

JDRF Applicant Guidelines for Clinical Classification

Scenario A. No Human Subjects Research

If no human subjects research is proposed in the application, select the appropriate option. No HSRP and CRRP required for this category.

If proposed studies using human data or biological specimens do not involve human subjects, provide an explanation of why the proposed studies do not constitute research involving human subjects.

The explanation could include: a description of the source of the data/biospecimens and whether there is any intervention or interaction with the subjects in order to obtain the specimens and data; what identifiers will be associated with the human specimens and data and who has access to subject identities; the role(s) of providers of the data/biological specimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be protected.

Research that does not involve intervention or interaction with living individuals, or identifiable private information, is not human subjects research. Research involving the use of coded private information or biological specimens may not constitute human subjects research if the conditions of the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens have been met (<http://www.hhs.gov/ohrp/policy/cdebiol.html>).

Research that only proposes the use of cadaver specimens is not human subjects research because human subjects are defined as “living individuals.” The use of cadaver specimens is not regulated by 45 CFR part 46, but may be governed by other Federal, State or local laws.

Scenario B. Non-Exempt Human Subjects Research

If research involving human subjects is anticipated to take place under the award, select the appropriate option. In the HSRP and CRRP, you must provide sufficient information for reviewers to determine that the proposed research meets the requirements of the DHHS regulations to protect human subjects from research risks (45 CFR part 46). Follow the instructions in the HSRP and CRRP to provide the required information.

Scenario C. Exempt Human Subjects Research

If **all** of the proposed human subjects research meets the criteria for one or more of the exemptions from the requirements in the DHHS regulations (46.101(b)), select the appropriate option and NA entered for the Human Subject Assurance Number since no OHRP assurance number is required for exempt research.

Please visit HHS’s website at to decide if the research falls into one of the exempt categories. <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>. Following are the six categories

Exemption 1, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement for continuing IRB review and approval, investigators must propose research in educational settings involving normal educational practices, such as:

- (i) Research on regular and special education instructional strategies, or
- (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Exemption 2, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval under exemption 2, researchers must propose the use of educational tests, survey or interview procedures, or observations of public behavior involving human subjects who:

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cannot be identified, either directly or indirectly; OR may be identified, but would not be put at risk if information is disclosed

Exemption 3, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval, investigators must propose the use of educational tests, survey or interview procedures, or observations of public behavior that does not meet the requirements for Exemption 2 if: the human subjects are elected or appointed public officials; or the human subjects are candidates for public office; or

Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained during and after the proposed research

Exemption 4, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval under Exemption 4, investigators must propose the use of data or samples that are either :

existing and publicly available; OR existing and unidentifiable to the research team

Exemption 5, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval under Exemption 5, investigators must propose research and demonstration projects conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

public benefit or service programs;

procedures for obtaining benefits or services under those programs;

possible changes in or alternatives to those programs or procedures;

OR

possible changes in the methods or levels of payment for benefits or services under those programs

Exemption 6, as it pertains to research involving human subjects

defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval under Exemption 6, investigators must propose research involving taste and food quality evaluation and consumer acceptance studies if:

wholesome foods without additives are consumed;

a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture; or

a food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

Provide a justification for the exemption(s) containing sufficient information about the involvement of the human subjects.

When in doubt, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services by accessing their Web site <http://www.hhs.gov/ohrp/> for guidance and further information.

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Please note: if the proposed research involves only the use of human data or biological specimens, you should first determine whether the research involves human subjects. The exemptions do not apply if the research does not involve human subjects. For help determining whether research that involves the use of human data or biological specimens is human subjects research, please refer to this Web site:

<http://grants.nih.gov/grants/policy/hs/>.

Scenario D. Delayed-Onset Human Subjects Research

If human subjects research is anticipated within the period of the award but plans for involvement of human subjects cannot be described in the application as allowed by the DHHS regulations (45 CFR part 46.118), select the appropriate option. In the section on Protection of Human Subjects in the Research Plan, you should either include an explanation of anticipated protections for human subjects or an explanation of why protections cannot be described.

Examples of delayed-onset of human subjects research include:

- Human subjects research is dependent upon the completion of animal or other studies; or
- Human subjects research protocols to be included will undergo an independent decision-making process (often defined by a FO).

In rare situations, applications are submitted with the knowledge that human subjects will be involved during the period of support, but plans are so indefinite that it is not possible to describe the involvement of human subjects in the application. The kinds of activities that lack definite plans are often institutional awards where the selection of specific projects is the institution's responsibility, research training grants, and projects in which the involvement of human subjects depends upon completion of instruments, animal studies, or purification of compounds.

If the involvement of human subjects cannot be fully described, in HSRP provide a detailed explanation why it is not possible to develop definite plans at this time. If the involvement of human subjects depends upon information that is not presently available (e.g., completion of instruments, animal studies, purification of compounds), be explicit about the information and the factors affecting the availability of the information. Describe the information that will be necessary in order to develop definite plans for the involvement of human subjects, why that information is not currently available, and when the information is expected to become available during the course of the project.

If an award is made, prior to the involvement of human subjects the grantee must submit for prior approval either (1) detailed information as required in the Research Plan, Protection of Human Subjects (addressing risks to the subjects, adequacy of protection against risks, potential benefits of the proposed research, importance of the knowledge to be gained, and data and safety monitoring plan if applicable) and certification of IRB approval, OR (2) if all of the research meets the criteria for one or more exemptions, identification of which exemption(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate.

Under no circumstance may human subjects be involved in research until approval is granted by the awarding entity, and certification of IRB approval has been accepted by the agency.

Follow the instructions that are identified for each of the topics in the HSRP and CRRP and EITHER provide as much of the information that is requested as possible, OR describe why it is not possible to provide the information due to delayed-onset of human subjects research