**Exempt Category 3 – Benign Behavioral Interventions**

**An Expanded Guide**

**NEW CATEGORY:** Research involving benign behavioral interventions with adult subjects if the subjects prospectively agrees to the intervention and information collection

**Three subcategories:**

1. Information recorded by the PI cannot readily identify the subject (i.e. the information is anonymous)

OR

1. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)

OR

1. Information is recorded with identifiers
	1. Must state how you protect the privacy of subjects and to maintain the confidentiality of data and this is subject to “Limited IRB Review” of the confidentiality measures

**What is a “benign behavioral intervention”?**

* Brief in duration
* Painless/harmless
* Not physically invasive
* Not likely to have a significant adverse lasting impact on subjects
* Unlikely that subjects will find interventions offensive or embarrassing

**What are the restrictions on this type of research?**

* NO children;
* May not include medical interventions;
* Data may only be collected through verbal or written responses (including data entry) or audiovisual recording
* Prospective consent required;
* No deception unless participant prospectively agrees to be deceived

**Einstein IRB requires submission of consent documents and scripts for this category.**

* May include short oral scripts, cover letters, introductory paragraphs on surveys/research instruments and e-mails introducing potential research subjects to the study.
* Signed documentation of consent not required (but may be required under HIPAA).
* Exempt consent template language is available in the iRIS help menu.

***Examples are on the next page!***

**Examples**

**Example 1: Research on self-control**

Graduate business students are asked to participate in research examining the influence of surfing a social media site on measures of self-control. Students were randomly assigned to browse a popular social networking site or a popular news site and then, as a measure of self-control and persistence, were timed in their efforts to solve a complex word puzzle (for which there was no solution). No identifiable information is recorded.

*Example 1 – Analysis:*

* *Behavioral intervention (the random assignment to browse the web site) followed by the collection of data on persistence on a complex task (by direct data entry).*
* *The intervention is benign, in that it involves no appreciable risk of harm or pain or emotional distress for the subjects.*
* *Assumption: Consent was obtained for participation*
* *Question: Must the data be collected anonymously to be exempt?*
	+ *Would disclosure of research results outside the research context place students at risk? Maybe.*
	+ *If yes, are there appropriate confidentiality measures?*

Example 2: Research on music in nursing homes

Nursing home staff interview patients to complete a brief self-report scale measuring mood and anxiety at baseline and two weeks after music is played nightly in patient rooms on half of the wards. All subjects are informed that a study of the effect of music is planned, and music is played only the rooms of those patients who agree to the intervention and ratings.

*Example 2 – Analysis:*

* *The intervention is benign and the methods of collecting data are consistent with the exemption criteria.*
* ***Duration is not brief – two weeks***
	+ *Considering the nature of the study (the playing of background music), the duration of exposure does not alter the fundamentally benign nature of the intervention.*
	+ *Nonetheless, it would not be considered brief.*
* *The study would NOT meet the requirements for exemption.*

Example 3: Assessments of memory, attention and information processing speed

Healthy adult subjects are asked to take part in two 2 hour-long assessments of memory, attention and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software. The procedures are conducted during a single visit, and subjects are encouraged to take breaks when desired.

*Example 3 – Analysis:*

* *The intervention is benign*
* *Requires healthy adult subjects to take part in a five-hour research study in which the benign behavioral intervention lasts one hour and the data collection lasts four hours. This would then meet the definition of brief in duration,*
* *The research itself is not likely to be offensive or harmful.*
* *Assumption: subjects are prospectively consented to participate.*
* *Must the data be collected anonymously to be exempt?*
	+ *No. Disclosure of research results outside the research context are unlikely to place participants at risk.*

Example 4: Physiological arousal and cognitive performance

Recordings of blood pressure and pulse are obtained along with the collection of a saliva specimen for the measure of cortisol level from adult subjects in a study linking physiological arousal to cognitive performance on a standard series of computer games. The procedures last 75 minutes.

*Example 4 – Analysis:*

* *The intervention is benign and brief.*
* *The collection of blood pressure, pulse, and serum cortisol data would be considered medical interventions and so not consistent with the exemption.*
* *Data collection (blood pressure, saliva analysis) is not consistent with the requirement that data collection be by oral or written responses only.*
* *The study would NOT meet the requirements for exemption.*