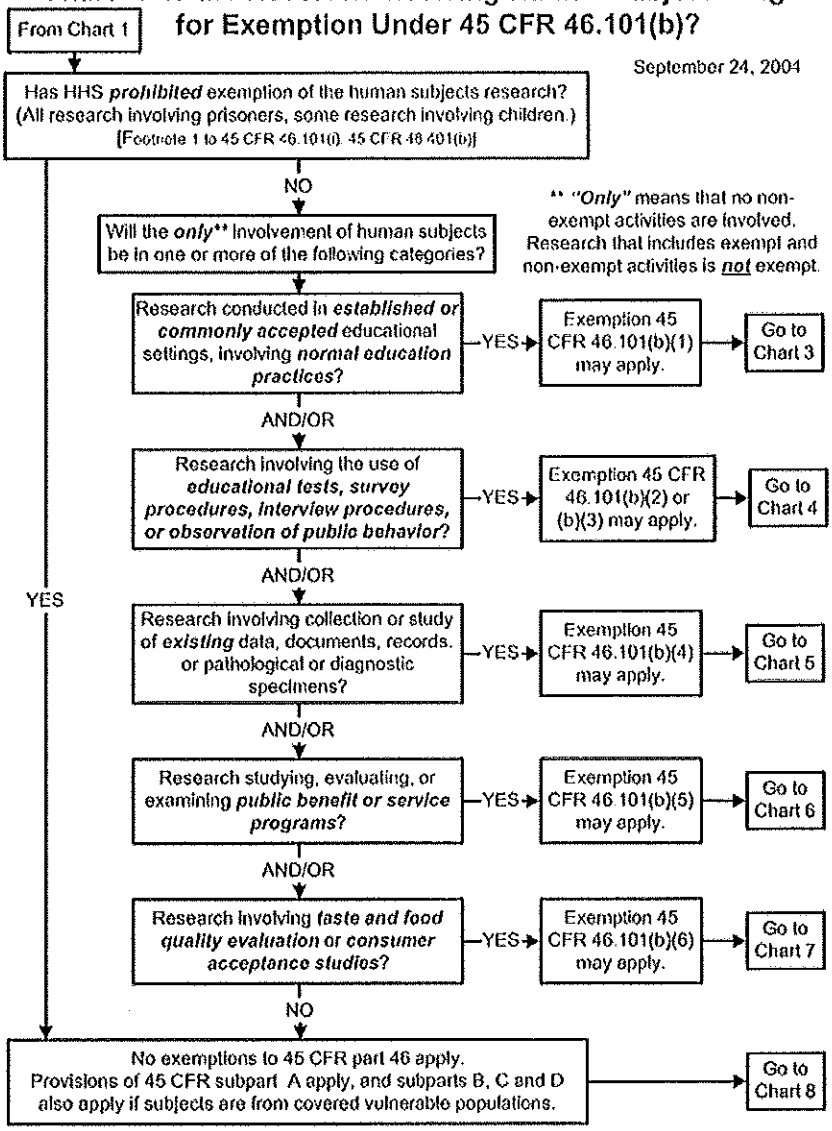

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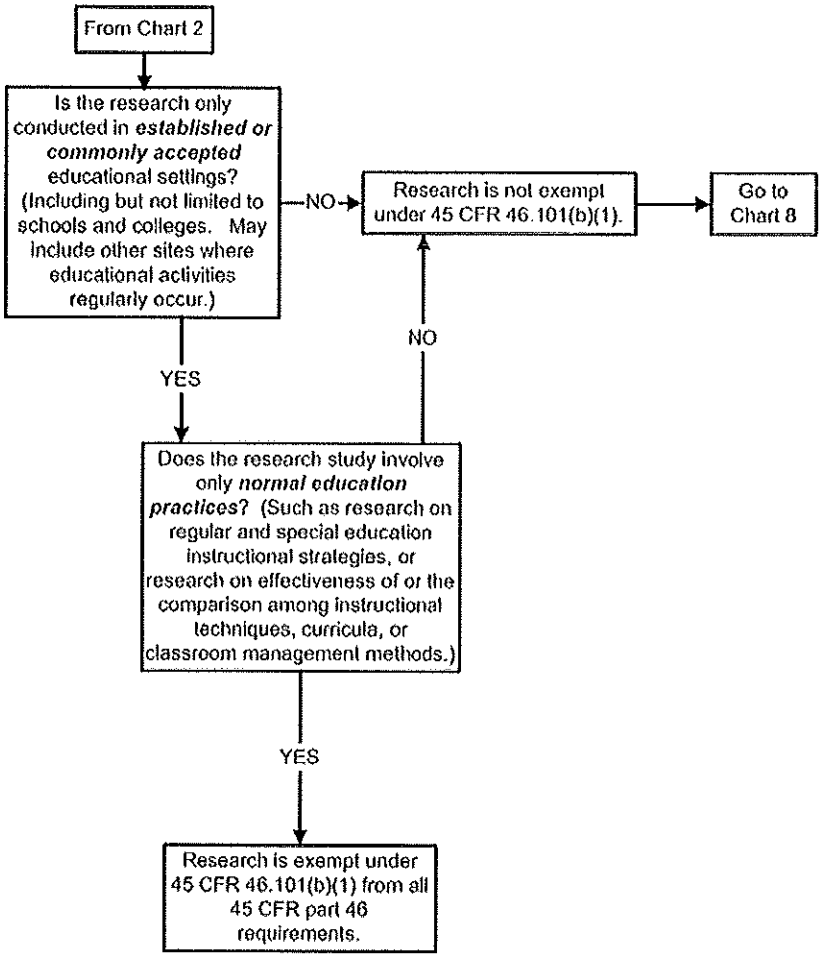

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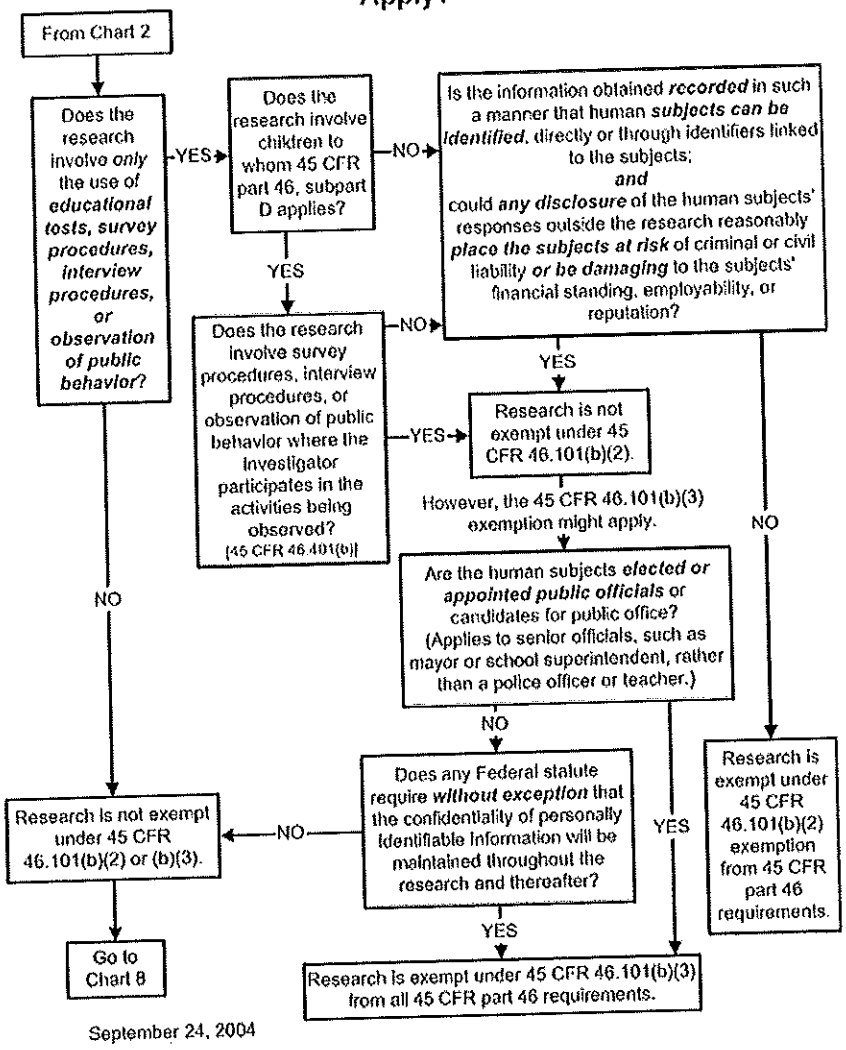

