**Involving Non-DeSales Institutions in DeSales Human Subjects Research**

When DeSales investigators are involved in research with collaborating institutions, DeSales will ensure the following:

1. If DeSales is the prime awardee under a federal grant, contract, or cooperative agreement, or is the coordinating center for federally conducted or supported research, then DeSales will ensure that all collaborating research sites engaged in such research operate appropriately following the OHRP-approved guidelines for the protection of human subjects.
2. Regardless of the source of sponsorship, all investigators must follow additional requirements of the non-DeSales institution (including additional IRB review, if required).

**Definitions**

**Engagement in Research**: A non-DeSales institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d)-(f)].

**Non-DeSales Institution**: An institution (or an employee or agent of the institution) that is not under the authority of DeSales and is located within the United States or a United States territory. Examples include clinics, schools, other universities, consulting firms, or other institutions where activities include interaction or intervention with human subjects and/or the collection or analysis of identifiable data.

**DeSales Research Activity**: any human subject research activity that is supported with DeSales funds or by funds awarded/contributed to DeSales and/or is conducted by a DeSales faculty, staff or student using DeSales facilities, personnel/students, research subjects, data or other non-public resources.

**Procedures and Guidance**

**Non-DeSales Institutions NOT ENGAGED - Submission Process:**

Principal investigators who plan to work with Non-DeSales institutions that are not engaged in the human subject research activity (not intervening or interacting with living individuals for research purposes and not obtaining individually identifiable private information for research purposes) must meet the following additional DeSales IRB requirements:

1. Submit an application for DeSales IRB review and approval and include a description of the non-DeSales institution’s role in the human subjects research, adequacy of the facility to support the research and to ensure human subject safety in the case of an unanticipated emergency, responsibilities of their agents/employees, and oversight that the DeSales investigator will be providing in order to ensure adequate and ongoing protection of the human subjects. Only institutions that have agreed to participate should be identified in the DeSales IRB submission.
2. Obtain a written letter of permission from an authorized individual at the non-DeSales institution that authorizes the PI to perform activities at that location. This letter of approval is submitted with the DeSales IRB application.
3. Follow any additional requirements of the non-DeSales institution.

**Non-DeSales Institutions ENGAGED - Submission Process:**

Principal investigators who plan to work with Non-DeSales institutions that are engaged in the human subject research activity must meet the following requirements:

* **EXEMPT Research**
  1. Submit an application for DeSales IRB review and approval and include a description of the

non-DeSales institution’s role in the human subjects research, adequacy of the facility to support the research and to ensure human subject safety in the case of an unanticipated emergency, responsibilities of their agents/employees, and oversight that the DeSales investigator will be providing in order to ensure adequate and ongoing protection of the human subjects. Only institutions that have agreed to participate should be identified in the DeSales IRB submission.

* 1. Obtain a written letter of permission from an authorized individual at the non-Desales institution that authorizes the PI to perform activities at that location. This letter of approval is submitted with the DeSales IRB application.
  2. Follow any additional requirements of the non-DeSales institution including additional IRB review if required.
* **EXPEDITED and FULL BOARD Research**
  1. Submit an application for DeSales IRB review and approval and include in a description of the non-DeSales institution’s role in the human subjects research, adequacy of the facility to support the research and to ensure human subject safety in the case of an unanticipated emergency, responsibilities of their agents/employees, and oversight that the DeSales investigator will be providing in order to ensure adequate and ongoing protection of the human subjects. Only institutions that have agreed to participate should be identified in the DeSales IRB submission.
  2. Obtain a written letter of permission from an authorized individual at the non-DeSales institution that authorizes the PI to perform activities at that location. This letter of approval is submitted with the DeSales IRB application.
  3. Follow any additional requirements of the non-DeSales institution including additional IRB review if required.
  4. DeSales strongly recommends that a single consent document be given to the research subject, whenever possible. In the case of more than one IRB reviewing the research, every effort should be made to develop a single consent document that explains the involvement of each institution and represents the decisions of each IRB involved. The consent form must name the DeSales PI.
* **ADDITIONAL REQUIREMENTS - IRB Reliance Arrangements (IRB Deferral)**

In some cases, it may be duplicative or it may not be practical for both DeSales and the non-DeSales organization to obtain separate IRB approval. In this situation, either entity may decide to rely on the IRB review of the other. *If you are requesting one of the below options, please follow the additional requirements described below for engaged non-DeSales institutions:*

Requests for the DeSales IRB to review on behalf of a Non-DeSales Institution:

When the non-DeSales organization wishes to rely on the DeSales IRB, this should be indicated in the IRB submission. The IRB will consider the request. If accepted, the IRB Committee will work with the DeSales investigator to establish the appropriate signed agreements.

