Guide to:
Informed Consent

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Institutional Review Board
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Overview

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___ 5. Alternatives (if applicable): It is specified whether there are proven, established treatment options available that may be advantageous to the subject (in lieu of the study treatment).

___ 6. Contacts: The names and telephone numbers of all investigators and hours available.

___ 7. Performance Sites: Where the study will be conducted.

___ 8. Number of Subjects: Maximum number of subjects anticipated including controls if relevant.

___ 9. Subjects:

___ A. Inclusion Criteria: All criteria for participation in the study are specified. Examples: >18 years old, left or right-handed, diagnosed with a specified condition; Subject pool, e.g. psychology undergraduate students, senior citizens, etc.

___ B. Exclusion Criteria: Specify any subset of those meeting the inclusion criteria to be excluded from the study. If none, indicate N/A & omit from Consent Form.

___ 10. Privacy: Specify whether the study is anonymous or confidential. An anonymous study is one in which the data cannot be linked to the identity of the subject directly or indirectly – either because the name/identity of the subject is never obtained by the investigator, or because there is no code linking data to the subject's identity. If the study is not anonymous, i.e., if there is a code linking data to identity, describe the extent, if any, to which confidentiality of records identifying the subject will be maintained. Confidentiality cannot be absolute. Always state “data will be kept confidential unless release is legally compelled.”

____ 11. Financial Information: Any compensation for participating and any uncompensated costs incurred by subjects are specified. State when incentives will be delivered.

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Identifiers might be removed from the identifiable private information or identifiable biospecimens. After removal, the information or biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

Yes, I give permission_____
Signature

No, I do not give permission_____
Signature

OR

Your information or biospecimens collected as part of the research, even if identifiers are removed, may be used or distributed for future research.

Yes, I give permission_____
Signature

No, I do not give permission_____
Signature

Guide to Assent for Minors

Guide t o Consent f or Mail & Te lephone S urveys

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11. Exclusion Criteria: Individuals under age 18 and over age 50. If you did not suffer a heart attack and are not currently in the hospital for this condition.

12. Right to Refuse: Subjects may choose not to participate or to withdraw from the study at any time with no jeopardy to their treatment by their respective doctors or other penalty at the present time or in the future.

13. Financial Information: There is no cost to the subjects, nor is there any compensation for participating in the study.

14. Privacy: Results of the study may be published, but no names or identifying information will be included in the publication. Subject identity will remain confidential unless disclosure is required by law. Please be aware that data collected in this Federally funded project will be posted to the ClinicalTrials.gov website and available to the public. All identifiers will be removed from the data prior to deposit at the website.

15. The LSU Institutional Review Board (which oversees university research with human subjects) and SPONSOR NAME (if applicable) may inspect and/or copy the study records. Results of the study may be published, but no names or identifying information will be included in the publication. Other than as set forth above, subject identity will remain confidential unless disclosure is legally compelled.

16. Signatures:
    The study has been discussed with me and all my questions have been answered. I may direct additional questions regarding study specifics to the investigators. For injury or illness, call your physician, or the Student Health Center if you are an LSU student. If I have questions about subjects' rights or other concerns, I can contact Alex Cohen, Institutional Review Board, (225) 578-8692, irb@lsu.edu, or www.lsu.edu/research. I agree to participate in the study described above and acknowledge the investigator's obligation to provide me with a signed copy of the consent form.

    Subject Signature: _____Date:_____

    The study subject has indicated to me that he/she is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above, the subject has agreed to participate.

    Signature of Reader: _____ Date: _____

Sample Consent Form for a Non -Clinical Study

Sample Parental Permission Form

1. Study Title: Comparison of Intervention Strategies for Addressing Inappropriate Classroom Behavior

2. The purpose of this research project is to develop effective strategies for teachers to use with students exhibiting disruptive classroom behavior. Over a period of one month, 2-3 days per week, the investigator, posing as a teacher's aide, will observe subjects' general classroom behavior, assign specific tasks to the subjects, and will use three intervention techniques with the subjects: positive attention, reprimand, and time-out.

