1 PURPOSE

1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
   1.1.1 Legally Authorized Representative (LAR)
   1.1.2 Children
   1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 Section 3: Remove reference to contact legal counsel.
2.2 Section 3.3: Change wording from “children consent” to “children permission.”
2.3 Section 7.1: Added additional CFR reference.

3 POLICY

3.1 Unless the HRRC has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative.
   3.1.1 When research is conducted in the State of New Mexico the following individuals meet this definition:
      3.1.1.1 Spouse
      3.1.1.2 Next of Kin
      3.1.1.3 Guardian or Guardian ad Litem
      3.1.1.4 Legal Custodian
   3.1.2 For research outside New Mexico, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.

3.2 DHHS and FDA’s Subpart D applies to all research involving children.
   3.2.1 When research is conducted in the state of New Mexico all individuals under the age of 18 years are children. Exceptions exist for individuals under the age of 18 who meet the definition of emancipated minors.
      3.2.1.1 An emancipated minor is any person 16 years of age or older who:
         3.2.1.1.1 Has entered into a valid marriage, whether or not the marriage was terminated by dissolution
         3.2.1.1.2 Is on active duty with any of the armed forces of the United States of America, or
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3.2.1.3 Has received a declaration of emancipation pursuant to the Emancipation of Minors Act

3.2.2 For research outside New Mexico, a determination of who is a child is to be made with consultation from legal counsel.

3.3 Unless the HRRC has waived the requirement to obtain consent, when research involves children permission may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care\(^1\). Before obtaining permission from an individual who is not a parent, contact legal counsel.

4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR §46.102, 45 CFR §46.402, 45 CFR 46.408

7.2 21 CFR §50.3

7.3 NMSA 24-7A-6.2; NMSA 32A-21-3; NMSA 32A-21-4

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\(^1\) This is the DHHS and FDA definition of “guardian”