

CHAPTER 1

Rules and Regulations for Health Care Innovation Studies

Section 1. Authority. The Wyoming Department of Health (“Department”) promulgates these rules pursuant to Wyoming Statutes 9-2-128 and -129.

Section 2. Purpose & Applicability.

(a) These rules establish the standards and procedures of the Department’s health care innovation account program and apply to applicants seeking to receive:

- (i) Health care innovation account funding under W.S. 9-2-128; or
- (ii) A waiver of existing rules under W.S. 9-2-129.

Section 3. Definitions.

(a) The following definitions apply to these rules:

- (i) “Director” means the Director of the Wyoming Department of Health, including the Director’s designee;
- (ii) “Health care innovation account funding” means the provision of funds from the health care innovation account established under W.S. 9-2-128(b); and
- (iii) “Innovative study” means as defined under W.S. 9-2-128(g)(i) and (ii).

Section 4. Application for Health Care Innovation Account Funding.

(a) If the Department elects to make health care innovation account funding available to persons undertaking innovative studies, the Department shall post an open call for applications. An open call for applications must:

- (i) Be open for a period no less than three months but no more than one year;
- (ii) Be publically posted online at the Department’s website: <https://health.wyo.gov>; and
- (iii) Establish the required form and manner to apply for funding.

(b) A person undertaking an innovative study is eligible to apply for health care innovation account funding if the purpose of the innovative study relates to one of the following:

(i) Reduction of costs associated with long-term care, chronic disease, or other health care services to the state of Wyoming;

(ii) Allowing individuals in need of long-term care to remain in their homes and communities;

(iii) Developing necessary long-term care or other health care services in Wyoming; or

(iv) Use of broadband internet to access health care services.

(c) In order to apply for health care innovation account funding, a person undertaking an innovative study shall timely submit a complete application in the form and manner established by the Department under Subsection (a) of this Section.

(d) An application for health care innovation account funding must include, at a minimum:

(i) A summary of the qualifications, experience, and capacity of the principal investigators and staff to conduct the innovative study, including licensure status and whether adverse action has ever been taken against an individual's license;

(ii) A summary of existing models of service delivery that are currently available in Wyoming and the need filled by the innovative service or model of service delivery to be studied;

(iii) The study question;

(iv) The proposed study design;

(v) A summary of potential harms to patients or clients participating in the study and strategies to mitigate those harms;

(vi) A summary of anticipated results and implications for health care service delivery in Wyoming; and

(vii) The amount of funding requested and a budget proposal summarizing how funds will be allocated to complete the study, including any outside funds that have already been secured for the purpose of undertaking the study.

Section 5. Award or Denial of Health Care Innovation Account Funding.

(a) At the close of the open call period established by the Department, the Department shall convene a review committee to evaluate each complete and timely-submitted application that has been submitted pursuant to Section 4 of this Chapter. The review committee must be comprised of at least three Department officials or employees, who possess relevant subject matter expertise and no conflict of interest.

(b) The review committee shall evaluate each application packet based on the criteria established under Section 4 of this Chapter. The committee may request additional information from the applicant or from outside experts as needed to evaluate the application.

(c) Based on the review committee's evaluation, the review committee shall recommend the Director to either approve or deny an application for funding.

(d) After receipt of the review committee's recommendations for all evaluated applications submitted during the open call period, the Director shall either approve or deny each application for funding. The Director shall base the decision on the review committee's recommendation and availability of funds.

(i) If the Director approves an application, the Department and applicant shall execute an agreement pursuant to W.S. 9-2-128. If an agreement cannot be reached or the Attorney General does not approve of the agreement, the Director's approval of health care innovation account funding is deemed revoked.

(ii) If the Director denies an application, the applicant is not entitled to request a contested case proceeding pursuant to the Wyoming Administrative Procedure Act, W.S. 16-3-101 to -115.

(e) Prior to entering into an agreement with an applicant, the Department may require an applicant's innovative study to undergo Investigational Review Board ("IRB") review pursuant to federal law or Department policy, as relevant, including 45 CFR part 46 (the "Common Rule") and *Wyoming Department of Health, Institutional Review Board, Policy and Procedures* (2005), available at: <https://health.wyo.gov/admin/irb/wdhirbguidelines/>. If the Department requires IRB review and the innovative study does not receive approval from the IRB, the Director's approval of the applicant's application for health care innovation account funding is deemed revoked.

Section 6. Application for Waiver of Rules to Conduct an Innovative Study.

(a) A person conducting an innovative study may request a waiver of Department rules if necessary to carry out the innovative study.

(b) In order to receive a waiver of rules to conduct an innovative study, a person undertaking an innovative study shall submit a waiver application to the Department. The waiver application must be submitted in the manner and form established by the Department and include a description of:

(i) The particular rule or rules for which a waiver is requested; and

(ii) The justifications for a waiver, including why no alternative exists to accomplish the purposes of the study but for a waiver being granted.

(c) The waiver application shall be submitted concurrent to an application for healthcare innovation funding as specified in Section 4 of this Chapter. The application for healthcare innovation funding may request a zero dollar amount if the applicant requires only a waiver of rule to conduct the innovative study, but the application must satisfy the other requirements of Section 4 of this Chapter.

(d) The review committee established under Section 5 of this Chapter shall evaluate waiver applications concurrent with the applications for health care innovation account funding. The committee may request additional information from the applicant or from outside experts as needed to evaluate the application.

(e) Based on the review committee's evaluation, the review committee shall recommend the Director to either approve or deny a waiver application.

(f) After receipt of the review committee's recommendations for all evaluated applications submitted during the open call period, the Director shall either approve or deny each waiver application.

(i) The Director shall base the decision on the review committee's recommendation and a determination that:

(A) The grant of a waiver does not pose a threat to the health, safety, or welfare of Wyoming residents; and

(B) No reasonable alternative exists to accomplish the purposes of the innovative study but for a waiver being granted.

(ii) If the Director approves a waiver request, the Department shall provide the applicant written notice that states:

(A) The rules being waived; and

(B) The purpose for the waiver.

(iii) The Director's approval of a waiver request is contingent upon successful execution of an agreement for the innovative study approved by the committee.

(A) An approved waiver request is in effect only while a successfully executed agreement is also in effect;

(B) If an agreement cannot be reached or the Attorney General does not approve of the agreement, the Director's approval of the waiver is deemed revoked.

(iv) If the Director denies a waiver request, the applicant is not entitled to request a contested case proceeding pursuant to the Wyoming Administrative Procedure Act, W.S. 16-3-101 to -115.

(g) If an innovative study is conducted under a waiver granted by the Director, the applicant shall provide notice of the waiver to all parties involved in the study. The notice must include the elements listed under Subsection (f)(ii)(A) and (B) of this Section as well as the time period for which the waiver is active.

(h) The Director may revoke a waiver at any time.

(i) The Director's decision to revoke a waiver must be based on a finding that:

(A) The grant of a waiver poses a threat to the health, safety, or welfare of Wyoming residents;

(B) A reasonable alternative to a waiver exists to accomplish the purposes of the innovative study; or

(C) The applicant or others responsible for conducting or overseeing the innovative study have violated the law or Department policies.

(ii) If the Director revokes a waiver, the Department shall provide written notice, including an effective date. The applicant is not entitled to request a contested case proceeding pursuant to the Wyoming Administrative Procedure Act, W.S. 16-3-101 to -115.

(i) If an innovative study was conducted under a waiver which has been revoked by the Department, the applicant shall provide notice of the revocation, including the effective date, to all parties involved in the study.