PURPOSE

procedures the IRB will use to review human subjects research proposals. Government regulations require Wittenberg to maintain an Institutional Review Board (IRB) to review research at the University f participating in

research projects, requesting modification of projects when risks can be reduced, and assuring that subjects give their informed consent to participate. approval.

DEFINITIONS Data: facts

- Wittenberg sponsors the research
 Wittenberg University property or University faculty or students are the subjects of the research
- A Wittenberg employee or student conducts or directs the research (whether or not it is in

on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

- (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
- 4) Secondary research for which consent is not required
- 5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to

- 1) Review at a convened meeting where a quorum (majority) is present; non-scientific member MUST be present
- 2) In order to approve the research, the IRB must determine that all of the requirements specified in 45 CFR 46.111 are met
- 3) A majority of those present must approve the research
- 4) Members with a conflict of interest may provide information but may not participate in the review ORbe present for a vote and he/she does not count toward the quorum
- 5) For any research involving prisoners, the full IRB must participate in the review and a prisoner advocate must be present as a voting member of the IRB

ADDITIONAL TYPES OF REVIEW

For research that has been approved, there are additional types of review carried out by the IRB.

Continuing review must be conducted at intervals appropriate to the degree of risk, but not less than once per year. Expedited review procedures may be used for continuing review if the initial review was expedited and no new risks were identified. Expedited review procedures may be used if the first review was through a full board if, (1) when during the initial review the IRB determined that the research involves no more than minimal risk and no additional risks have been identified, or (2) the remaining activities are limited to data analysis.

Changes or modifications to approved research plans must be reviewed and approved before implementation. Expedited review procedures may be used to approve "minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Reports of unanticipated problems involving risk to the research subjects also must be reviewed through the procedures outlined in Wittenberg policy on Reporting on Unanticipated Problems in Rese2eic

An initial review of the application is conducted by an IRB member.	If a study is approved as exempt or
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