Look AHEAD Continuation Protocol Issue and Revision Dates

- 14th Revision July 27, 2015
- 13th Revision August 18, 2014
- 12th Revision June 6, 2014
- 11th Revision Look AHEAD Continuation Trial June 27, 2013

14th Revision – July 27, 2015

Summary of IRB Changes Page 6 and Page 22 the dates for data collection have been changed to reflect the date of the No Cost Extension of 1/31/2016

Summary of Changes to Look AHEAD Protocol 13th Amendment

Page 1

- 1. Header Changed to reflect August 18, 2014 h date
- 2. Thirteenth Revision added

Page 2

1. And mortality added to study outcomes

Page 7

1. Paragraph added on mortality under secondary aims.

Page 8

1. Dates corrected for closeout and analysis corrected

Page 10

1. Of reflexes added to sentence.

Page 22

1. Dates corrected for closeout and analysis corrected

Page 31 - 38

1. ADDENDUM TO ANALYSIS PLAN: Action for Health in Diabetes Continuation (Look AHEAD-C)

Protocol changes

- P. 1 Twelfth Revision June 6, 2014
- P.7 Dates changed to reflect the additional funding with No-cost extension to November 30, 2015.
- P. 9 Measuring waist and height were left out of this section but are part of the original protocol.
- P. 11 Spacing between words corrected
- P.10 Neuropathy tests include mono-filament, reflex testing, and vibration test using a tuning fork which was left out of this section.
- P.13 Correction to grammar: word and added
- P.14 Correction to grammar: comma added
- P.20 Correction to grammar: comma added
- P.22 Correction to grammar: comma added dates changed to reflect the additional No-cost extension funding to November 30, 2015. Sentence re-worded for clarity, as depending when the participant was randomized they could have 2 or 3 phone calls.