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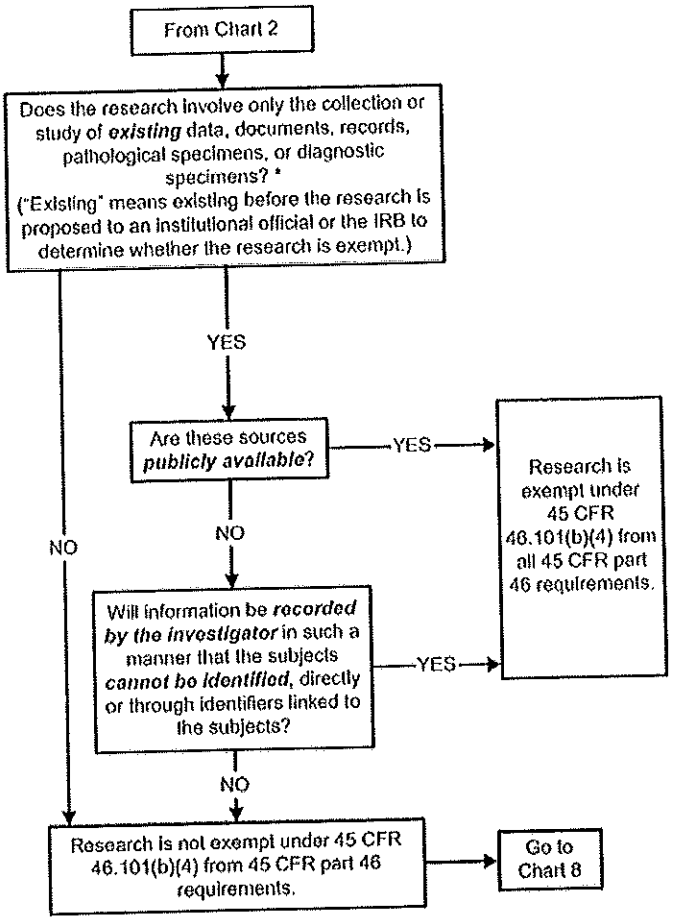

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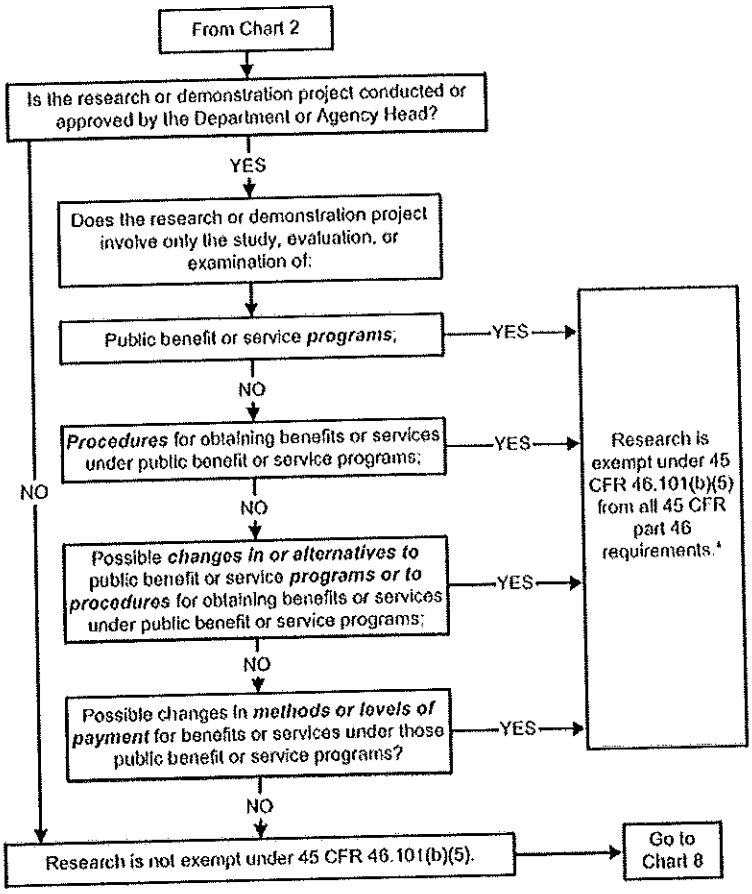

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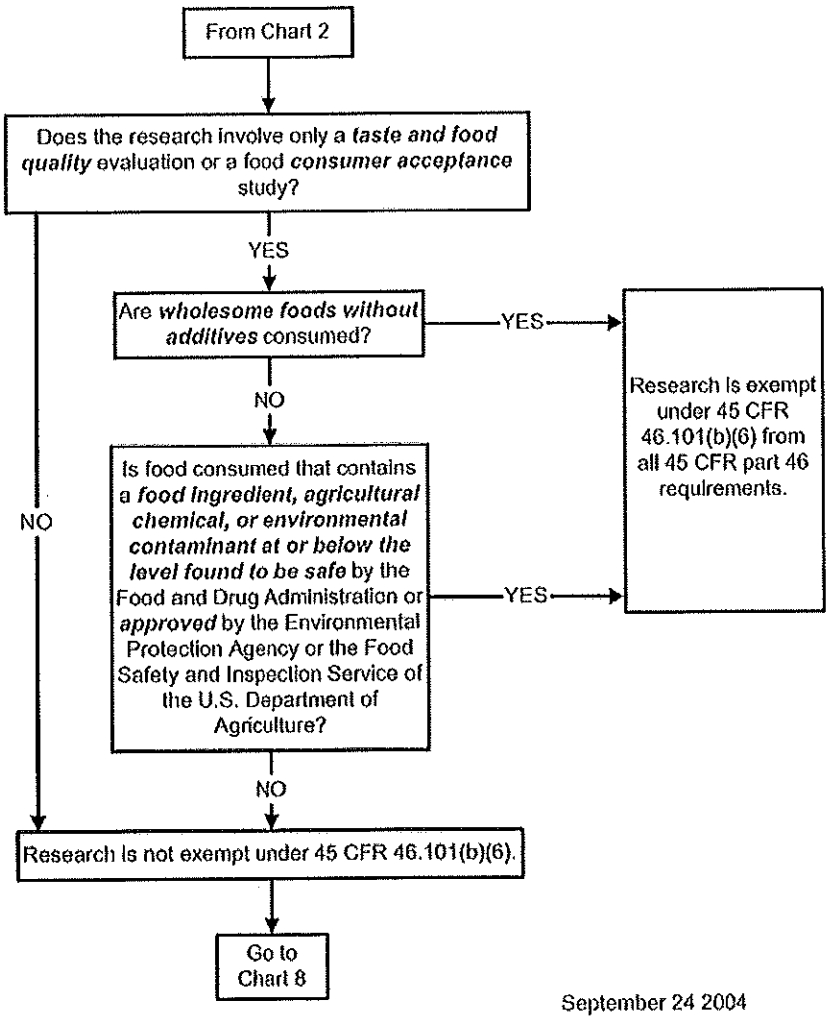

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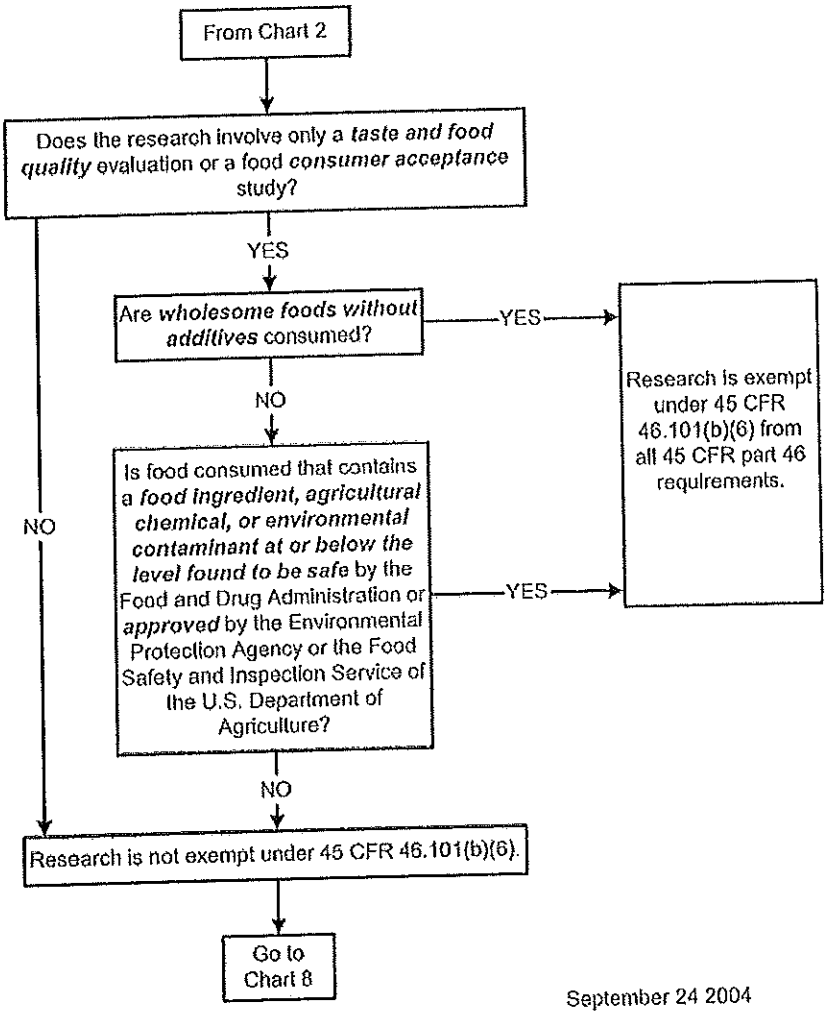

