1. PURPOSE

1.1. This policy describes the calculation of the <End Approval Date>.

2. POLICY

2.1. Exempt research has no <End Approval Date>.

2.2. The remainder of this policy applies to non-exempt research.

2.2.1. The Approval Interval is the period of approval granted by the convened IRB or <Designated Reviewer>. (e.g., 1 year, 6 months, 3 months)

2.3. For initial review:

2.3.1 The Effective Approval Date is the date the convened IRB or <Designated Reviewer> made the determination to fully approve the research; or

2.3.2 The Effective Approval Date, if the convened IRB or <Designated Reviewer> approved the study with stipulations, the date the IRB or <Designated Reviewer> confirmed that the responsive materials met the requirements of the stipulations

2.3.3 The <End approval Date> is the Effective Approval Date plus the approval interval minus one day.

2.4. For continuing review:

2.4.1 The Effective Approval Date is the date the convened IRB or <Designated Reviewer> made the determination to fully approve the research; or

2.4.2 The Effective Approval Date, if the convened IRB or <Designated Reviewer> approved the study with stipulations, the date the IRB or <Designated Reviewer> approved the study with stipulations (not the date the stipulations were determined to be addressed)

2.4.3 When the Effective Approval Date is less than or equal to 30 days before the current <End Approval Date>, the new <End Approval Date> is the previous <End Approval Date> plus the current approval interval.

2.4.4 When the Effective Approval Date is greater 30 days before the current <End Approval Date>, the new <End Approval Date> is the Effective Approval Date plus the approval interval minus one day.

2.5. For modifications, the <End Approval Date> is unchanged.

2.6 Examples:

2.6.1 Initial review: The IRB conducts initial review of a research project at a convened meeting on October 15, 2014 and approves the project for one year without requiring (a) any changes to protocol or informed consent documents, or (b) submission of any clarifications or additional documents. The effective date of the initial IRB approval would be October 15, 2014, and the End Approval Date is October 14, 2015.

2.6.2 Initial review: The IRB conducts an initial review of a research project at a convened meeting on October 15, 2014, and approves with stipulations the project for one year. The IRB directs the IRB chairperson to review, on behalf of the IRB, the revised protocol and determine whether the changes required by the

IRB have been made. On October 25, 2014, the IRB Chairperson reviews the revised protocol and determines that the changes made by the investigator are satisfactory. The effective date of the initial IRB approval is October 25, 2014, and the End Approval Date is October 24, 2015

2.6.2 Continuing Review: An IRB conducts initial review of a research project at a convened meeting and approves it without conditions on October 15, 2014 for one year. The Effective Approval Date of the initial IRB approval is October 15, 2014, and the End Approval Date is October 14, 2015. The IRB follows a procedure for maintaining fixed anniversary dates for the expiration of annual IRB approvals. The IRB conducts its first continuing review of the research project at a convened meeting on September 20, 2015 and re-approves the project without conditions for another one-year period. The new Effective Approval Date is September 20, 2015, and the new End Approval Date is October 14, 2016.

2.6.3 Continuing Review: An IRB conducts initial review of a research project at a convened meeting and approves it without conditions on October 15, 2014 for one year. The Effective Approval Date of the initial IRB approval is October 15, 2014, and the End Approval Date is October 14, 2015. The IRB follows a procedure for maintaining fixed anniversary dates for the expiration of annual IRB approvals. The IRB conducts its first continuing review of the research project at a convened meeting on September 20, 2015 and re-approves the research for another one-year period with a stipulation that the investigator makes a change to the informed consent document. The IRB directs the IRB chairperson to review, on behalf of the IRB, the revised informed consent document and determine whether the changes required by the IRB have been made. On October 31, 2015, the IRB chairperson reviews the revised informed consent document and determines that the changes made by the investigator are satisfactory. The new Effective Approval Date is September 20, 2015 and the new End Approval Date is October 14, 2016 since the study was reviewed by the fully convened committee and approved with stipulations within 30 days of the prior End Approval Date. Note that under this scenario, there is no lapse in IRB approval between October 15 and October 31, 2015 since the study was approved with stipulations, and during this time, the investigator is permitted to continue research activities involving already enrolled subjects.

2.6.4 Continuing Review: An IRB conducts initial review of a research project at a convened meeting and approves it without conditions on October 15, 2014 for one year. The Effective Approval Date of the initial IRB approval is October 15, 2014, and the End Approval Date is October 14, 2015. The IRB follows a procedure for maintaining fixed anniversary dates for the expiration of annual IRB approvals. The IRB conducts its first continuing review of the research project at a convened meeting on September 10, 2015 and re-approves the research for another one-year period without requiring (a) any changes to protocol or informed consent documents, or (b) submission of any clarifications or additional documents. The new Effective Approval Date is September 10, 2015, and the new End Approval Date is September 9, 2016. Note that under this scenario, the anniversary date for the End Approval Date is not maintained because the Continuing Review was not reviewed at the convened meeting within 30 days of the End Approval Date.

2.6.5 Continuing Review: An IRB conducts initial review of a research project at a convened meeting and approves it without conditions on October 15, 2014 for one year. The Effective Approval Date of the initial IRB approval is October 15, 2014, and the End Approval Date is October 14, 2015. The IRB follows a procedure for maintaining fixed anniversary dates for the expiration of annual IRB approvals. The IRB conducts its first continuing review of the research project at a convened meeting on September 10, 2015 and re-approves the research for another one-year period with a stipulation that the investigator makes a change

to the informed consent document. The IRB directs the IRB chairperson to review, on behalf of the IRB, the revised informed consent document and determine whether the changes required by the IRB have been made. On October 31, 2015, the IRB chairperson reviews the revised informed consent document and determines that the changes made by the investigator are satisfactory. The new Effective Approval Date is September 10, 2015, and the new End Approval Date is September 9, 2016. Note that under this scenario, the anniversary date for the End Approval Date is not maintained because the Continuing Review was not reviewed at the convened meeting within 30 days of the End Approval Date

2.6.6 Continuing Review: An IRB conducts initial review of a research project at a convened meeting and approves it without conditions on October 15, 2014 for one year. The Effective Approval Date of the initial IRB approval is October 15, 2014, and the End Approval Date is October 14, 2015. The IRB follows a procedure for maintaining fixed anniversary dates for the expiration of annual IRB approvals. The PI submits the continuing review 30 days prior to the End Approval Date of October 14, 2015, but the study is not able to be scheduled for convened meeting until October 20, 2015, so all research must cease after October 14, 2015. The IRB conducts its first continuing review of the research project at a convened meeting on October 20, 2015 and re-approves the research for another one-year period with a stipulation that the investigator makes a change to the informed consent document. The IRB directs the IRB chairperson to review, on behalf of the IRB, the revised informed consent document and determine whether the changes required by the IRB have been made. On October 31, 2015, the IRB chairperson reviews the revised informed consent document and determines that the changes made by the investigator are satisfactory. The new Effective Approval Date is October 20, 2015, and the new End Approval Date is October 14, 2016. Note that under this scenario, the anniversary date is maintained and therefore the study is reapproved for a period of less than 364 days.

3 REFERENCES

3.4 21 CFR §56.109(f)
3.5 45 CFR §46.109(e)