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| ***A close up of a sign  Description automatically generated*** | NIH Protocol Summary For Studies Proposing the Use of Exempt Human Subjects Studies (Exemption 4) |

# **NIH Protocol Summary Template**

The UCLA Clinical and Translational Science Institute (CTSI) Grants Submission Unit has created this protocol summary template as a tool to facilitate the development of required components for NIH applications involving Exempt Human Subjects studies (Exemption 4). Each section contains requirements from the NIH and these guidelines should be removed before finalizing. Please be aware of components for which [Text Field rules apply](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/rules-for-text-fields.htm) and their character limitations. It is not meant to replace your review of all applicable notices, guidelines, and updates from the NIH related to the specific funding opportunity being responded to. Investigators and research administration staff should continue to refer to NIH’s official policies and guidelines available here: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general-forms-h.pdf>.

This template refers only to those sections of FORMS-H related to human subjects and clinical trials for applications on or after January 25th, 2023; it does not cover the entirety of the SF424 or other portions of the grant application process. Investigators should always remember to refer to the specific Funding Opportunity Announcement (FOA) for any submission-specific information, including whether clinical trials are allowed and other FOA-specific requirements that may not be reflected on this form.

Questions? Contact the UCLA CTSI Grants Submission Unit at [gsu@mednet.ucla.edu](mailto:gsu@mednet.ucla.edu) or (310) 267-4258.

**Note: Only Section 1 and 3.1 are required for Exemption 4 studies. The other components included here are optional and can be accessed** [**here**](https://ctsi-sandbox.healthsciences.ucla.edu/non-exempt-HS-studies)**.**

# **Section 1. Basic Information**

* 1. **Study Title** **(600 character limit):**

For additional studies within the same application, fill out this form separately, each with its own unique study title.

* 1. **Is this study exempt from federal regulations?** 
  2. **Exemption Number**

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Please note that UCLA does not currently utilize Exemption 7 and 8.

* 1. **Clinical Trial Questionnaire:**

**1.4.a** Does this study involve human subject participants? 

**1.4.b** Are the participants prospectively assigned to an intervention? 

**1.4.c** Is the study designed to evaluate the effect of the intervention on the participants? 

**1.4.d** Is the effect that will be evaluated a health-related biomedical or behavioral outcome? 

If you answered YES to all questions in 1.4, this study is a Clinical Trial. Please complete the documentation for [Clinical Trials](https://ctsi-sandbox.healthsciences.ucla.edu/clinical-trials-documentation).

# **Section 2. Study Population Characteristics**

**This Section is Optional for Exemption 4 studies.**

**Section 3. Protection and Monitoring Plans**

**REQUIRED: 3.1 Protection of Human Subjects** (Additional guidelines available [here](https://ctsi-sandbox.healthsciences.ucla.edu/sites/g/files/oketem271/files/media/documents/3.1_Protection_of_Human_Subject_Exemption_Justification__Guidelines.docx).)

1. Justify why the research meets the criteria for the exemption(s) that you have claimed and is exempt from regulatory requirements in 45 CFR 46. Reasons for Exemption 4 can include:
   1. Study involves the collection or study of existing data, documents, records, or specimens but sources are publicly available
   2. Information is recorded by the investigator and/or collaborators in a manner that subjects cannot be subsequently identified directly or through identifiers that are linked to the subjects
   3. Investigator and/or collaborators will not retain or access any identifiers
2. Do not merely repeat the criteria or definitions for Exemption 4 themselves

**For human subjects studies that fall under Exemption 4, skip the rest of the PHS Human Subjects and Clinical Trials Information Form.**