Changes made to the HIPAA Privacy Rule via HITECH allowed covered entities to combine conditioned and unconditioned authorizations for research in the consent form. Conditioned research activities are those for which the subjects’ participation is conditioned upon authorization (e.g., HIPAA authorization), and unconditioned authorizations are optional components (e.g., sub-studies). The rule specifies that the subject must be allowed to opt-in to the unconditioned (optional) component. A common example of this is future contact by the research team or future research on blood samples. If the subject does not opt-in, the subject is not giving authorization to participate in the optional component.

Sometimes this is in the form of a separate “optional” consent form or “sub-study” consent form that requires signature/date, but as stated above, the optional components may be allowed to be embedded in the main informed consent document.

When the optional components are embedded in the main consent document, it’s important that the consent gives the subject background information on the optional component(s) and clearly indicates that it’s optional. This must be followed by signature/date lines where the subject can clearly indicate whether or not they want to take part in the optional component(s).

**This is an example of two optional components in a main consent form:**

After completion of the study procedures the study team may continue follow up with you by phone at 90 days and 1 year. If you do not wish to receive follow-up phone calls from the study team, you have the choice to opt out.

- Yes, you may contact me by phone for follow-up.

  ___________________________  ___________________________
  Signature                      Date

- No, I do not want to be contacted by phone for follow up.

  ___________________________  ___________________________
  Signature                      Date

After the study test is completed your remaining blood samples may be stored for possible future research that is undefined at this time. You have the option to indicate whether or not you wish to have your left over samples stored for possible future research.

- Yes, you may store my left over blood samples for future research.

  ___________________________  ___________________________
  Signature                      Date

- No, I do not want my left over blood samples stored for future research.

  ___________________________  ___________________________
  Signature                      Date