IRB Website has been updated!

Over the summer the DU Human Subjects Research (IRB) website went through a transformation. The website was updated with new tabs to improve how investigators can easily find the resources for completing IRB applications and re-formatted the site to provide better access to answer investigator’s common questions. Special tabs were also created for obtaining information on specific research topics from “what needs IRB review” to “collaborative research”. Since 49% of the IRB submissions reviewed last year were submitted by students, a new section was created just for student investigators.

As we begin the fall quarter, the volume of IRB submissions has already spiked to a record high during the first month of a new academic year. The IRB has received over 60 new IRB submissions from faculty, staff, and students during the first three weeks. With the new developments to the website, we hope the information and tools we have provided will give you the necessary information to achieve your research goals.

Please take the time to become familiar with the revised website. If you have any questions on any IRB-related issue or have suggestions for other topics to include on the website, please contact the DU IRB Office at 303-871-2121 or through IRBAdmin@du.edu.
Collaborating with Researchers at Other Institutions and other Non-DU Sites

What are your responsibilities as the DU investigator?

Have you written a grant to fund a research project that involves an investigator from another institution or with an organization that is not affiliated with DU? Do you know what the research regulatory requirements are to establish a collaborative project?

Collaborative projects are projects that involve more than one institution (e.g., working with an unaffiliated investigator) or conducting research activities at a non-DU site.

When conducting collaborative human subject research, each institution involved is responsible for safeguarding the rights and welfare of the human participants. If your research will involve collaborating with a non-DU investigator or will be conducted at a site other than DU, agreements and forms must be completed to protect the research participants and ensure research regulatory requirements are fulfilled.

Outlined below are the steps, agreements and forms that should be completed in order to collaborate on human subjects research projects with other organizations & unaffiliated investigators:

**Step 1: Select a Primary IRB for the Collaborative Project**

If you wish to avoid duplicate IRB review, DU investigators working with investigators from another institution can establish one institution’s IRB to serve as the primary IRB to review and approve the research. This process is known as **ceding**. This is accomplished through the completion of the IRB Authorization Agreement (IAA), also referred to as the Reliance Agreement. This document is implemented only if both institutions have a valid Federal Wide Assurance (FWA), a signed document established between an organization and the federal government to ensure research policies and practices are maintained when conducting human subjects research. Additionally, both institutions must agree to this type of arrangement to relinquish to or accept IRB oversight from another institution. Typically, the institution that serves as the primary grantee and assume more responsibility or risk will serve as the Primary IRB. IAA’s need to be negotiated at each institution, on a case-by-case basis, and must be signed and authorized by each Institutional Official before an IRB assumes this additional responsibility and oversight of a project.

In addition to the IAA document, the completion of **Appendix P: Collaborative Research with Ceding** form must accompany the submission of the IAA for signature.

For additional information on collaborative research, please refer to **Appendix A** on pages 8 and 9. Contact Mary Travis, at mary.travis@du.edu, to discuss the conditions under which ceding may be granted for a project.
Step 2: Add Unaffiliated Investigator /External Individual to a DU Collaborative Research Project

If the DU IRB has been selected to serve as the Primary IRB for a collaborative project, the following documents must be completed based on whether the other institutions or investigators are covered by a Federal Wide Assurance (FWA)*:

If you are collaborating on a project with an unaffiliated investigator from an institution covered by a Federal Wide Assurance (FWA), an IRB Authorization Agreement (IAA) must be signed by both institutions along with completing the Appendix P: Collaborative Research with Ceding form.

OR

If you are collaborating on a project with an unaffiliated investigator who is NOT covered by a Federal Wide Assurance, an Individual Investigator Agreement (IIA) must be signed by each unaffiliated investigator along with the Appendix Q: Unaffiliated Investigator Agreement Approval Request Form for each unaffiliated investigator involved and posted as part of your IRBNet package.