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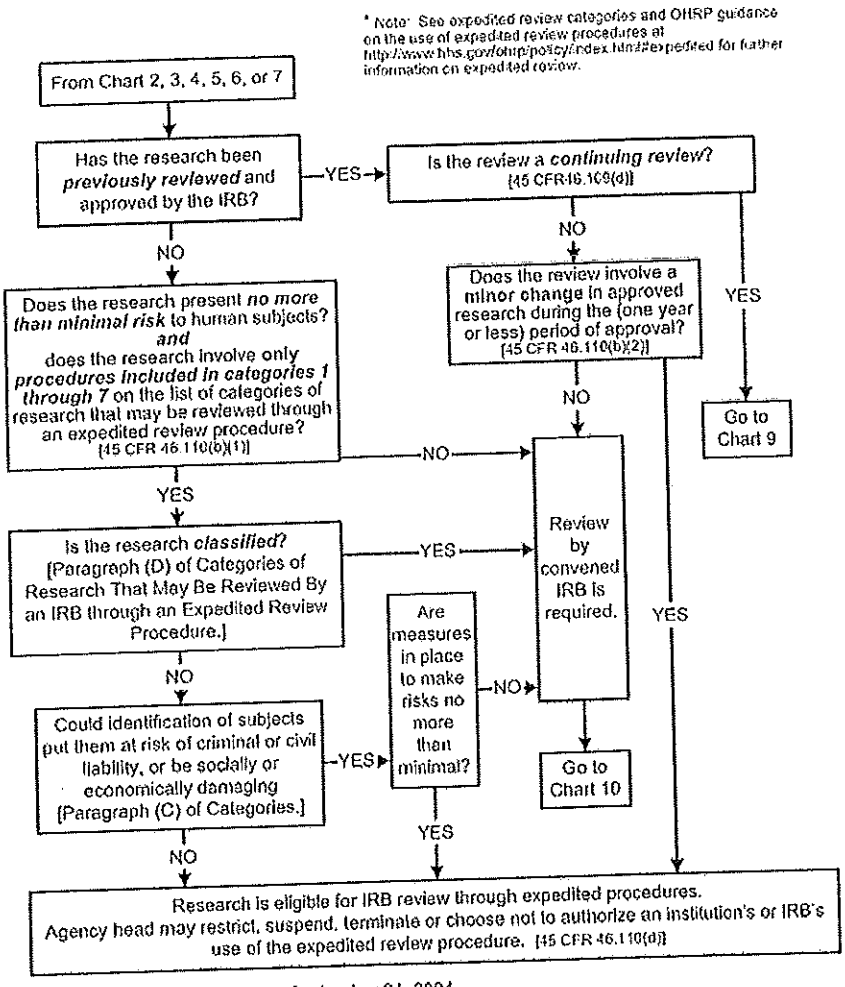

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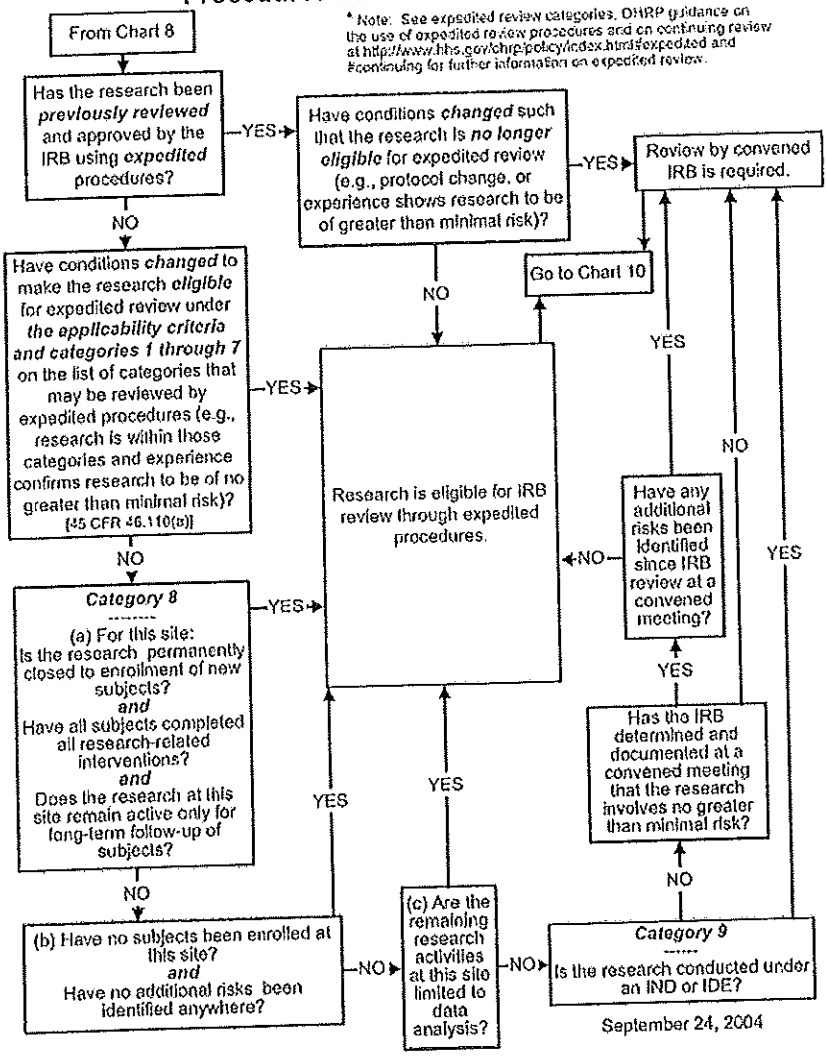

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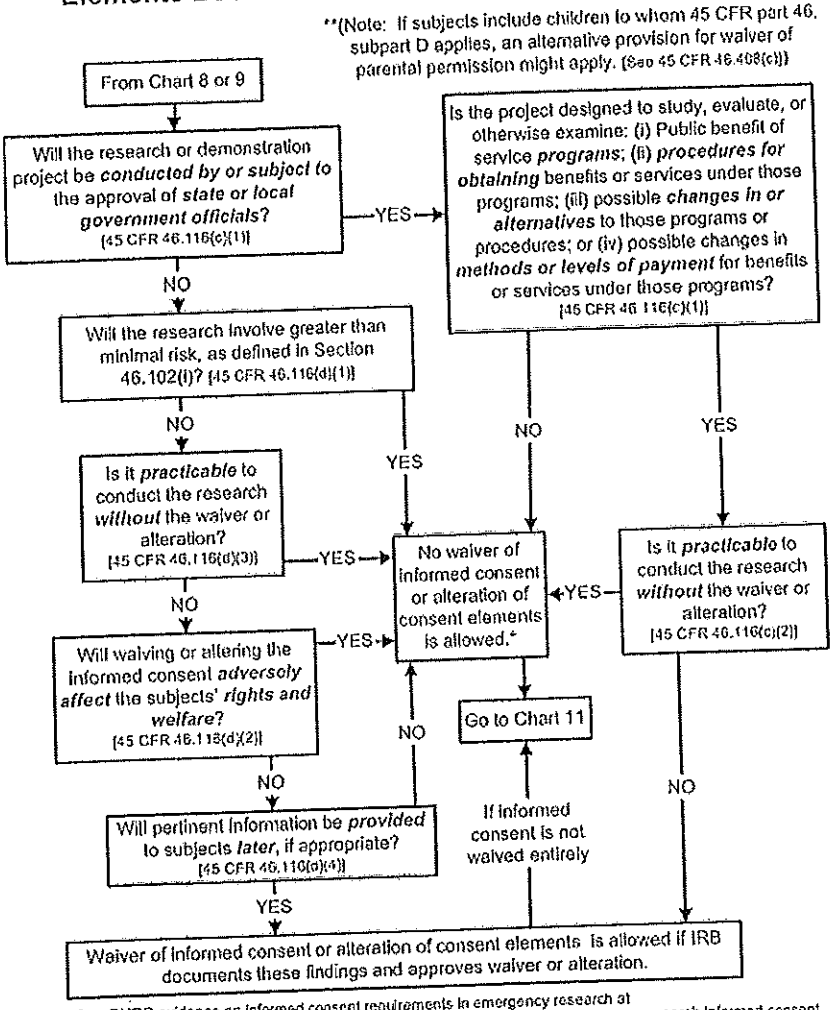

