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|  | <b>Standard Operating Procedure Number: 201</b> | <b>Title: Management of the Board</b> |
|   | <b>Version: 2.0</b>                             | <b>Effective Date: 10/10/2019</b>     |

### 1. PURPOSE

To describe staff administration and oversight of the IRB to ensure continuity of membership that has the expertise and commitment to meet its regulatory and institutional mandates.

### 2. PROCEDURE

The management of the membership of the IRB and oversight of member appointments, IRB-related activities, communications, and other administrative details are the responsibility of the IRB Manager and staff.

### 3. SPECIFIC PROCEDURES

#### 3.1 Term

As stated in SOP 202, IRB members and Chairs serve a three year term. Reappointment for additional years or terms may occur, by mutual agreement of the IRB member, IRB Chair, Executive Director of Research Compliance, and/or the Institutional Official.

#### 3.2 Appointments

The Institutional Official in consultation with the IRB Manager and/or Chair(s) has the authority to appoint regular and alternate IRB members. Members will be solicited from Avera and surrounding communities.

The Chair and/or Co-Chairs of the IRB will be determined by interest in the position and expertise among current and former IRB members. The Institutional Official in consultation with the IRB Manager has the authority to appoint Chair(s) and/or Co-Chairs.

#### 3.3 Resignations and Removals

An IRB member may resign before the conclusion of his/her term by notifying the IRB Manager or Chair. The vacancy will be filled as quickly as possible when necessary.

The Institutional Official or designee may remove an IRB member, alternate member, or IRB Chair, with consultation from the Executive Director of Research Compliance, IRB Manager and/or IRB Chair(s). Examples of grounds for removal include failure to attend IRB meetings on a regular basis without reasonable cause, or inability to perform the functions of an IRB member or IRB Chair.


#### 3.4 Liability Insurance

Regular and alternate members have liability insurance coverage as part of their IRB membership.

#### 3.5 Evaluation

IRB composition will be continually evaluated to ensure IRB composition meets regulatory and organizational requirements.

- *IRB Member Evaluation:* Annually, each IRB member will complete a self-evaluation. The member self-evaluation will be reviewed by the IRB Manager and/or Chair. Feedback will be given to each member either by e-mail, phone call, or in person.
- *Chair Evaluation:* Annually, each IRB member will complete an anonymous evaluation of the Chair. The evaluations will be reviewed by the IRB Manager. Feedback will be gathered and

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given to the Chair(s) by the Chief Compliance Officer and the Institutional Official (IO). All evaluations will be kept anonymous and only de-identified data will be presented to the Chair(s) to ensure IRB member confidentiality.

#### 4. RESPONSIBILITY

IRB Manager and Institutional Official are responsible for the appointment and removal of IRB members, IRB Chair(s), and Co-Chair(s).

IRB Manager is responsible for day-to-day management of the activities of the IRB.

IRB Manager and Chair are responsible for IRB member yearly evaluations and feedback.

Chief Compliance Officer and IO are responsible for IRB Chair Evaluations and feedback.

#### 5. APPLICABLE REGULATIONS AND GUIDELINES

None

#### 6. APPLICABLE DOCUMENTS

IRB Member Self Evaluation

IRB Chairperson Evaluation

SOP 202

| Revision Number   | Version Date | Approved By,                 | Date Approved |
|---|--------------|------------------------------|---------------|
| 2.0   | 10/4/2019    | Avera Institutional Official | 10/10/2019    |
| <ul style="list-style-type: none"> <li>• Terms of the IRB are three years.</li> <li>• Removal from the IRB can be done by the IO or designee, after consulting with appropriate group.</li> <li>• Annual IRB Member evaluations will be completed and reviewed by the IRB Manager and/or Chair.</li> <li>• Annual IRB Chair evaluations will be completed and reviewed by the Chief Compliance Officer and the Institutional Official.</li> </ul> |              |                              |               |
| 1.0   | August 2016  | Director HSRP / August 2016  |               |