

HAC Policies and Procedures

Description of Research Proposal

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What is the Purpose of the Description of Research Proposal (DRP)?

The DRP describes the research proposal in paragraphs according to the headings indicated below. The DRP is used to describe how a protocol will be conducted locally.

Do all protocols (regardless of the level of review) require the submission of a Description of Research Proposal (DRP)?

Yes.

Can I Just Say That This New Protocol Is Like My Other Approved Protocol?

No. Each protocol should stand on its own.

Can a Sponsor's Protocol Take the Place of the DRP?

No. A sponsor-initiated protocol cannot be submitted in lieu of the DRP.

Can the Extramural Application (e.g., the NIH Protocol) Take the Place Of the DRP?

No. Neither a sponsor-initiated protocol nor an extramural application takes the place of this document.

Is there a Template for the DRP?

Yes. Please refer to the template web site.

Are We Required To Use the DRP Outline or DRP Template?

Yes. If the document does not utilize this outline or template, it will be returned without review. The HAC Administrative Office staff will usually send an email to notify the research team of the incorrect format.

Why Are We Required To Use Lay Terms?

The use of lay terminology is required since the Human Assurance Committee (HAC) reviewers include a combination of lay personnel who may not be familiar with the specifics of a submitted protocol as well as clinicians and scientists who are very familiar with principles of clinical research design.

Why Does the HAC Require a DRP?

The HAC requires the DRP to provide documentation about the research protocol and conduct of that protocol. The HAC considers the purposes of the research, the setting in which the research occurs, the scientific and ethical reasons for including vulnerable

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populations, and the scientific and ethical reasons for excluding classes of persons who may benefit from the research. Each member of the HAC receives a copy of the DRP to review.

What Are the Requirements for the Description of Research Proposal (DRP)?

1. Formatting

- a. Must state “Description of Research Proposal” on the first page
- b. Do not use a font size smaller than 12 pt (Times New Roman or Arial is recommended).
- c. Pagination – MUST be in upper right corner of each page as follows: Page 1 of ___ Pages. The Header feature in most word processing software is useful for this item. Paginate the DRP independently from the ICD and/or CAD.
- d. Version date of document must appear in lower left corner of each page as follows: Version date: 10/01/1999. The Footer feature in most word processing software is useful for this item. The version date is the date that the documents are prepared and the revision date is the date the document is revised.
- e. Protocol/study title (MUST be word for word identical to the title on the protocol, investigator’s brochure, [Form FDA 1572](#), all HAC forms and the Division of Sponsored Programs Administration (DSPA) paperwork) on the first page.
- f. Name of Principal Investigator (PI): State the PI’s name.
- g. Name(s) of Sub-investigators (Sub-I): State the name(s) of the Sub-I(s).
- h. Name of Study Coordinator (SC): State the name of the Study Coordinators (SC).
- i. Name of Sponsor: State the name of the external sponsor.
- j. Use the following paragraph headings in bold font.
 - i. Purpose
 - ii. Specific Aims
 - iii. Study Design
 - iv. Use Of Human Subjects And/Or Human Derived Materials

2. What Should The “Purpose” Section Of The DRP Include?

The Purpose section of the DRP should give a concise statement of the background (i.e., cite complete references, if applicable), rationale, nature and significance of the proposed study (e.g., to examine test results, compare Agent A to Agent B, establish safety and efficacy, etc.)

3. What Should The “Specific Aims” Section Of The DRP Include?

The Specific Aims section of the DRP should state the objectives of the study in a brief paragraph or outline form.

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4. What Should The “Study Design” Section Of The DRP Include?

The Study Design section of the DRP should describe in brief paragraph, outline or graphic form, the following:

- Study design
- Identify control and experimental groups
- Procedures to be used
- Duration and sequence of treatment schedules
- Analysis of data
- Description of procedures being performed already for diagnostic or treatment purposes

This section should provide enough information so that the reader understands what the experiment/proposal entails, without having to read any other materials. You may refer to particular sections of sponsor-initiated protocols or extramural application for minutia, but the DRP must be able to stand alone. NOTE: If certain pages of the sponsor’s protocol or investigator’s brochure are referenced here, attach copies of those pages to the end of this document.

Only the primary HAC reviewers, and not the full Committee members, receive the sponsor protocols.

What If The Study Design Is Similar To A Previously HAC Approved Study?

If the submitted study is similar to previously approved studies, indicate the HAC file number and protocol title.

What If I Am Requesting Exempt From Full Review or Expedited Review Of The Protocol?

If requesting exempt or expedited review, the investigator must include information in the Study Design section as to why the submitted information meets the regulatory requirements for exempt or expedited review.

