

<b>SOP: FO 302</b> <b>Version No.:06</b> <b>Effective Date: 12/2/10</b>	<b>RESEARCH EXEMPT FROM IRB</b> <b>REVIEW</b>	<b>Supersedes</b> <b>Document</b> <b>Dated: 7/1/08</b>
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## 1. POLICY

Steering Committee approved 2/25/11

Research activities in which the only involvement of human subjects will be in one or more specific categories may be exempt from IRB review. The determination by the IRB of exemption must be based on regulatory, institutional and ethical criteria, be appropriately documented, and may only be conducted by the RSPP Manager or IRB chair. Research studies involving emergency use and treatment use are not exempt from prospective IRB review. In addition, the IRB must determine whether research that qualifies for an exemption requires either a HIPAA authorization or a waiver of HIPAA authorization in accordance with Policy HI 1201.

### Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

#### 1.1. Exempt Research Activities

1.1.1. Research activities in which the only involvement of human subjects will be in one or more of the categories listed on the Exempt Determination Form (FO 302-C) may be exempt from IRB review.

1.1.2. The initial emergency use of an investigational drug and investigational device outside a research protocol is exempt, provided that all requirements in Policy EU 1301 related to emergency use of investigational articles are satisfied. Note that research studies involving an expanded access mechanism such as emergency use special exception or single patient IND of an investigational article are not exempt from prospective IRB review.

#### 1.2. Documentation of Exemption

1.2.1. If an Investigator believes that his/her study meets the federal regulations, and institutional and ethical criteria for an exemption from IRB review, he/she should complete the Exempt Protocol Submission Application (FO 302-A). [See policy 301 for required materials/process for submission of an Exempt application]. All investigators listed on the protocol are required to complete the training tutorial found at <http://phrp.nihtraining.com/users/login.php> (or an equivalent training program considered to be acceptable by the RSPP Manager). A copy of the completion certificate must be in the RSPP office prior to issuance of final approval letter.

1.2.2. The Research Compliance Analyst shall review the Exempt Protocol Submission Application for completeness and compliance with IRB policies and applicable laws and regulations. The Senior IRB Chair or RSPP Manager shall then review the protocol submission as well as any other documents he/she deems relevant to determine whether the submission is exempt from IRB review using the Exempt Determination Form (FO 302-C).

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1.2.3. The Senior IRB Chair or RSPP Manager must evaluate whether he or she has a conflict of interest with respect to the activity being reviewed (according to definition of IRB Member conflict of interest). If the reviewing Senior IRB Chair has a conflict of interest, then the RSPP Manager will be responsible for reviewing the activity. In the unlikely event that both the Senior IRB Chair and RSPP Manager have a conflict of interest, then another Aurora IRB Chair will be responsible for making the determination.

1.2.4. If the RSPP Manager or IRB Chair determines that a research study is exempt from IRB review, a letter will be sent to the Investigator and the exemption shall be reported on the IRB meeting agenda.

1.2.5. If the plan or intent of the activity changes, the Investigator must bring this information to the attention of the RSPP office prior to implementing the change. The RSPP Manager or Senior IRB Chair will determine if further IRB review is required.

### 1.3. **HIPAA Compliance**

1.3.1. Even if a research study is exempt from IRB review under the federal regulations governing human subject protections, the IRB, acting as the HIPAA Privacy Board, must determine whether the research involves the use and disclosure of PHI and that such use and disclosure complies with Policy HI 1201 as applicable. The Research Compliance Analyst will review the Exempt Protocol Submission Application to determine compliance with Policy HI 1201, and the RSPP Manager or Senior IRB Chair shall make the HIPAA determination at the time of protocol review/approval.

## 2. **SCOPE**

These policies and procedures apply to investigator requests for exemption from IRB review.

## 3. **APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS**

45 CFR 46.101(b)

45 CFR 46.102(d) and (f)

45 CFR Parts 160 and 164

21 CFR 56.104, 105

OHRP IRB Guidebook, Section IV (A)

OHRP Compliance Activities: Common Findings and Guidance, Section D (July 10, 2002)

OHRP Guidance on Written IRB Procedures (January 15, 2007)

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AAHRPP Elements II.2.A. and II.2.B.

**4. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 1201