**FORM 5.2E- WAIVER OF INFORMED CONSENT FOR ACCESS TO MEDICAL RECORDS FOR RESEARCH**

For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, the documentation must include all of the following:

[ ]  Identification and date of action

[ ]  Date approved

|  |  |  |
| --- | --- | --- |
| **Does alteration or waiver, in whole or in part, of authorization satisfy the following criteria?** | **Yes** | **No** |
| * The use or disclosure of protected health information involves no more than minimal risk to the individuals;
 |[ ] [ ]
| * The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
 |[ ] [ ]
| * The research could not practicably be conducted without the alteration or waiver;
 |[ ] [ ]
| * The research could not practicably be conducted without access to and use of the protected health information;
 |[ ] [ ]
| * The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;
 |[ ] [ ]
| * There is an adequate plan to protect the identifiers from improper use and disclosure;
 |[ ] [ ]
| * There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law;
 |[ ] [ ]
| * (There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.
 |[ ] [ ]
| * Can authorization (consent) of the individual patient be waived?
 |[ ] [ ]

Primary Reviewer Date