5. What Should The Use Of Human Subjects And/Or Human Derived Materials Section Of The DRP Include?

Please begin this section with the heading "Human Subjects and/or Human Derived Materials" so that one continuous segment serves for both grant application and HAC review requirements.

The following headings and information are required.

1. SUBJECT CHARACTERISTICS

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Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in the “Study Design” section.

- a. Describe the following characteristics of the subject population including their:
 - i. Anticipated number
 - ii. Age range
 - iii. Health status
 - iv. Recruitment sites and methods including:
 - a. The nature of any compensation to subjects for participation in research
 - b. Advertisements and compensation to investigators, physicians, and other health care providers for identifying and/or enrolling subjects [NOTE: The HAC and the Association of American Medical Colleges (AAMC) do not allow the use of finder’s fees.]
 - v. Summarize the gender and racial/ethnic composition of the subject population.
 - vi. Identify the criteria for inclusion or exclusion of any sub-population.
 - vii. If a gender and/or minority are excluded in a given study, provide a clear rationale for the exclusion.
 - viii. Likewise, provide rationale and justification if children or women of childbearing potential are specifically excluded.
 - ix. Provide documentation to support the subject selection criteria as equitable and fairly distributes the burdens, risks and benefits of the research. Exclusion of classes of persons who might benefit from the research must be justified scientifically and ethically.
 - x. If minors will be involved, describe plans for handling issues of pregnancy, abuse, etc. If school will be missed, identify solutions for making up classroom assignments.
 - xi. Address the issue of the drug being transferred in seminal fluid and how often pregnancy tests will be obtained. NOTE: The HAC recommends monthly pregnancy testing for women of childbearing potential that will be involved in long-term dosing of investigational medications.
 - xii. Explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, human in vitro fertilization, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. The HAC carefully considers the scientific and ethical reasons for including vulnerable populations (such as children, prisoners, pregnant women, mentally disabled persons, or non-English speakers), and the scientific and ethical reasons for excluding classes of persons who might benefit from the research. The proposal should detail reasons for including vulnerable populations in the research. It should also

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include additional safeguards to protect the rights and welfare of vulnerable subjects. Additional regulations regarding special categories of subjects, e.g., children, prisoners, etc., involved in research can be obtained by reviewing the information noted above in the Vulnerable Subjects section.

2. RESEARCH MATERIALS OBTAINED

a. Identify the sources of research material obtained from individually identifiable living human subjects in the form of:

- Specimens
- Records
- Data

Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data. Note that if using genetic materials and a code, the code may not contain the subjects' initials. NOTE: Information obtained on questionnaires or surveys, etc. is human derived material.

b. If human derived materials are to be used, state:

- Where they were obtained.
- How long they will be used.
- How they will be discarded.
- Who will have access to the materials, etc.

The HAC will assess whether there are adequate provisions to protect subject privacy and maintain confidentiality that requires evaluation of:

- Methods used to obtain information about subjects.
- Methods used to obtain information about individuals who may be recruited to participate in studies.
- Use of personally identifiable records.
- Methods used to protect the confidentiality of research data.

Include the following information for investigator-initiated protocols:

- Indicate how data will be collected and analyzed.
- Include copies of the data capture form(s) (DCF) or data collection tool(s) (DCT) that will be used to document the data obtained during the course of the research.

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3. SUBJECT RECRUITMENT AND INFORMED CONSENT PROCESS

Describe the plans for subject recruitment and the informed consent process that will be followed:

- Describe the circumstances under which informed consent will be sought and obtained to support the subject selection criteria are equitable and fairly distribute the burdens, risks and benefits of research.
- Describe who will seek informed consent from the prospective subject and the language they will use to obtain consent. NOTE: Research Informed Consent must be obtained by someone qualified to answer the questions that the subject or their representative may ask regarding the research who has received prior approval from the HAC to obtain consent. Only an approved investigator is allowed to conduct the interview and obtain consent.
- Indicate the person who would provide consent or permission.
- Indicate the language understood by the prospective subject or the legally authorized representative.
- The nature of the information to be provided to prospective subjects including financial impact to the subject.
- Include information regarding any waiting period between informing the prospective subject and obtaining consent
- The method of documenting the informed consent process.
- Describe how the continuing informed consent process will be conducted. Remember informed consent is a process, not just a signed document, and informed consent means the subject must be informed about the study in language they understand.
- If the PI is requesting waiver of the requirement to obtain written consent, include a description of the information that would be provided to subjects
- Describe the provisions to protect the privacy interests of the subjects:
 - i) How will subjects be approached about participating in the study in a private manner?
 - ii) How will the study be conducted so that subjects will be treated in a private manner?
 - iii) Include a plan to give subjects control of the release of private information, tissues, or biological specimens, as applicable?