*Federal Wide Assurance (FWA): HHS human subject protection regulations and policies require that any institution engaged in non-exempt human subjects research conducted or supported by HHS (federally-funded) must maintain a written assurance of compliance with the Office of Human Research Protections (OHRP). Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

Step 3: Provide training documentation for each unaffiliated investigator and add them to the DU IRB application forms in IRBNet:

- **Documentation of human subjects protection (HSP) training for the unaffiliated investigator.** This mandatory training may not need to be completed through the DU CITI Program but documentation must be provided that the unaffiliated individual has completed human subjects protection (HSP) training through their institution within the last four years. If they have not completed HSP training at their institution, then they must complete the Unaffiliated Investigator training curriculum offered through the DU CITI Program and have their training linked (affiliated) with the University of Denver-COLORADO Seminary.

- **Add unaffiliated investigator to the DU IRB Application Form (Wizard Form).** Include the unaffiliated investigator information on the DU IRB Application Form, under Section V—Additional Personnel, and provide name, status (title) and role on the project.

- **Incorporate the unaffiliated investigator’s role into Part I: Human Research Application.** Include the unaffiliated investigator’s role and specific activities that will be conducted by them in the research under Section D: Research Setting, Collaborative Research.
Serving as a Mentor to Student Investigators

As we begin the 2018 fall quarter, many undergraduate and graduate students will be introduced to conducting research for the first time. These research projects may be part of fulfilling an academic requirement or as part of an internship. Students will be assigned the task of navigating through the IRB process by completing forms, creating consents and learning how to recruit subjects to participate in their research projects.

Faculty Sponsors Must Review & Sign Student Projects

At DU, students are allowed to serve as the Principal Investigator (PI), however, all student investigators must follow certain rules to serve in that capacity. First, they must identify and work closely with a faculty sponsor. Second, students must obtain the electronic signature of their faculty sponsor in the IRBNet system. If the IRB receives a student research project without the involvement or electronic signature of their faculty sponsor, the project will be returned to the student as an incomplete application and the project will not be reviewed.

NOTE: Students are not allowed to sign on the behalf of their faculty sponsor.

Encourage Students to Plan Ahead

First-time student researchers often have big ideas about what they would like to accomplish with their studies. It is not uncommon for the IRB to receive student research projects that are more complicated than a seasoned researcher’s proposal, and the likelihood of a student researcher completing such a project is small. An inexperienced student researcher with little or no training should take on research projects that are realistic for them and easily accomplished in the time available. It is important for faculty sponsors to help mentor students to design realistic proposals that will yield valid results, ensure minimal risk for participants, and provide a valuable learning experience.

Checklist for Working with Student Investigators

1. All students and faculty sponsors must obtain certification in human subjects protection training through the CITI program. (Basic Course I and all relevant protocol-specific modules)
2. Students and their faculty sponsor (FS) must register in IRBNet. Full access must be granted by the student to allow their FS to review and approve the student’s IRB application prior to submission.
3. Proper documentation must be maintained by students
4. Faculty sponsor must have ongoing access to the study records.
5. Any modifications or changes to a student’s protocol must be reviewed & approved by the faculty sponsor.
6. Ongoing communication with the student must occur throughout the life of the student’s study.
7. Once a student’s project is completed, a Final Report must be submitted to the IRB.
Letters of Support/Approval Must be Obtained from Schools, Community Groups, or Jails Before IRB Approval is Granted

If a community agency, school district(s) and/or individual schools, or prison/jails have been identified as a site(s) for conducting a research project, the IRB requires documentation verifying that support or approval has been obtained from non-DU sites before the research begins. The letter of support or approval must be included in the IRBNet package.

For many school districts, proposed research requests from investigators involving a school’s students, teachers, and/or administrators must be submitted to the school’s review committees. Some districts require a formal review process that mandates investigators to submit an official application to be reviewed internally.

What if a school district requires IRB approval as part of their research application process?

If a study will be conducted in a school involving students, teachers or administrators, the DU IRB will not grant full approval until the investigator provides adequate documentation obtained from the school district/school. To accomplish this, the IRB encourages investigators to submit their research protocol through IRBNet so a review of the project can begin by the DU IRB. Once the research protocol has met all the IRB requirements for approval except for the authorization from the school district/school, the IRB will issue a conditional approval letter. The conditional approval letter can then be used to complete a school district application requirement requesting an IRB approval letter.

PLEASE NOTE: Allow adequate time in obtaining the appropriate authorization as some targeted school districts may meet infrequently.

