Changes to Protocol Form:

Page 01. Study Identification
- “Study Organization” has been renamed to “Owning Organization”.
- Two yes/no questions have been added to assist in SBR selection.
- Study Coordinator, the role that also served as the primary IRB contact, has been renamed to “Primary Regulatory Coordinator”. An additional field labeled “Primary Study Coordinator” has been added.
- When adding someone to the Other Key Personnel section, a Receive Email: Yes/No selection has been added. This determines whether or not the person will receive study related emails sent from the eIRB.

Page 03. Protocol Application Type
- For studies which include FDA regulated drugs or biologics, the Protocol Phase selection now only allows one selection rather than multiple selections.

Page 04. Sponsor and Funding Source
- An additional organization pick-list has been added for the study sponsor. It is only required in the event that the sponsor is a different entity than the funding source.
- The question “Does this study require a contract from the sponsor or Material Transfer Agreement (MTA) with the funding source (or drug/device provider if different from funding source) before study activities can begin at Duke?” has been re-worded to now say “Will any samples/data be transferred to/from Duke as part of this study?”

Page 07. Full Protocol
- The Protocol Source question now only allows one selection rather than multiple selections. In the case of joint authorships, the primary author should now be selected.

Page 08. Drugs, Biologics, and Other Substances
- Two additional Yes/No questions have been added regarding the use of the Investigational Chemotherapy Service or Infectious Disease Research Pharmacy.
- The Drug/Biologic/Substance Source question has been changed from a free-text entry field to an organization pick-list (similar to funding source selection).

Page 09. Devices
- The Device Source question has been changed from a free-text entry field to an organization pick-list (similar to funding source selection).

Page 10. Subject Population Groups and Enrollment
- “Maximum number of subjects to be enrolled at Duke” and “Maximum number of subjects to be enrolled at all sites” has had the word “enrolled” replaced with “consented”.

Page 12. Privacy and Confidentiality
- This is a new page. It contains two questions regarding how subjects’ privacy and confidential data will be protected.

Page 14. Consent Forms
- Several questions have been added regarding study staff procedures in the use of consent forms.
Changes to Study Personnel:
I. Study related email sent from the eIRB
   • When adding Key Personnel to a study, there will now be the option to choose whether or not the person should receive study related emails. Additionally, Co-Principal Investigators will now receive all study related correspondence sent from the eIRB. If a Co-Principal Investigator does not want to receive email for a particular study, they should be moved to the Key Personnel list as an investigator (this can be easily done via a Personnel Change Request) and the Receive Email option should be set to “No”.

II. New amendment type added – “Personnel Change Request”
   • Personnel changes will no longer be handled via a normal Amendment. There will now be a new create button available for approved studies called “Personnel Change Request”. A personnel change request does not have a “modified study” associated with it and can be created and submitted even when there is a normal Amendment undergoing review and vice-versa. The Principal Investigator listed on the personnel change request will be required to electronically sign-off on the change request to route it to the IRB office. The goal for IRB review and approval of personnel change requests is 1 day or less.

III. “Edit Key Personnel” activity button
   • The functionality of this button has been changed. You will no longer be able to add or remove personnel using this button – those changes are now processed via a Personnel Change Request. The button will only allow you to change the Edit Rights and Receive Email preferences for existing Other Key Personnel. The button name has been changed to “Modify Existing Key Personnel” to reflect the new functionality.

Paper Conversion Process:
• All non-exempt IRB studies originally submitted via paper have now been either converted to eIRB or closed. The paper conversion process will be removed from the system June 1st. Any active exempt studies which were originally submitted on paper will continue to receive expiration reminder notices. However, when renewing an exempt study, study staff will create them as a new study request rather than a paper conversion.

Other Changes:
• When navigating an amendment with a modified study, the modified study “short-cut” pages have been removed. The user will now be taken directly to a standard copy of the currently approved study in all cases.
• The history log has been changed to display 25 entries per page, down from 50.
• The printer-friendly version of the protocol form now displays the protocol ID on the first page.