



Office of the
Vice President
for **Research**
at the university of georgia[®]

What is exempt research?

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IRB Protocol Types

- Not Human Subjects Research
- Exempt
- Expedited
- Full Committee

Exempt Categories

- Category 1: Research conducted in commonly accepted educational settings.
 - Examples:
 - a) research on regular and special education instructional strategies or
 - b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods
- Category 3: Research involving educational tests, survey procedures, interview procedures, observation of public behavior of public officials
 - Examples:
 - Interviewing public officials about a local or global issue
 - Comparing personality assessments scores of appointed judges in the state of NJ.

Exempt Categories

- **Category 4: Existing Data: Records Review, Pathological Specimens**
 - **Examples:**
 - Analyzing de-identified data or tissue samples
 - Analyzing census data about aging or housing
 - Collecting de-identified data from patient charts that underwent knee replacement from 1995 to 2005

 - **Category 5: Public Service Programs**
 - **Examples:**
 - A researcher is sponsored by the Department of Health and Human Services wants to conduct a study analyzing the effectiveness of various government sponsored programs in decreasing obesity in the United States.
 - A researcher sponsored by the Department of Agriculture- Food and Nutrition Service wants to compare the current use of the Supplemental Nutrition Assistance Program (i.e., food stamps) by Americans compared to twenty years ago.

 - **Category 6: Taste Tests (this is the only exempt category allowable by the FDA)**
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Exempt Categories

- Category 2: Public behavior or anonymous questionnaires
 - Research involving the use of:
 - educational tests (cognitive, diagnostic, aptitude, achievement),
 - survey procedures,
 - interview procedures, or
 - observation of public behavior may be exempt,

NOTE: This exemption does not apply to research with children except for research involving observation of public behavior where the investigator(s) do not participate in the activities being observed.

Subpart D – Exemptions

- Subpart D allows minors to be included in categories 1, 3, 4, 5, and 6.
 - New changes to UGA Exempt Policy allows minors to be included in UGA Flex Categories for Non-Federally Sponsored Research!
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UGA Flex Categories for Non-Federally Sponsored Research

- Category 7: Involves research of individual or group characteristics or behavior using established qualitative or quantitative data collection procedures that may include benign interventions or performance of non-physically invasive tasks and physical actions by a subject, presentation of stimuli, or manipulations.
 - Ethnography, action research teams and focus groups.
 - Reading, writing, card-sorting tasks; eye-tracking technology; computer and video games, photo/video elicitations; game or role playing
 - Interventions would be brief, harmless, painless, not physically invasive
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UGA Flex Categories for Non-Federally Sponsored Research

- Category 8: Limited to analysis of existing or prospective information or biological specimens, and information may be recorded by the Investigator in such a manner that subjects can be identified, directly or through identifiers linked to the subjects. Ethnography, action research teams and focus groups.
 - Research which is FDA regulated are excluded from this category.
 - Research with a Certificate of Confidentiality are excluded from this category.
 - Studies that typically fall under expedited category 5 may now fall under exempt category 8. This category may include information or specimens from children.
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Consideration for Exempt

- No more than minimal risk
 - No particularly vulnerable populations
 - ~~No minors unless strictly educational test/practice without interviews or observing of public behavior that is not instigated~~
 - ~~No deception or incomplete disclosure~~
 - A breach of confidentiality could not result in participant's loss of employability, insurability, or result in stigmatization or legal consequences
 - Not physically invasive
 - No genetic information collected
 - Not subject to FDA regulations
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Changes to Other Policies

- Vulnerable Populations
 - Deception
 - Participant Selection and Recruitment
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Changes to Vulnerable Populations Policy and Procedure

- Minors can be included in Category 7 (when not federally sponsored)
 - For federally supported non-exempt research involving minors, UGA IRB applies Subpart D to studies to the extent of the sponsoring agency has adopted these standards
 - For non-federally sponsored non-exempt research involving minors, the IRB may waive the requirements of Subpart D such as obtaining parental permission
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Changes to Deception Policy and Procedure

- Deception or incomplete disclosure regarding the nature or purpose of the research is eligible for exempt determination if it meets the exempt criteria (remember slide 9) and only if the subject authorizes the deception or incomplete disclosure
 - No requirement for debriefing if it is determined to be exempt
 - No requirement to seek waiver or alteration of the consent process
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Changes to Recruitment Policy and Procedure



More advantages of “Exempt”...

- Do not need to notify IRB for most minor modifications of exempt protocols.
 - Except...
 - If the modification disqualifies the study for exempt review
 - If there is federal funding or support
 - If there are changes to study team personnel
 - Do not have to request a continuing review for continued data analysis.
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