The documentation from the school district/school must be on official letterhead and signed by an authorized administrator. After the school authorization or approval has been obtained and posted in IRBNet, the study will be issued a full IRB approval determination letter if it has been issued a conditional approval letter.

Why is an authorization/approval letter required from community organizations if the only involvement is to recruit potential participants on site?

Any time an investigator uses a non-DU site for recruitment purposes, the IRB requires documentation that verifies that the site is aware and approves this research activity to be conducted at their site. The letter should be on the organization’s letterhead and signed by an authorized signatory official. All recruitment strategies must be clearly outlined in the IRB application and all recruitment documents (flyers, scripts, etc.) must be utilized to ensure it is a voluntary process and confidentiality is maintained.
CITI Human Subjects Protection Training
Requirements Revised

Individuals that conduct human subjects research must be certified in human subjects protection training. At DU, this certification can only be completed through the on-line Collaborative Institutional Training Initiative (CITI) Program.

Over the summer, the Office of Research Integrity & Education (ORIE) reviewed the CITI curriculums that are currently required to complete the human subjects protections certification. During the review, the training modules were evaluated and modified to streamline the requirements. Beginning this fall, investigators will be required to complete a basic course along with any protocol-specific modules if they are applicable to the study design. For example, if a faculty or staff investigator is conducting an exempt project that involves the internet, the required training would include the Exempt Basic Course along with the Internet-Based Research protocol-specific module.

With these changes, do PIs need to take the CITI training again?

No, if you have completed modules as part of your current training profile those modules will automatically be transferred to your training profile and will not need to be completed until they expire.

Most of the modules that are included in the two basic courses for exempt and non-exempt research are already included in both the Social, Behavioral & Educational Research (SBER) and Biomedical Research curriculums. If you submit a new project that involves a protocol-specific activity or a vulnerable population and that specific training module has not been previously completed, then completing the appropriate protocol-specific module will be required before final approval will be issued (i.e., your new project will involve prisoners, but no training module on “Research Involving Prisoners” has been completed).

Who Needs to Complete this Training?

- DU faculty and staff who serve as Principal Investigator and all other research team members on the project who will interact/intervene with human subjects or have access to any subjects identifiable data
- Students who are listed on the protocol as the Principal Investigator
- Faculty Advisors/Sponsors of a Student Investigator
- Unaffiliated investigators
- IRB Full Board Members

How has the DU human subjects protection training program changed?

The training program has been modified to first identify the end user’s status at DU, selecting whether the end user is faculty or staff, a student, an unaffiliated investigator, or an IRB full board member. The program changes further simplify which training modules are required based on the type of research to be conducted.
If I am mentoring a student investigator who will be conducting an
exempt project, which basic course does the student need to com-
plete?

All students, regardless of which type of IRB review (exempt, expedited
or full board) will be conducted on their project, must complete the SBER
or Biomedical Basic Course for Student Investigators.

What if I have a valid certification for the Social, Behavioral & Educa-
tional Research (SBER) curriculum, and I am submitting a new exempt
research project, do I have to take the Exempt Basic Course?

No, the SBER modules fulfill all of the requirements of the Exempt Basic
Course. During the preliminary review of a study submission, an IRB administrator will notify the investigator on whether additional
training modules are required. If the investigator’s training profile does include the necessary training modules for the specific
study design or involving a vulnerable population, a stipulation letter will be issued outlining the training modules to be completed.

CITI Training Curriculum Options

- **For Faculty and Staff Investigators:** Options have been created to allow faculty and staff to select a training curriculum
  that is developed for Social, Behavioral & Educational Research (SBER) or Biomedical Research. Investigators will select a Basic
  Course for either an Exempt or Non-Exempt (expedited or full board review) projects. In addition to selecting the appropriate
  Basic Course, faculty and staff investigators will then select supplemental modules that are applicable to their research. For
  example, if a research project qualifies as an exempt project, and will involve the use of the internet, the investigator and their
  research team members would need to complete the Exempt Basic Course along with the supplemental modules on “Research Involving the Internet”. The Exempt Basic Course is a modified, streamlined curriculum in comparison to the Non-Exempt Basic Course.

