All investigators engaged in UIW IRB-approved research are required to comply with all ethical standards, institutional policies, governmental regulations, and conditions placed on the conduct of research involving human participants. Failure to adhere to these requirements may constitute noncompliance. All instances of suspected noncompliance must be reported to the Office of Research and Sponsored Projects Operations (ORSPO). General noncompliance may be managed by the ORSPO in consultation with the IRB Chair. Suspected serious or continuing noncompliance will be referred to the convened IRB for review. Serious noncompliance and continuing noncompliance are findings that are determined by the convened IRB. The ORSPO reports serious and continuing noncompliance determinations in accordance with the requirements of federal oversight agencies.

Failure on the part of any member of the research team to follow

- the terms of UIW IRB approval;
- applicable laws, regulations; and/or
- UIW policies related to the conduct of research involving human participants.

Examples of general noncompliance may include, but are not limited to

- failure to obtain an institutional exempt determination prior to beginning exempt research;
- continuing research activities beyond study expiration date or during protocol suspension;
- failure to conduct the research as described in and required by the Protocol;f

Noncompli ance that

- presents actual or potential increased risk to participants or to research personnel;
- adversely affects the rights, welfare, or safety of the participants; and/or
- adversely affects the scientific integrity of the study.

Noncompliance that

- is repeated either on a single protocol, or across multiple protocols under an individual investigator, and/or
- represents a pattern of ongoing activities that indicate a lack of understanding of human research requirements that may affect research participants or the validity of the research.

Examples of serious or continuing noncompliance may include, but are not limited to:

- failure to obtain expedited or full board IRB approval prior to initiating human research activities,
- failure to obtain informed consent/assent/parental permission as required by the IRB approved protocol,
- failure to report unanticipated events involving risk to partics inos B7 (ea)2.7 91.8 2 (lt)-3 (i)10.6 (n)-5 9 Td( )TjEMC/Body

or corresponding with the Principal Investigator and research personnel to determine whether the allegation is substantiated. The IRB Chair may participate with the ORSPO. All reports of noncompliance should also be evaluated to determine if the criteria for an unanticipated problem involving risk to participants or others are met.

4. Outcomes of Fact Finding and Initial Evaluation: Possible outcomes of the fact finding may include

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- requirement that participants be re-contacted and provided with updated information or re-consented,
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