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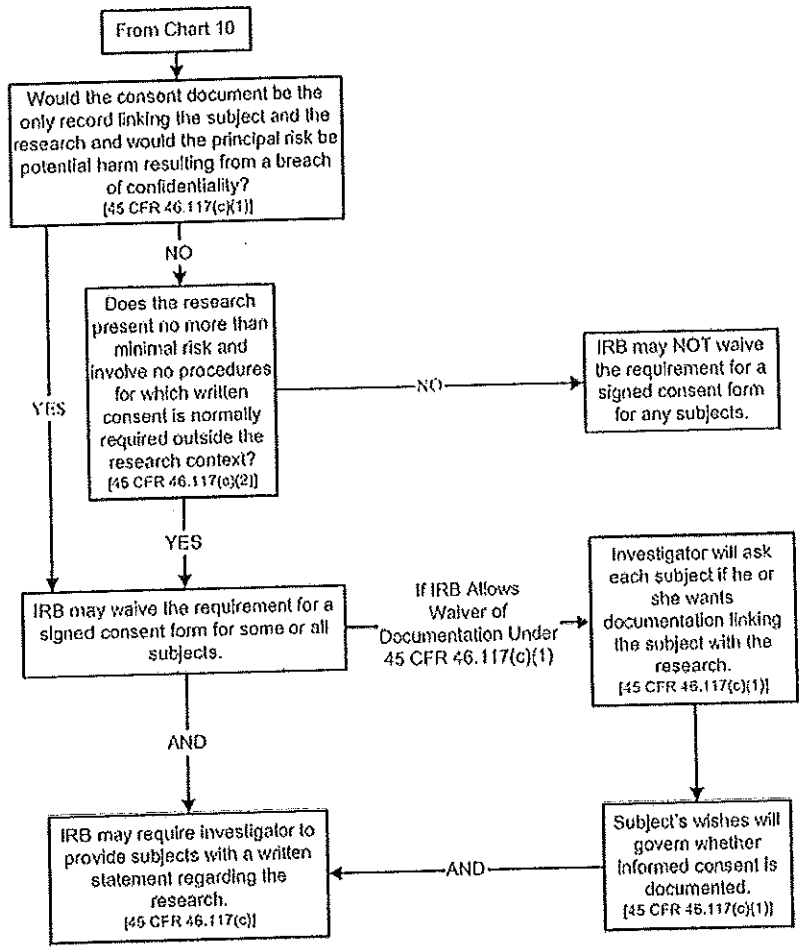

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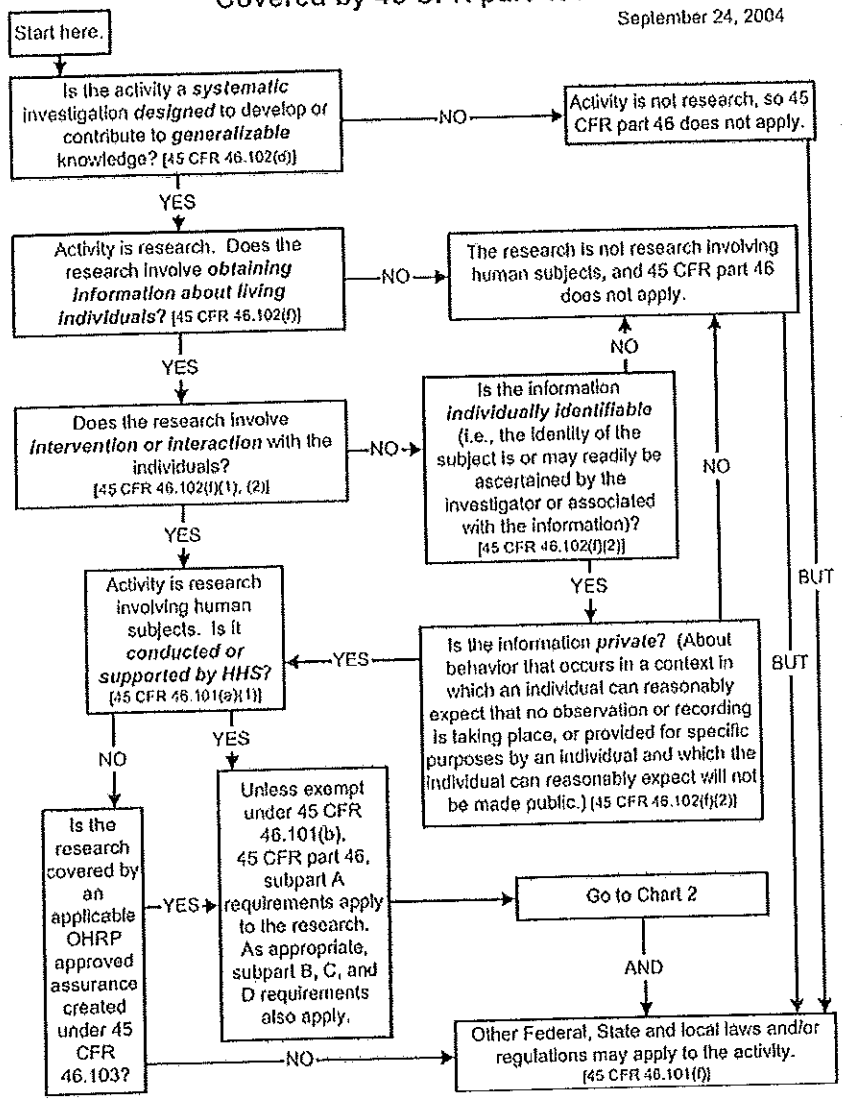

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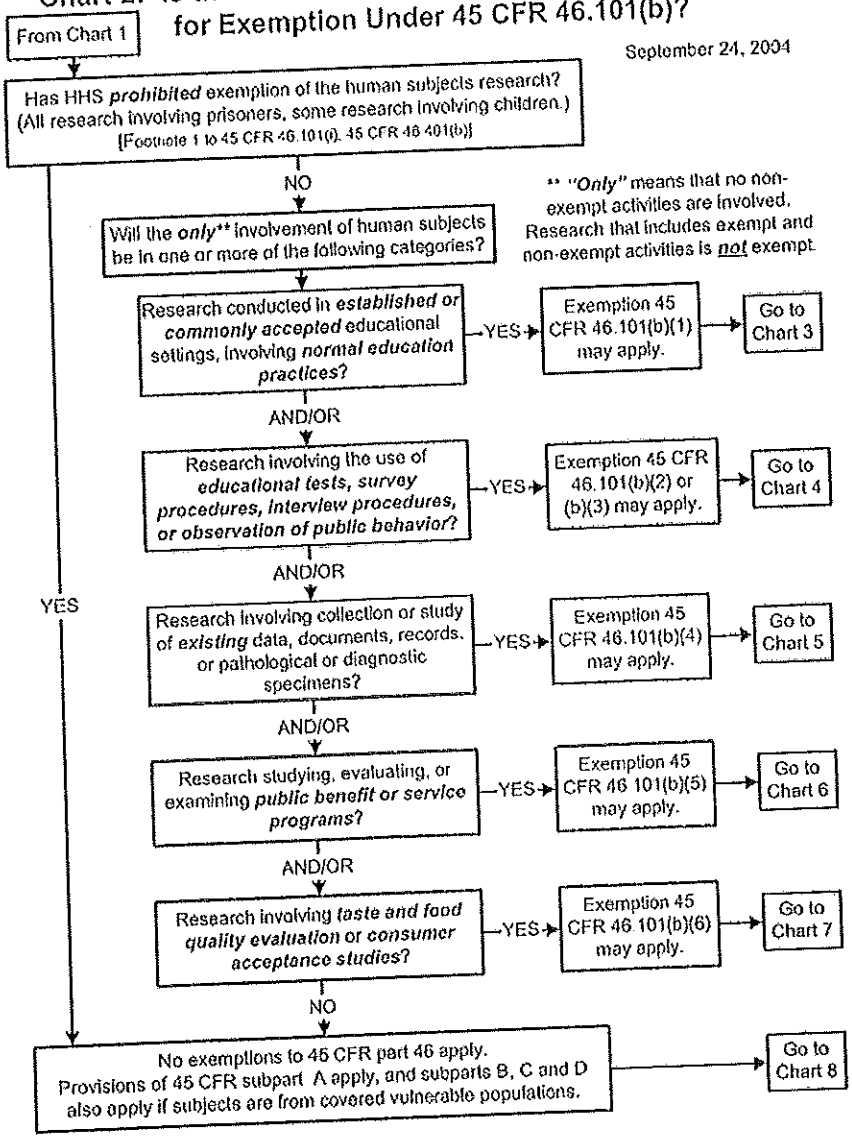

