**PURPOSE**

1.1 This procedure establishes the process to prepare for an Administrative Review.

1.2 The process begins when and IRB staff member identifies an application as being possibly eligible for Administrative Review.

1.3 The process ends when the IRB staff member provides the materials to the Designated Reviewer.

**REVISIONS FROM PREVIOUS VERSION**

2.1 Minor revisions since AAHRPP re-accreditation; replaces version dated 12/10/2012.

**POLICY**

3.1 None

**RESPONSIBILITIES**

4.1 IRB staff members carry out these procedures.

**PROCEDURE**

5.1 Refer to the “IRB Roster” and select a Designated Reviewer who has scientific or scholarly expertise in the area of research.

5.1.1 If such expertise is not available, set up the protocol to be reviewed by the convened IRB.

5.2 Use the “WORKSHEET: Expectations of Reviewers” to ensure all information is provided to the IRB member.

5.3 Checklist needed:

   5.3.1 “CHECKLIST: Administrative Review.”

5.4 Worksheets needed, as when likely to be relevant:

   5.4.1 “WORKSHEET: Human Research Determination.”

   5.4.2 “WORKSHEET: Exemption Determination.”

   5.4.3 “WORKSHEET: Expedited Review.”

5.5 For modifications required to secure approval:

   5.5.1 Copy of all IRB meeting minutes relevant to the submission.

   5.5.2 Copy of previous “CHECKLIST: Administrative Review.”

5.6 Place a copy of all materials and all correspondence in the protocol file.

**MATERIALS**

6.1 IRB Roster.

6.2 WORKSHEET: Human Research Determination.

6.3 WORKSHEET: Exemption Determination.

6.4 WORKSHEET: Expedited Review.

6.5 WORKSHEET: Expectations of Reviewers.

6.6 CHECKLIST: Administrative Review.

**REFERENCES**

7.1 21 CFR §56.110(b).

7.2 45 CFR §46.110(b).