Criteria for Waiver of Informed Consent (Adults)
45 CFR 46.116(d)

All four criteria must be met:
1) The research involves no more than minimal risk to subjects;
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3) The research could not practicably be carried out without the waiver or alteration ("inconvenient" does not meet this threshold);
AND
4) Whenever appropriate, subjects will be provided with additional pertinent information after participation.

Criteria for Waiver of Parental or Guardian Permission (Minors)¹
45 CFR 46.408(c)

Either of the following two criteria must be met:
1) The criteria for waiver of informed consent are met.
   ➢ See Criteria for Waiver of Informed Consent (Adults)
   OR
2) Because of the nature of the research, it is not reasonable to require parental or guardian permission to protect the children participating in the study; and
   a) There are appropriate provisions to protect the children (e.g., appointing a child advocate or an assent monitor); and
   b) The waiver is not inconsistent with federal, state, or local law.

¹Effective March 16, 2015, the Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240) eliminates the ability of the IRB to waive informed consent/parental permission for Department of Health and Human Services (HHS)-funded research involving newborn dried blood spots.
Criteria for Waiver or Alteration of Documentation of Informed Consent
45 CFR 46.117(c)

Either of the following two criteria must be met:

1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
   OR

2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context
   (Examples: drawing a blood sample; shopping mall survey)

The IRB may require the investigator to provide subjects with an Information Sheet about the research.

Criteria for Waiver of Assent
45 CFR 46.408(a)

One of the following three criteria must be met:

1) The capability of some or all of the children is so limited that they cannot reasonably be consulted;

2) The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;
   OR

3) The criteria for waiver of informed consent are met
   ➢ See Criteria for Waiver of Informed Consent (Adults)
Exceptions from Requirements for Obtaining Informed Consent in Emergencies

FDA regulations:
- Emergency use of a test article (21 CFR 50.23)
- Exception from Informed Consent (EFIC) for research in emergency settings (21 CFR 50.24)

DHHS regulations:
- Research activities carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects’ medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained (45 CFR 46.101(i))

Criteria for FDA Exceptions

For both Emergency Use of a Test Article and Planned Emergency Research:
- The subject is in a life-threatening situation.
- The subject is incapable of giving informed consent due to his or her condition.
- There may be insufficient time to obtain consent from the subject’s legally authorized representative.
- The requirement to obtain prospective informed consent can be waived by the IRB if it is not feasible.

Differences between the two:

<table>
<thead>
<tr>
<th>Emergency Use</th>
<th>Planned Emergency Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment paradigm</td>
<td>Research paradigm</td>
</tr>
<tr>
<td>Exempt from prospective IRB approval</td>
<td>Requires prospective IRB approval</td>
</tr>
<tr>
<td>Single patient use</td>
<td>Multiple subjects</td>
</tr>
<tr>
<td>No alternative treatment is available</td>
<td>May compare competing standard of care treatments</td>
</tr>
<tr>
<td>Requires an IND (either the manufacturer’s existing IND or an Emergency IND)</td>
<td>Requires community consultation and public disclosure</td>
</tr>
</tbody>
</table>