- **For Student Investigators:** A separate curriculum option has been created specifically for students who will be serving as
  the Principal Investigator. The training curriculum for students is more comprehensive and does not change regardless of the
  project or type of IRB review. The Student Basic Course is designed to cover all aspects about conducting human subjects re-
  search and does not give students the option to select an exempt or non-exempt basic course. Student investigators must also
  select supplemental modules that are applicable to their specific research project. For example, if a student investigator will
  conduct research in a school involving children and the research qualifies for one of the expedited review categories, the stu-
  dent would need to complete the Student Basic Course along with the supplemental modules on “Research in Schools” and
  “Research Involving Children”.

- **For Unaffiliated Investigators:** If a DU investigator collaborates with another investigator that is not affiliated with DU, and
  the unaffiliated investigator has not completed the mandatory human subjects protection training, a separate curriculum op-
  tion has been developed to assist the unaffiliated investigator fulfill the training requirement. The unaffiliated investigator
  would need to select a training curriculum that is designed for Social, Behavioral & Educational Research or Biomedical Re-
  search, and then select the Basic Course for Non-Exempt (expedited or full board review) projects. If the unaffiliated investiga-
  tor has requested that their IRB or organization cede to the DU IRB for IRB oversight, the project must qualify as a non-exempt
  project. Ceding to the DU IRB when an exempt project is involved will not be processed.

- **For IRB Full Board Members:** The curriculum for IRB members includes training modules that were developed specifically
  for individuals who serve on the IRB. The training modules provide information on how to understand and interpret the re-
  search principles that regulate whether a project fulfills all of the requirements for IRB approval. The IRB Full Board Member
curriculum is not intended for fulfilling the training requirements for investigators.
## COLLABORATIVE RESEARCH
### Required IRB Documents for Research with Other Sites

