

## **Certificate of Exemption**

19-Oct-2023

**Title:** The impossible choice: the role of insurance design on financial toxicity and access to care for individuals with blood cancer

**COMIRB#:** 23-1697

**Investigator:** Cathy Bradley

**Subject:** Initial Application

**Funding Source(s):** None~

**Panel:** UCD Panel D

**Effective Date:** 13-Oct-2023

**Exemption Category:** 4

**Submission ID:** APP001-1

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### **SUBMISSION DESCRIPTION:**

Initial Exempt Secondary Research Submission

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**Your COMIRB Initial submission APP001-1 has been determined to be EXEMPT from IRB review.** There is no requirement for continuing review and your study has not been given an expiration date.

For the duration of your protocol, any change to the Principal Investigator, or any changes that may affect the exemption determination must be submitted to COMIRB before implementation of the changes. Information on how to submit changes (amendments) and reports of unanticipated problems for your study to COMIRB can be found on the COMIRB website <http://www.ucdenver.edu/research/comirb/submissions/>.

**When your research is complete, please notify COMIRB by e-mail at [COMIRB@ucdenver.edu](mailto:COMIRB@ucdenver.edu)**

### **REVIEW DETAILS:**

The research was reviewed by an IRB member and determined to meet the criteria for exemption under Category 4, as it is analyzing secondary data. This determination will be reported to the IRB.

An IRB member reviewed and approved the request for a full waiver of HIPAA Authorization. All criteria for a waiver of HIPAA Authorization were met.

The following documents have been reviewed as part of this approval:

1. Application Form 8.30.23
2. LLS Project Summary\_Final Submitted 1\_13.pdf
3. Personnel eForm 1-3-15
4. PI Attestation
5. PRMS Protocol Approval.pdf
6. Protocol - Secondary Research 8.30.23
7. Routing eForm 2021

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