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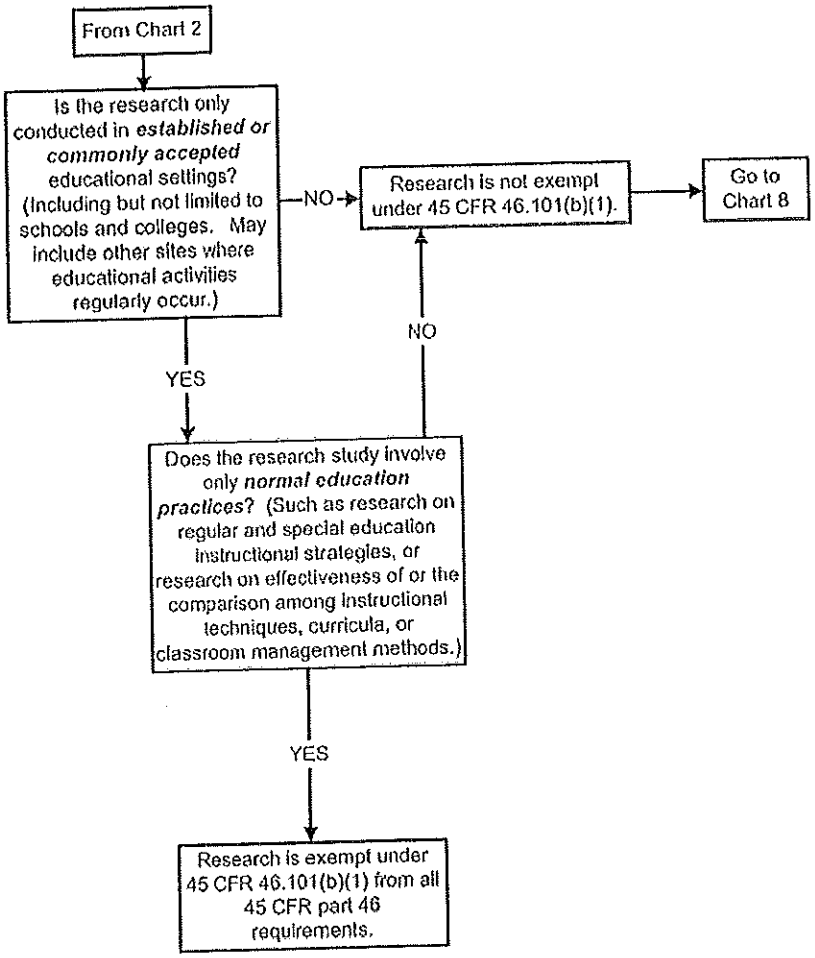

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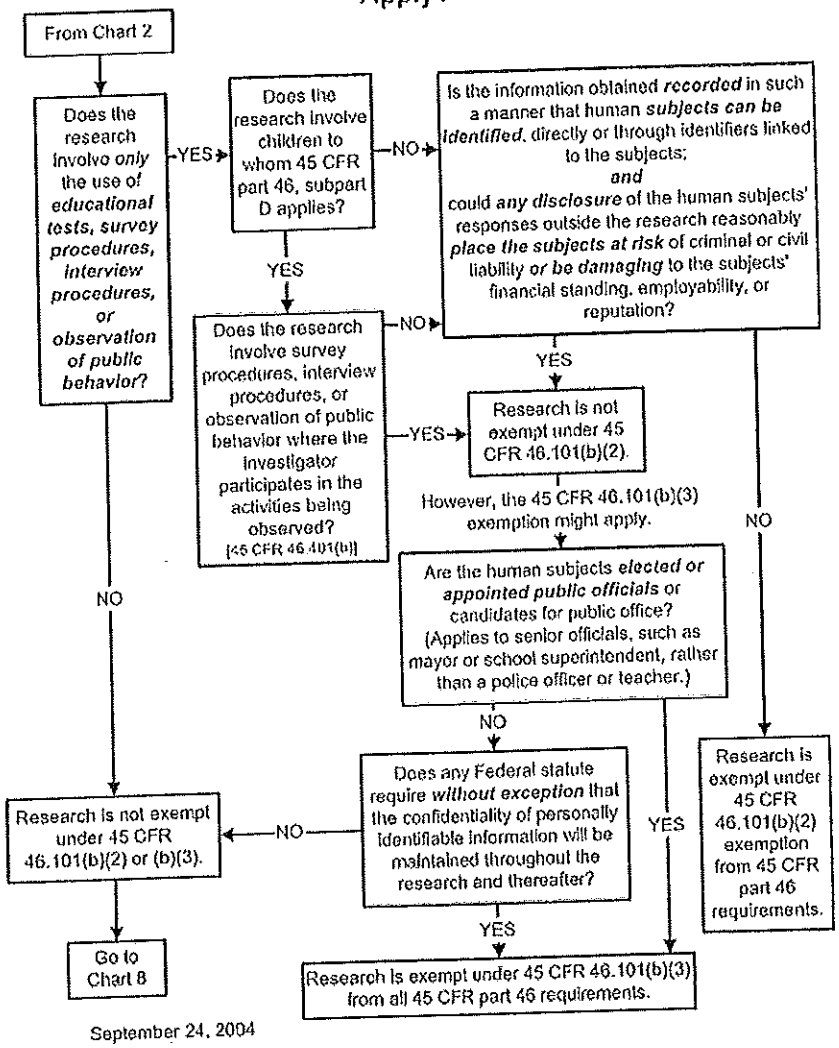

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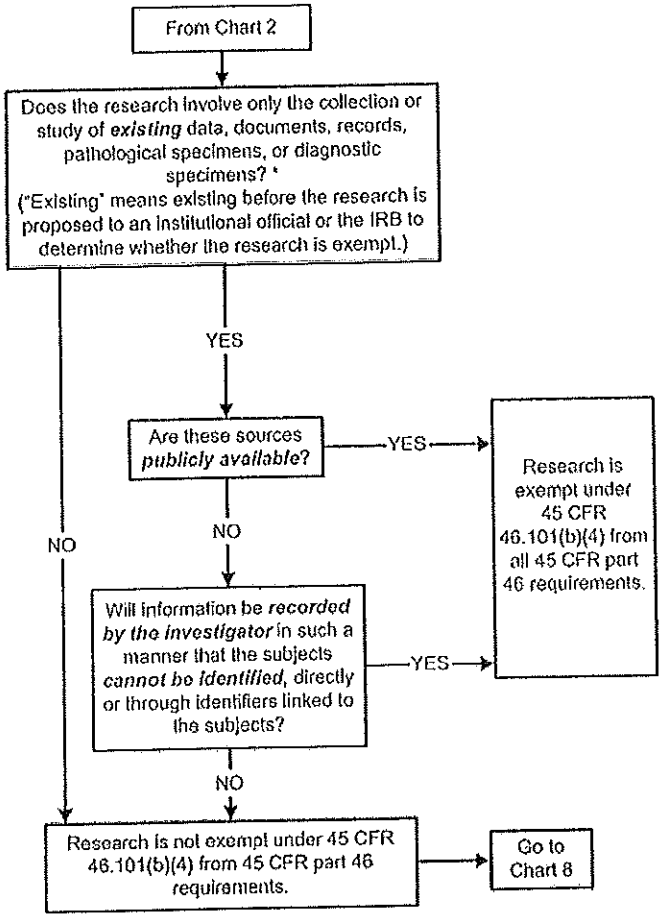

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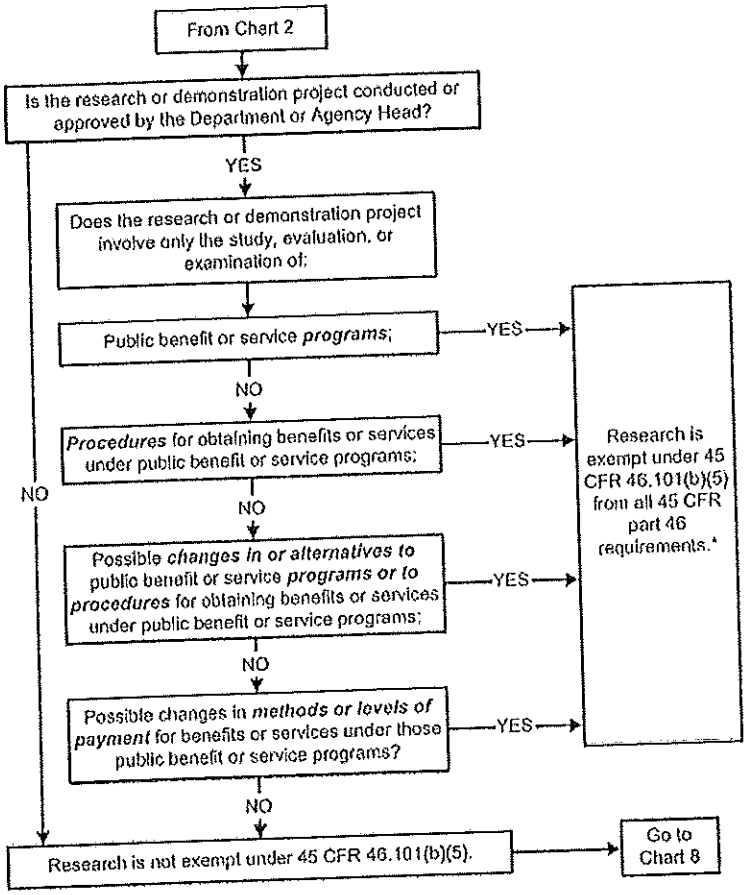

