

1.11 HRPP Access to Legal Counsel

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for HRPP access to legal counsel for the purpose of interpreting federal, state, and local law.

2.0 Policy

It is the policy of the Organization that

- 2.1. The HRPP will have ready access to legal counsel in order to ensure the correct interpretation and application of federal, state, and local law.
- 2.2. When laws or regulations are issued or amended, the appropriate component of the HRPP will be advised in a timely manner and any necessary actions taken in accordance with effective dates.

3.0 Organizational Responsibilities

- 3.1. The IRB and ORA have access to legal counsel. Depending upon the issue, consultation will be obtained from one or more of the following individuals:
 - 3.1.1. UNMC Chief Compliance Officer
 - 3.1.2. UNMC Office of the General Counsel (GC)
 - 3.1.3. University of Nebraska (NU) Office of the General Counsel
 - 3.1.4. Children's Nebraska General Counsel or Assistant GC
 - 3.1.5. Children's Nebraska Compliance Director / Privacy Director
 - 3.1.6. Nebraska Medicine General Counsel / Chief Legal and Compliance Officer
- 3.2. The UNMC Chief Compliance Officer and the CN General Counsel or Compliance Director may attend meetings of the various IRBs as guests at their convenience, or at the request of the IRB and/or the IRB Chair or Executive Chair.
- 3.3. The Assistant Vice-Chancellor for Regulatory Affairs and the UNMC Chief Compliance Officer are responsible for advising the IO, the IRB and other HRPP components of new applicable legislation, as well as changes in interpretation of laws that impact human subject protection.

DOCUMENT HISTORY:

? Written: 5/6/2016 (Approved: 5/6/2016) - original author not recorded

? Revised: 2/2/2018 - revision not documented

? Revised 1/22/2025 – clarified job descriptions of persons available for legal consultation; clarified that legal may not regularly attend IRB meeting but are available for consultation; stylistic changes {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 2/11/2025 – added NM General Counsel and Chief Legal & Compliance Officer {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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