



1. Identification of the IRB or Privacy Board and the date on which the alteration of waiver of authorization was approved;
2. A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization in whole or in part, satisfies the three criteria in the rule;
3. A brief description of the PHI for which use or access has been determined to be necessary by the IRB or Privacy Board;
4. A statement that the alteration or waiver of authorization has been reviewed and approved by the IRB or Privacy Board.