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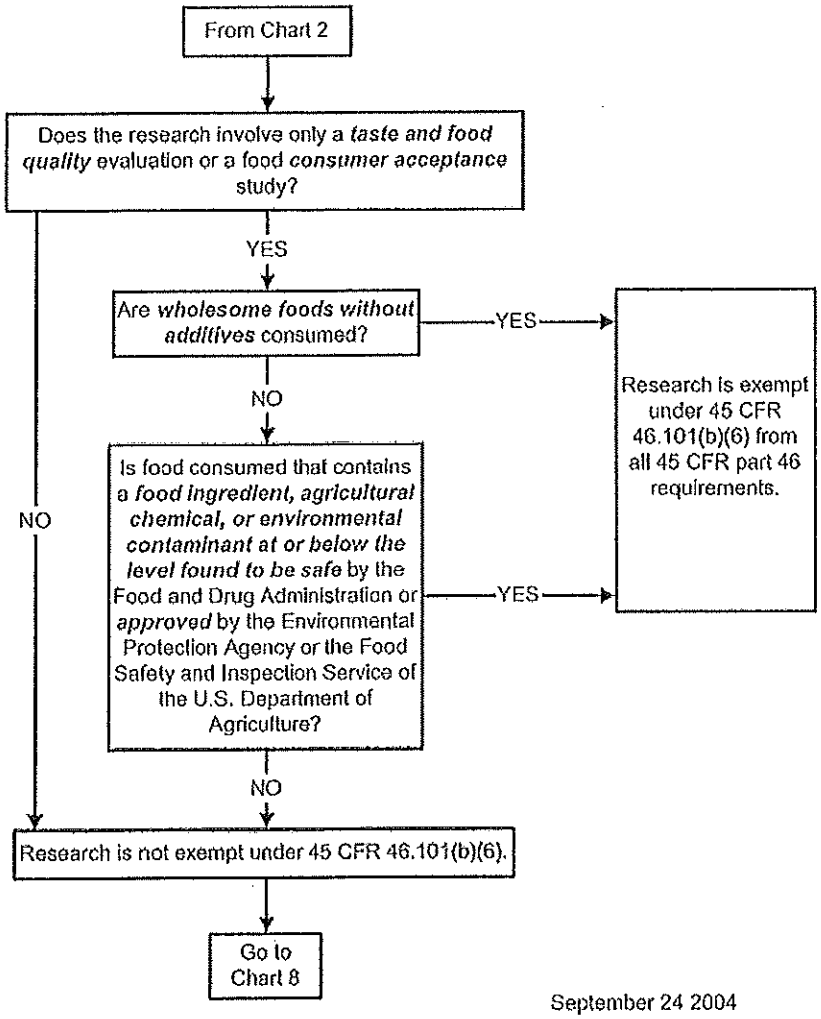

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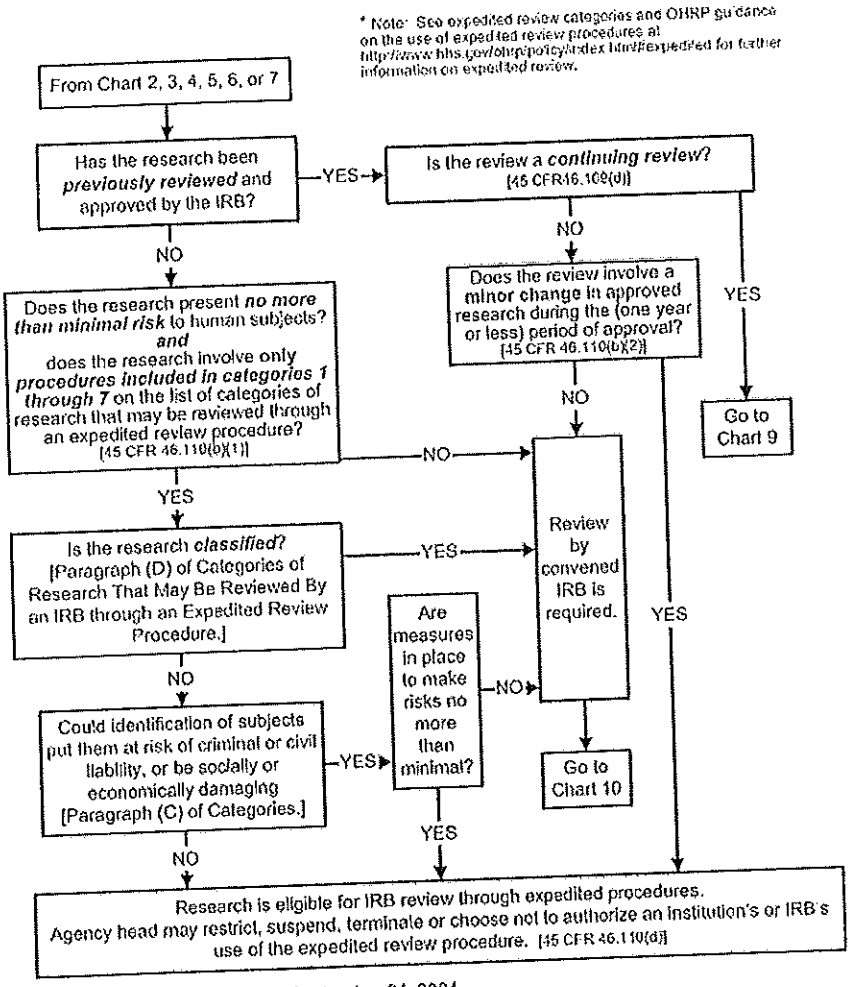

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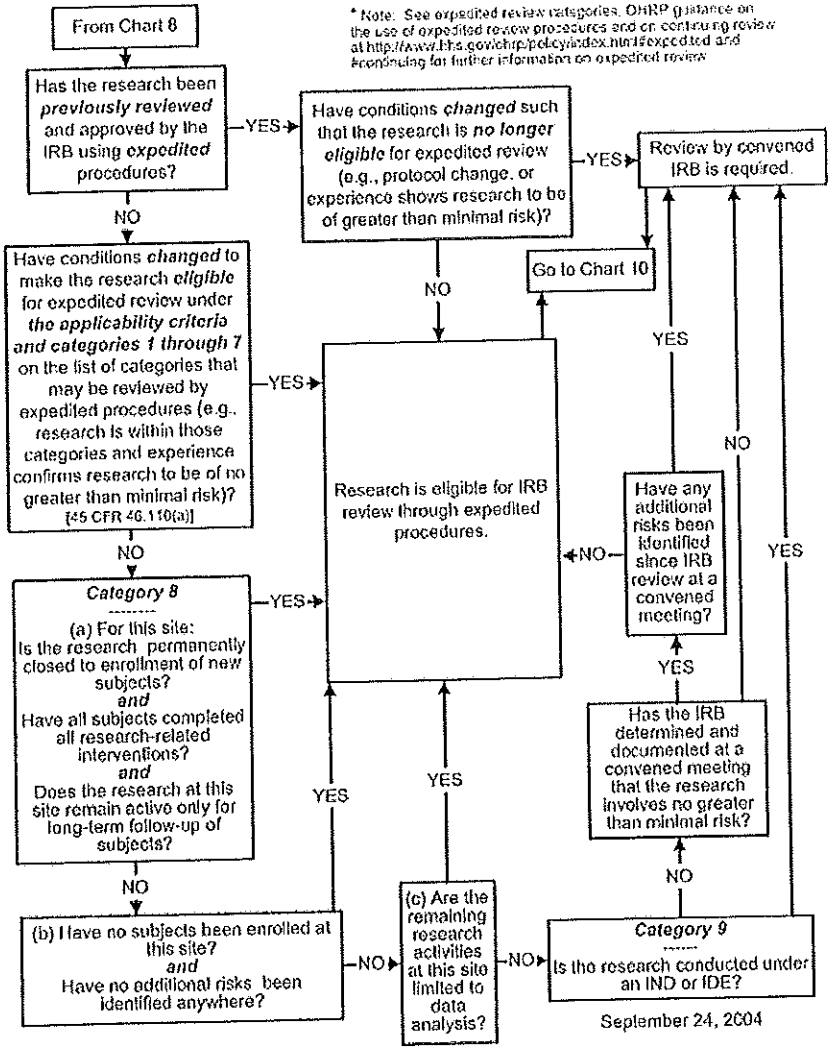

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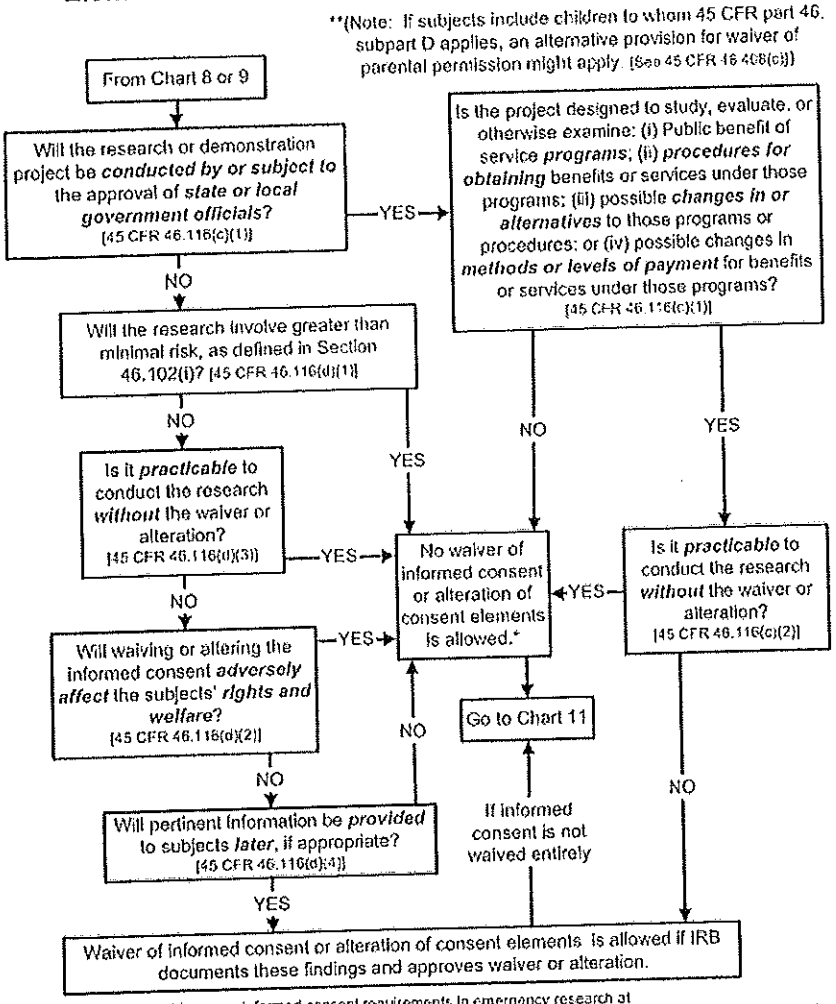