<table>
<thead>
<tr>
<th>Arrangement</th>
<th>DU IRB Requirement</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>DU is IRB of Record and research involves a non-DU site engaged in the research</td>
<td>• DU IRB Approval</td>
<td>Non-DU site Institutional Official signing the IIA is assuring that their researchers are adhering to DU policies/procedures</td>
</tr>
<tr>
<td>a) Non-DU sites with an FWA</td>
<td>• IRB approval from that site OR • IRB Authorization Agreement (IAA) ALONG WITH • Appendix P: Collaborative Research with Ceding</td>
<td>DU PI is responsible for any follow up or monitoring adherence to DU Policies &amp; Procedures. These documents must be completed for each unaffiliated investigator involved in project.</td>
</tr>
<tr>
<td>b) Non-DU sites without an FWA</td>
<td>• Appendix Q: Individual Investigator Agreement Approval Request form AND • Individual Investigator Agreement form</td>
<td></td>
</tr>
<tr>
<td>c) Unaffiliated Investigator engaged in research (unaffiliated with any institution with respect to the research being conducted)</td>
<td>• Appendix Q: Individual Investigator Agreement Approval Request form AND • Individual Investigator Agreement form</td>
<td></td>
</tr>
<tr>
<td>DU research engaged in research at /with non-DU site</td>
<td>• DU IRB Approval OR/AND • IRB approval from non-DU site OR/AND • Non-engagement determinations for non-DU site OR/AND • IRB Authorization Agreement Examples 1) Non-DU site is engaged. Need: (a) site IRB approval plus DU IRB approval OR (b) site IRB approval plus IRB Authorization Agreement (DU defers to site) OR (c) DU IRB approval plus IRB Authorization Agreement (site defers to DU) 2) Non-DU site is not engaged. Need: DU IRB approval only (no IRB Authorization needed)</td>
<td>Is non-DU site “engaged”? Engagement depends on what is occurring at that site and the involvement of that site’s employees.</td>
</tr>
<tr>
<td>Non-DU site/researcher engaged in research at/with DU</td>
<td>• IRB Approval from that site OR • IRB Authorization Agreement deferring to DU as IRB of record OR • Individual Investigator Agreement</td>
<td>Will need letter of support from site</td>
</tr>
<tr>
<td>Non-DU site NOT engaged but serving as study site (schools, community organizations/agencies, businesses, etc.) for non-exempt research</td>
<td>• Written permission from that site allowing the research to be conducted Examples: permission from school for school/child research, permission from ministry of health for international research review</td>
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<tr>
<td>DU is the direct awardee of federal grant/contract and human subjects research (HSR) is at DU</td>
<td>• DU is IRB of Record and conducts IRB review • Grant proposal, budget detail, and award letter provided to DU IRB</td>
<td></td>
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<tr>
<td>DU is the direct awardee of grant/contract with subcontracted site/research elsewhere. Both sites engaged in HSR.</td>
<td>• IRB Approval from that site OR • IRB Authorization Agreement (one site deferring to the other as IRB of record) OR • Individual Investigator Agreement</td>
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<tr>
<td>DU has a subcontract for HSR and is IRB of record for whole award</td>
<td>• IRB Authorization Agreement, direct awardee defers to DU as the IRB of record. • Grant proposal, award letter, and budget detail provided to DU IRB. When award is pending, DU will accept budget based on anticipated award.</td>
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<tr>
<td>DU is the direct awardee of the HHS/NIH grant/contract but there is no HSR at DU</td>
<td>• IRB Authorization Agreement deferring to the site where the highest risk to subjects occurs</td>
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<tr>
<td>DU has a subcontract for HSR but is not the IRB of record for the entire grant (DU responsible for DU HSR)</td>
<td>DU IRB Approval (for research activities at DU) The portion of the DU grant proposal, budget detail and award letter that covers the HSR conducted under DU subcontract is required.</td>
<td>PI may provide the whole contract</td>
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<td>For situations where faculty and grant from another institution transfer to DU</td>
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<tr>
<td>---------------------------------------------------------------</td>
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<td></td>
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<tr>
<td>a) Researcher joins DU faculty and transfers grant/contract to DU</td>
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<td></td>
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<tr>
<td>(DU becomes awardee)</td>
<td></td>
<td></td>
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<tr>
<td>HSR conducted at DU</td>
<td></td>
<td></td>
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<tr>
<td>• DU conducts IRB review</td>
<td></td>
<td></td>
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<tr>
<td>• Grant proposal, budget detail, and award letter provided to DU IRB.</td>
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<tr>
<td>b) HSR does not move with the PI</td>
<td></td>
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<tr>
<td>• IRB Authorization Agreement deferring to the other site</td>
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<td></td>
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<tr>
<td>c) HSR may be conducted at both sites</td>
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<tr>
<td>• IRB Authorization Agreement deferring to the site with the highest risk</td>
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<td></td>
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<tr>
<td>• Each site may conduct its own IRB review</td>
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<tr>
<td>If DU conducts an IRB Review: The portion of the grant proposal, budget detail and award letter that covers the HSR conducted at DU is required.</td>
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<tr>
<th>For non-federally funded, non-FDA research that would otherwise require an IRB Authorization Agreement</th>
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<tbody>
<tr>
<td>• IRB Authorization Agreement is not required unless the outside institution requests an Agreement</td>
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<tr>
<td>• If requested by the outside institution, DU will comply with the request</td>
</tr>
<tr>
<td>• Additionally, DU may require an IRB Authorization Agreement at its discretion</td>
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<tr>
<th>For non-federally funded, non-FDA research that would otherwise require an Individual Investigator Agreement (IAA)</th>
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<tr>
<td>• Individual Investigator Agreement does not require a DU Institutional Official (IO) signature</td>
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<tr>
<td>• The Research Integrity Director or IRB Chair signature can substitute for the IO signature</td>
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</table>

**Glossary:**

- FDA – Food and Drug Administration
- FWA – Federal Wide Assurance
- HHS – Health and Human Services
- HSR – Human Subject Research
- IO – Institutional Official
- IIA – Individual Investigator Agreement
Student IRB Workshops Offered

Encourage your student investigators to attend these free workshops as an opportunity to work directly with one of our IRB experts.

What if a student is not able to attend the workshop during the set time and date?

Other options are available for students who cannot attend the scheduled workshop. Students can arrange a one-on-one consultation or schedule a conference call with Cami Lind, IRB Research Compliance Administrator, through sending an email to: IRBAadmin@du.edu or by calling 303-871-2121.