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iv) If applicable, how will privacy be handled for any information which may be viewed by the subjects as unusually sensitive or objectionable?

4. NON-ENGLISH SPEAKING/NON-READING, NON-WRITING SUBJECTS

Describe the plans for the informed consent process for non-English speaking/non-reading, non-writing subjects that will be followed:

- Explain how informed consent will be obtained if subjects who do not speak or read English will be involved. If translators or interpreters will be used, who are they and who will pay for their services?
- Explain how informed consent will be obtained and documented if a potential subject does not read or write.
- NOTE: Subjects may not be excluded if they are non-English speakers.

5. RECOGNIZING AND MANAGING SIDE EFFECTS

a. Describe any potential risks and assess their likelihood and seriousness:

- Physical
- Psychological
- Social
- Legal
- Other, including confidentiality and financial.

b. Where appropriate, describe alternative treatments and procedures that may be advantageous to the subjects. If the only alternative is to not participate in the research, then inform the subjects and the HAC reviewers of that information.

c. The researchers must identify who will manage the subject's care if a research related event arises.

d. Describe the standard of care and how this research study will affect that standard.

e. Describe how the provisions for pregnancy testing in Section 1, Subject Characteristics will be monitored.

f. For Multi-Center Trials in which the PI is the Lead Investigator:

a. Description of how the following information from sites will be managed:

i. Unanticipated problems involving risks to subjects or others

ii. Interim results

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iii. Protocol amendments

6. MONITORING FOR ALL RISKS

The investigator must document the consideration of the study design regarding risk and indicate that all risks have been minimized to the extent possible. Describe the procedures for:

- Protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
- Also, where appropriate, describe the provisions for monitoring the data collected and provisions for protecting the confidentiality of research to ensure the safety of subjects. (Including methods used to obtain information about participants).
- Describe the provisions for sharing, monitoring, storing and transmitting of confidential and protected data collected to ensure the safety of subjects and the integrity of the research.
- Describe the process for purging or destroying confidential and protected data when the research study is completed.
- Describe the standard of care and how this research study will affect that standard.
- Discuss provisions for pregnancy testing, if applicable.

7. RISK TO BENEFIT RATIO

Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

- State if there are no benefits.
- If a test article (investigational new drug, device, or biologic) is involved, name the test article.
- State whether the 30-day interval between submission and applicant certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the FDA.

8. INDUSTRY SPONSORED DRUG OR DEVICE TRIALS

For sponsored drug studies, summarize the sponsor's protocol and how the protocol will be followed at your site. Indicate the plans to work with other sections or departments to ensure protocol compliance and human research protections.

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9. DATA AND SAFETY MONITORING PLAN (DSMP)

The data and safety monitoring plan is thorough plan that should ensure the:

- a. Safety of clinical research subjects
- b. Validity and integrity of research data
- c. Clinical research subjects are not exposed to undue risk

The following studies do not require a DSMP:

- Studies that qualify for exempt review.
- Studies that do not involve contact with a living human subject, as defined in 45 CFR 46.102, Subpart F.
- A DSMP is not required if a Data and Safety Monitoring Board (DSMB) has been established by an external entity. The sponsor may include provisions for a Data and Safety Monitoring Plan/Board in the protocol. Please include this information in the protocol.

The DSMP should be commensurate with the level of risk as well as with the size and complexity of the research study. At a minimum, all monitoring plans should include:

1. A description of all anticipated risks (physical, social, psychological) involved with the research study.
2. A description of the measures to minimize the risks.
3. A definition of the preparations for recognizing and responding to anticipated and unanticipated risks.
4. A description of the reporting mechanisms of adverse events (AE) to the HAC, sponsor, and/or the FDA and the NIH.
5. The appropriate monitoring activities required for the research study.

For additional information on DSMP and DSMB, please refer to the DSMP and DSMB Section.

10. LISTING OF ACRONYMS AND/OR TERMS

Please provide a listing of acronyms and/or terms. Include definitions for those used in the DRP and ICD(s) (e.g., Progression Free Survival (PFS), Complete Responses (CR), Genetics Tissue Core Lab (GTCL), etc.). This

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additional information is needed to facilitate the review process since the HAC members may not be familiar with the specific area of research submitted although they are familiar with clinical research design principles and may be experts in their own fields.

Who Do I Contact if I Have Any Questions?

For additional guidance, contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.