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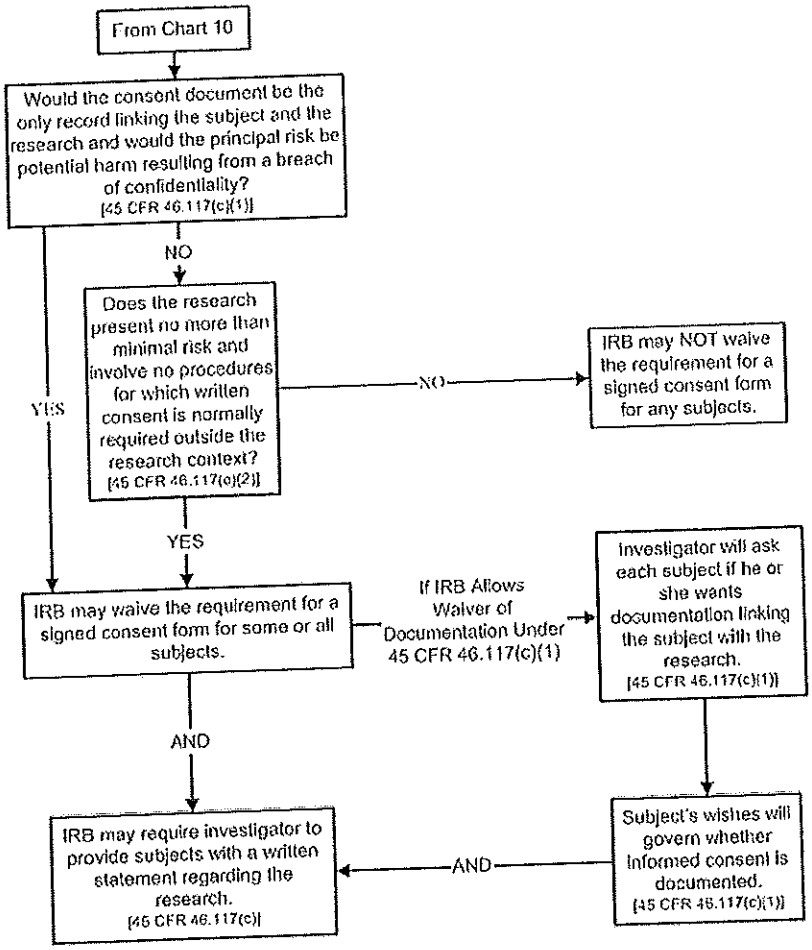

September 24, 2004

Rowan University

ROWAN UNIVERSITY SCHOOL OF OSTEOPATHIC MEDICINE
INSTITUTIONAL REVIEW BOARD (IRB)

Reviewer Checklist for Initial and Continuing Review

PI Last Name: _____ **Reviewer Name:** _____

Protocol Number: _____ **Date:** _____

Criteria for Approval

☐ YES ☐ NO	**1. Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.**
	Points to Consider: • Consider physical, psychological, social, legal, and economic risks. • Has the appropriate departmental scientific review occurred? • Are the aims and objectives clearly defined? • Are there adequate preliminary data and is there appropriate justification for the research? • Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question? • Are there qualified staff and resources to conduct the research? • Is there appropriate monitoring of the subject during and after the research? • Are medical or psychological resources available that participants might require as a consequence of the research? • Are adequate references provided? **Comments:**
☐ YES ☐ NO	**2. HIPAA Requirement**
	Points to Consider: • HIPAA is not required. • HIPAA Authorization Confirms with University's model language • HIPAA is not required for all RowanSOM faculty **Comments:**
☐ YES ☐ NO	**3. Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.**
	Points to Consider: • Consider physical, psychological, social, legal, and economic risks. • Are procedures that will answer the scientific question being performed anyway? • If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm? • Is there a clear differentiation between research and standard of care procedures? **Comments:**
☐ YES ☐ NO	**4. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.**
	Points to Consider: • Consider physical, psychological, social, legal, and economic risks. Are the risks and benefits adequately described? • Does the investigator have access to a population that will allow recruitment of the necessary number of participants? • Does the investigator have sufficient time to conduct and complete the research? • Is the research and timeline for completion feasible? • Does the knowledge expected to result have importance? • Are there adequate plans to notify the subjects about the research results (clinical issues, suicidal, referrals) **Comments:**

☐ YES NO	**5. Brochures and Publications** **Points to Consider:** • Drug/device brochure or research proposal included • Previous publications (for studies involving drugs/device PDR info or websites) pertinent to the study submitted.
☐ YES ☐ NO	**6. Advertisement** **Points to Consider:** • Radio, video, web, e-mail or newspaper ad provided • Advertisement says it is a research • It is free of coercive language • Mentions remuneration • Responsibility for costs.
☐ YES ☐ NO	**7. Enrollment Information** **Points to Consider:** • How many subjects are to be enrolled at Rowan/RowanSOM • Who is to be enrolled? a. Healthy volunteers b. Ill subjects c. Minors d. Pregnant women, fetuses or neonates e. Prisoners (if prisoners, if you are prisoner advocate, mark yes in comments column) f. Decisionally impaired subjects g. Subject population is appropriate for study h. Students i. Equitable selection process The process requires consideration of the extent to which a proposed subject population is already burdened by poverty, illness, poor education, or chronic disabilities in deciding whether they ar the appropriate population for the proposed study. Does procedures investigator will be using ensure that everyone has an equal chance of being selected with appropriate consent, free of coercion by not being in a position to make vulnerable decision making position, providing accurate information (without deception) and the rights to privacy and confidentiality respected.
☐ YES ☐ NO	**8. Selection of participants is equitable.** **Points to Consider:** • Consider the purpose of the research. • Are the inclusion and exclusion criteria adequately defined and equitable? • Are there populations vulnerable to coercion and undue influence and has this been addressed? • Are there acceptable procedures for screening subjects prior to recruitment? • If there is exclusion of women, minorities, and other vulnerable populations are they justified? **Comments:**
☐ YES ☐ NO	**9. Inclusion Criteria:** **Points to Consider:** • Subject's inclusion criteria delineated and rationalized?
☐ YES ☐ NO	**10. Exclusion Criteria:** **Points to Consider:** • **Are subject's exclusion criteria correctly delineated and rationalized?**

	11. Recruitment procedures are acceptable
☐ YES ☐ NO	**Points to Consider:** • Is the setting, location and timing of recruitment appropriate for the research being conducted? • Are recruitment methods well defined and appropriate for the population? • Are all recruitment materials non coercive, and easily understood? **Comments:**
	12. The research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants. ***(Not applicable if the research involves no more than minimal risk.)***
☐ YES ☐ NO ☐ NA	**Points to Consider:** • Does the protocol adequately specify: Who will monitor the data? What data will be monitored? How frequently will data be monitored? What analyses will be performed on the data? What decision rules (e.g., stopping rules) will be considered? • Is there a plan to promptly detect unexpected harms or an increase in frequency or severity of harms? • Is there an adequate plan to stop the protocol if benefits are proven to outweigh harms or harms are proven to outweigh benefits? **Comments:**
	13. There are adequate provisions to protect the privacy of participants.
☐ YES ☐ NO	**Points to Consider:** • Will participants have an expectation of privacy? • Will participants think that the information sought by the investigator is appropriate? • Will participants be comfortable in the research setting? • Are there adequate provisions to consider and assure the privacy of the subject? **Comments:**
	14. There are adequate provisions to maintain the confidentiality of the data.
☐ YES ☐ NO	**Points to Consider:** • Is confidentiality assured? • Are there adequate provisions to protect the confidentiality of the data? • Will data release cause risk of harm? • Are appropriate techniques being used to protect confidentiality (storage, coding, use of identifiers) • Does the protocol specify where the data and consent form will be stored? **Comments:**
	15. Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence. (do not complete if these populations are not included)
☐ YES ☐ NO ☐ NA	**Points to Consider:** • If the research involves pregnant women, fetuses, or neonates complete *Research Involving Pregnant Women, Fetuses, or Neonates* checklist. • If the research involves prisoners complete *Research Involving Prisoners* checklist. • If the research involves children complete *Research Involving Children* checklist. • If the research involves a surrogate consent process complete *Research Involving Use of Surrogate Consent Process* checklist

16. Drugs, Biologics, Devices ☐ NA

IF THE PROTOCOL INVOLVES THE TESTING OF DRUGS & BIOLOGICS select category as appropriate:

a. ☐ Drug is marketed / FDA-approved & will be used as marketed/approved.
b. ☐ Drug is investigational and research is conducted under IND. IND information included and investigational drug brochure is attached.
c. ☐ Drug is marketed but being studied in an off label indication. IND information included
d. ☐ Drug is marketed but being studied in an off label indication. PI claims no IND is required.
In order for no IND to be required all of the following must be true:

- The results will not be reported to the FDA as a well controlled study in support a new drug indication for use will it be reported or to support any significant change in the labeling of the drug?
- The study is not intended to be reported to the FDA in support of a new indication for use or to support any other significant change in labeling.
- The study is not intended to support a significant change in the advertisement for the product.
- The study does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks associated with the use of the product.)
- The study is conducted in compliance with the requirements for CCI review and informed consent.
- The study is conducted in compliance with the requirements for the promotion and sale of drugs.