   In the positive attention technique, the "teacher's aide" will provide the subject with positive attention, regardless of the occurrence of problem/disruptive behavior. In the reprimand technique, the "teacher's aide" will respond to each instance of disruptive behavior with a neutral reminder (e.g., you need to be working). In the time out technique, for each instance of problem behavior, the "teacher's aide" will remove the subject's work and turn his/her desk away from the classroom activities and other students for 30 seconds. At the end of 30 seconds, the investigator will turn the subject's desk back toor11.3 (t)(t)-6.6 (TJ 0 -1.141 Td [(pos)-2 (i)2.6 (t (i)2.6 (m) (s)-2 (r)-5.9 (ee)10.5 (c)

Sample Child Assent Form

I, _____, agree to be in a study to find ways to help children act better in school.

11. Right to Refuse: Participation is voluntary, and a child will become part of the study only if both child and parent agree to the child's participation. At any time, either the subject may withdraw from the study or the subject's parent may withdraw the subject from the study without penalty or loss of any benefit to which they might otherwise be entitled.

12. Privacy: The school records of participants in this study may be reviewed by investigators. Results of the study may be published, but no names or identifying information will be included for publication. Subject identity will remain confidential unless disclosure is required by law.

13. Financial Information: There is no cost for participation in the study, nor is there any compensation to the subjects for participation.

14. Signatures:
    The study has been discussed with me and all my questions have been answered. I may direct additional questions regarding study specifics to the investigator. For injury or illness, call your physician, or the Student Health Center if you are an LSU student. If I have questions about subjects' rights or other concerns, I can contact Alex Cohen, Chairman, Institutional Review Board, (225) 578-8692, irb@lsu.edu, or www.lsu.edu/research. I will allow students to participate in the study described above and acknowledge the investigator's obligation to provide me with a signed copy of this consent form.

School Administrator Signature: _____ Date: _____

15. For research involving the collection of identifiable private information or identifiable biospecimens one of the following must____ be listed on the consent form:

    Identifiers might be removed from the identifiable private information or identifiable biospecimens. After removal, the information or biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

    Yes, I give permission_____
    Signature

    No, I do not give permission_____
    Signature

    OR

    Your information or biospecimens collected as part of the research, even if identifiers are removed, may be used or distributed for future research

    Yes, I give permission_____
    Signature

    No, I do not give permission_____
    Signature

Guide to Consent Script

The consent script should include the following items:

Study Title: Name of the study.

Explain the study procedures and state how long it will take to complete the study. Inform the participants of the purpose of the research including any sensitive types of information to be collected (e.g., sexual orientation or behaviors, drug use, etc.) If the participant will be recorded, it must be stated.

Inclusion criteria: List everything required to be in the study including the age of participants needed.

Exclusion criteria: List everything that would disqualify a participant from being able to participate in the study.

Inform the participants of any risk involved in the study. If your project could elicit emotional or psychological issues in the subjects, you need to insert contact information for relevant support services in this consent. When possible, the listings need to be local and national. Please contact the IRB office if you have questions.

State the name and contact information of the investigator(s).

Inform the participants of their right to refuse. The text could read: "Subjects may choose not to participate or to withdraw from the study at any time without penalty or loss of any benefit to which they might otherwise be entitled."

Inform the participants of the procedures by which and the extent to which their privacy will be protected.

This text must be included: "This study has been approved by the LSU IRB. For questions concerning participant rights, please contact the IRB Chair, , 225-578-8692, or irb@lsu.edu."

For online surveys and questionnaires this text must be included: "By continuing this survey, you are giving consent to participate in this study."

Your information or biospecimens collected as part of the research, even if identifiers are

removed, may be used or distributed for future research.

_____ Yes, I give permission

_____ No, I do not give permission