To facilitate an efficient reliance decision, the DeSales investigator should address all of the following when completing the DeSales IRB application submission:

* + - Describe your understanding of the local research context of the non-DeSales organization or how the knowledge will be obtained (i.e., use of consultants).
    - Does the non-DeSales Institution have a Federalwide Assurance (FWA)? If yes, provide the FWA Number and effective dates.
    - If the research is ongoing at another institution (such as in the case of a multi-center study) provide a report on research results to date and a summary of all unanticipated problems and/or serious adverse events and other reportable adverse events.
    - If a DeSales researcher is the lead researcher of a multi-site study, applications should include information about the management of information that is relevant to the protection of human subjects, such as interim results and protocol modifications.

The DeSales IRB will review the material and make a recommendation to the DeSales Signatory Official (or designee) regarding approval.

Requests for DeSales to rely on the IRB of a non-DeSales Institution:

In some cases, the DeSales IRB may elect to rely on the IRB of a collaborating organization. The DeSales investigator may make this request by making note of the request in the DeSales IRB application. Such requests will be carefully considered when the other IRB demonstrates equivalent standards to those of the DeSales IRB. If the request is accepted, the DeSales investigator will need to provide to the DeSales IRB the approved IRB application, approved informed consent document(s), and IRB approval letter. The IRB Committee will work with the DeSales investigator and the other organization to enter into the appropriate signed agreements. If a request is made for DeSales to rely on the IRB of a non-DeSales Institution, **A WRITTEN LETTER OF PERMISSION IS NOT REQUIRED with the initial IRB application.**

**Helpful Links/Notes:**

* 1. Allowing another institution to rely upon the DeSales IRB requires knowledge of the local research context. DeSales will consider geographic proximity and similarities of communities in the decision to allow for a deferral and/or request information from the other organization pertaining to local context.
  2. DeSales considers requests for IRB deferrals on a case-by-case basis.
* Tips for conducting research at LVHN
* Submit the DeSales IRB Application and indicate that you will conduct the study at LVHN.  A DeSales faculty member will serve as the Principal Investigator (PI) on this application.
* Please contact Vicki Sabella at [Victoria.Sabella@lvhn.org](mailto:Victoria.Sabella@lvhn.org).  She is your first point of contact at LVHN.
* Please allow at minimum 60 days to receive approval from the LVHN IRB Office for studies conducted at LVHN.
* LVHN uses a 3-step research approval process.
  + Departmental Review,
  + Network Office of Research and Innovation Feasibility Review, and
  + IRB Review.

Please carefully read the materials provided on the Network Office of Research and Innovation’s website and follow each step in the process.

**(**[**http://lvhwebcontent.lvh.com/?id=2254&sid=1**](http://lvhwebcontent.lvh.com/?id=2254&sid=1)**).** This website contains the necessary templates, forms, and guidance that each investigator must follow to safely conduct research at LVHN.

**DeSales Principal Investigator Responsibilities for Collaborative Research**

When collaborating with non-DeSales organizations, it is the responsibility of the DeSales principal investigator to ensure that:

* + adequate resources will be available at the non-DeSales institution to conduct the research safely and effectively in full accordance with the approved protocol;
  + all persons interacting with human subjects and/or their identifiable data are adequately trained in the protection of human subjects, regardless of their employment status with DeSales;
  + the DeSales IRB receives complete reports of all IRB-reportable events occurring both at DeSales and at the non-DeSales institution;
  + applicable state law relative to research outside of Pennsylvania is incorporated into the research design, especially as it applies to enrollment and informed consent; and
  + the consent documents fairly and accurately represent the involvement of DeSales in the research and the decisions of all responsible IRBs reviewing the research.