↳ Do you agree that all the above are true? ☐ YES ☐ NO

Comments:

16B. IF PROTOCOL INVOLVES THE TESTING OF DEVICES complete and select appropriate:

a. ☐ Sponsor categorizes investigational device as significant risk (SR) and IDE is provided.
b. ☐ Sponsor categorizes investigational device as non-significant risk (NSR)
In order for the device to be considered a NSR, all the following must true:

- is not intended as an implant to remain more than 30 days in the human body and does not present a potential for serious risk to the health, safety, or welfare of a subject;
- is not purported or represented to be for a use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject;
- is not for a use of substantial importance in diagnosing, curing, mitigating, treating, or otherwise preventing impairment of human health and does not presents a potential for serious risk to the health, safety, or welfare of a subject
- the device does not present a potential for serious risk to the health, safety and welfare of the subject.

Do you agree that the following are true? ☐ YES ☐ NO

d. ☐ Device is marketed / FDA-approved & will be used as marketed/approved

e. ☐ 501(k) is marketed / FDA-approved & will be used as marketed/approved ☐ documentation attached

f. ☐ Humanitarian Use Device ☐ documentation attached

Comments:

10 C. Does the protocol describe acceptable accountability, storage, access, and control of the drug or device? ☐ YES ☐ NO

Comments:

17. CONSENT FORM AND DOCUMENTATION OF CONSENT

17a. Complete if there is a request Complete WAIVER OF INFORMED CONSENT (no consent obtained by any method) NA☐

Do you agree that the following are true? ☐ YES ☐ NO

1. The research involves no more than minimal risk to the subjects
2. The waiver/alternation will not adversely affect the rights and welfare of the subjects
3. The research could not practicably be carried out without the waiver or alteration, and
4. When appropriate, the subject will be provided with pertinent information after participation.

Comments:

1 ,.. Complete if there is a request for WAIVER OF DOCUMENTATION OF CONSENT (there is another method of consent (verbal, information sheet) NA☐

One of the criteria must be checked:

☐ The consent form would be the only record linking the subject with the research, and a potential risk would be a breach in confidentiality. In such case, each subject should be asked if they want documentation. And their wishes would govern **(cannot apply to FDA regulated research)**

or

☐ Study is no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Comments:

17c. Complete if Informed Consent will be appropriately documented in accordance with the regulations NA☐

18. HIPAA authorization conforms with University's model authorization language? ☐ YES ☐ NO

19. Collaborative Research:

• **Outside collaborators are directly involved**	☐ YES	☐ NO
• **Outside IRB has approved the study (if necessary)**	☐ YES	☐ NO
• **Outside collaborators have signed agreement with Rowan/RowanSOM to enroll subjects in this study**	☐ YES	☐ NO
• **Name of the institution and approval from outside institution included**	☐ YES	☐ NO

I ; review the consent document verifying that it contains the following required elements:

A statement that the study involves research.	☐ YES	☐ NO	
An explanation of the purposes of the research.	☐ YES	☐ NO	
An explanation of the expected duration of the participant's participation.	☐ YES	☐ NO	
A description of the procedures to be followed.	☐ YES	☐ NO	
Identification of procedures that are experimental. (May be omitted if there are none.)	☐ YES	☐ NO	☐ NA
A description of any reasonably foreseeable risks or discomforts to the participant. (May be omitted if there are none.)	☐ YES	☐ NO	☐ NA
A description of any benefits to the participant or to others, which may reasonably be expected from the research. (May be omitted if there are none.)	☐ YES	☐ NO	☐ NA
A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the participant. (May be omitted if there are none.)	☐ YES	☐ NO	☐ NA
A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. (May be omitted if confidentiality will not be maintained.)	☐ YES	☐ NO	☐ NA
A statement that notes the possibility that the Food and Drug Administration may inspect the records (May be omitted for research that is not FDA-regulated.)	☐ YES	☐ NO	☐ NA
An explanation as to whether compensation is available if injury occurs. (May be omitted if the research involves no more than minimal risk.)	☐ YES	☐ NO	☐ NA
If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. (May be omitted if the research involves no more than minimal risk.)	☐ YES	☐ NO	☐ NA
An explanation as to whether any medical treatments are available if injury occurs. (May be omitted if the research involves no more than minimal risk.)	☐ YES	☐ NO	☐ NA
An explanation of whom to contact for answers to pertinent questions about the research.	☐ YES	☐ NO	
An explanation of whom to contact for answers to pertinent questions about the research participant's rights.	☐ YES	☐ NO	
An explanation of whom to contact in the event of a research-related injury to the participant. (Note: May not be omitted just because the research involves no more than minimal risk.)	☐ YES	☐ NO	

Contact information for the research team for questions, concerns, or complaints.	☐ YES	☐ NO	
C :t information for someone independent of the research team for problems, concerns,	☐ YES	☐ NO	
A statement that participation is voluntary.	☐ YES	☐ NO	
tement that refusal to participate will involve no penalty or loss of benefits to which participant is otherwise ed.	☐ YES	☐ NO	
A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.	☐ YES	☐ NO	

Additional

A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. (Look for when research involves investigational drugs/devices, novel procedures involving risk, or where a goal of the research is to define safety.)	☐ YES	☐ NO	☐ NA
A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)	☐ YES	☐ NO	☐ NA
Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. (Look for when the protocol mentions this as a possibility.)	☐ YES	☐ NO	☐ NA
Any additional costs to the participant that may result from participation in the research. (Look for when additional costs are expected.)	☐ YES	☐ NO	☐ NA
The consequences of a participant's decision to withdraw from the research. (Look for when withdrawal from the research will have adverse consequence.)	☐ YES	☐ NO	☐ NA
Procedures for orderly termination of participation by the participant. (Look for when such procedures are part of the tocol.)	☐ YES	☐ NO	☐ NA
A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. (Look for on long-term clinical t)	☐ YES	☐ NO	☐ NA
The approximate number of participants involved in the study.	☐ YES	☐ NO	☐ NA
The amount and schedule of all payments to the participant.	☐ YES	☐ NO	☐ NA

Comments:

15d. Complete if the investigator has requested use of the short form

Short Form Used? ☐ YES ☐ NO

(There is a provision in the regulations to allow verbal explanation of the research followed by the subject signing a brief statement that the research was explained. This is used most frequently when an interpreter is used for a non-English speaking subject.

Comments:

16. Complete if this project is federally funded and Rowan is the primary awardee

? ☐ YES ☐ NO

ıments:

17. Reviewer's Final Assessment/Opinion	
Risk Level	☐ Minimal Risk ☐ Greater than minimal risk
Approval	☐ No changes: there is an acceptable risk/benefit ratio and protocol and consent document are acceptable as submitted
Conditional Approval	☐ Minor changes needed in the informed consent document, protocol or other study materials ☐ Administrative review (typos, missing signatures) ☐ Review by Chair or designee ☐ Review by Subcommittee
Deferral	☐ (For Expedited Research) Refer to Full Board ☐ Clarifications or additional information is required regarding a specific aspect of study ☐ There is an unacceptable risk/benefit ratio, because (check all that apply): ☐ Protocol poorly written, lacking significant amounts of information regarding scientific justification, study procedures, risk reduction, etc. ☐ It is possible that a response for the investigator could alter the risk/benefit ratio ☐ There are ethical concerns that can be addressed by obtaining more information or requiring changes in study design and procedures.
Disapproval	☐ Risks significantly outweigh the benefit or value of the knowledge to be gained ☐ There are significant ethical concerns or questions that result in the study being unacceptable
☐ **YES** ☐ **NO**	**Should review occur more frequently than once a year?** ↳ *If YES,* please specify how often: _____
☐ **YES** ☐ **NO**	If this protocol is minimal risk and there are no changes in risk during the next year, can continuing review be conducted by expedited review procedures?

You may attach a marked up copy of the consent/assent forms and/or other study materials with any edits, changes, typos or suggested wording. Circle word/phrases that need to be rewritten in lay language or clarified. Please make clear which comments are suggestions and which are required.

Additional Comments/Questions you would like the Principal Investigator to address: