Conversion
Preparation Checklist

1. Plan Your Conversion

<table>
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<th>Will you convert the study?</th>
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REQUIRED CONVERSION

In general, conversion is required for studies that are labelled with a single-letter designation of A, B, D, or J, unless the study will close in one year or has completed all study procedures except data analysis. You can find your letter designation on the most recent application materials or in the conversion/renewal notice you receive via email.

Most other studies do not need to be converted. However, HSD may require that other studies be converted if they would benefit from conversion now. HSD staff will contact research teams directly as these are identified.

OPTIONAL CONVERSION

Research teams may choose to convert studies with a letter designation of EA, EB, ED or EJ, unless the study will close in one year or has completed all study procedures except data analysis.

NOT SURE? Review the table “What to Submit” on the HSD website to confirm if your study needs to be converted.

<table>
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<th>When to prepare and submit?</th>
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Conversion is required at the time of continuing review and is done in conjunction with the IRB’s regular continuing review. Your application must be submitted at least 8 weeks prior to the expiration date, or there may be insufficient time for the IRB to review and re-approve the study.

TAKE NOTE! For full conversions, HSD recommends beginning application preparation at least 10-12 weeks before the study expires.

2. Collect Documents

<table>
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<th>Do you have all the paper documents you need?</th>
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Before Zipline, all of the UW IRB’s formal documentation was paper-based. After an item was approved, a hard copy of the approval “packet” was sent to the research team. These materials include:

1. The initial application
2. Modifications, numbered sequentially
• Status Reports, numbered sequentially
• Problem Reports, numbered sequentially
• Protocols, Investigator’s Brochures, Data and Safety Monitoring Plans, Conflict of Interest Management Plans, Confidentiality Agreements, Funding Proposals, and other standalone documents

You will need to refer to these documents as you prepare the conversion. Many of these paper approval packets contain correspondence and additional information requested by the IRB after the initial submission. It is important to refer to this correspondence as you prepare the conversion because often this correspondence contains significant changes to the study design, procedures for subjects, or information requested by the IRB which should be included in the conversion.
| ✅ Do you have all the electronic documents you need? | You will be asked to upload supporting documents as part of the conversion application. Because Zipline makes use of the tracked changes feature in **Word** for capturing modifications to a study you will need **Word** versions of currently approved:
- Consent documents
- Recruitment materials (e.g. flyers, scripts)
- Data collection forms to be used with subjects
- Protocols, Investigator’s Brochures, Data and Safety Monitoring Plans, Conflict of Interest Management Plans, and other standalone documents

HSD may accept PDFs of some documents if that is the only version available, however having **Word** documents will speed review of your application and make future modifications easier.

_TAKE NOTE AND SAVE TIME!_ You do not need to upload copies of Confidentiality Agreements and Funding Proposals that have already been submitted to the IRB.

You will also need to enter significant amounts of information from the previous IRB reviews into the new Zipline IRB Protocol. This will be easier if you have access to **Word** versions of previous submissions (e.g. the initial application) from which to copy and paste information, but _make sure you are copying information that is current and accurate._ |

| ✅ Is anything missing? | You will not be able to prepare a quality conversion without these documents, so make sure to double check that you have everything. If you do not regularly manage these materials, you may need to work with the Principal Investigator and other members of the study team to obtain everything you need.

If the study team cannot locate all of these documents, contact HSD at hsdinfo@uw.edu for assistance. HSD expects the study team to maintain a complete record of all IRB submissions and correspondence, but may be able to provide limited assistance with replacing missing documents. |

| 3 Understand the Study | In order to correctly prepare a conversion, you will need to understand the current state of the study. You will need to know:
1) **What are the current, ongoing activities**
2) **What is currently IRB approved**
3) **Whether modifications are needed** |

| ✅ What is ongoing? | The conversion application should only include study activities that are **ongoing**. Activities that have been completed should not be described and their corresponding supporting documents should not be uploaded. To identify what the current study activities are, you will need to **talk with the study team**.

_TAKE NOTE!_ The study team may need to **make decisions** about whether or not some activities will continue in the future. For example, some recruitment strategies may have been discontinued, or subjects in an arm of the study may have completed all study procedures. |

| ✅ What is approved? | The conversion application should only describe activities that are **currently** approved by the IRB. To identify this, you will need to synthesize information that may appear across many different submissions and in many pieces of correspondence attached to submissions. **Do NOT** simply rely on the initial application.

To do this quickly and efficiently: |
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<tbody>
<tr>
<td></td>
<td><strong>Start with the currently approved consent and recruitment materials.</strong> These should accurately reflect much of what is currently approved, including study procedures, data confidentiality protection plans, funding, etc.</td>
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<td></td>
<td><strong>For studies with many modifications, work backwards historically</strong> from the most recent submissions.</td>
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<tr>
<td></td>
<td><strong>Look at the most recent status report.</strong> These summarize study activities that were current at renewal.</td>
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<td></td>
<td><strong>Use a protocol as reference.</strong> Some studies, such as clinical trials, have a standalone protocol document that is updated to reflect all changes in the study and which will incorporate all changes submitted to the IRB.</td>
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<tr>
<td>Plan for modifications?</td>
<td>In general, changes to the study (new procedures, populations, consent plans, etc.) should <strong>not</strong> be included in the conversion application because this will significantly delay review of the conversion, may not be allowed by study reviewers, and can lead to substantial additional work for you. As you review the study materials, take note of whether any changes to the study are needed and plan for submitting modifications either:</td>
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| **Plan for modifications?** | • **On paper before you submit the conversion application.** You will need to plan enough time for the modification to be approved before you submit the conversion. The changes should be incorporated into your conversion.  
• **In Zipline after you submit the conversion application and it has been approved.**  
If you believe that a change needs to be incorporated into the conversion application, you must [contact HSD](#) before you submit the conversion to obtain permission to include these changes. |
| 4 Prepare Materials | To correctly prepare a conversion you will need to:  
1) **Know what materials to prepare**  
2) **Know what information to include**  
3) **Obtain new information, if needed** |
| What materials to prepare? | Conversion applications serve two purposes: to request renewal of a study and to convert that study into the Zipline system, in essence replacing the paper file. A full conversion application includes all of the following documents:  
• The [Zipline Status Report for Conversion Studies](#). Captures information about study activities since the last renewal or initial approval. The IRB will use this information to renew the study.  
• The [Zipline IRB Protocol](#). Captures information about the study activities that will occur from this time forward. For conversions, the IRB Protocol will replace most of the paper file.  
  o **or** the [Zipline IRB Protocol, No Contact](#). An alternative form for studies with no contact with subjects (e.g. medical records reviews without consent)  
• Any supplemental forms applicable to your study. These forms are specific to different types of research and you will be directed to complete these as you answer questions in the IRB Protocol  
• Any already approved supporting documents such as consent forms, recruitment materials, protocols, etc. |
**Zipline Status Report for Conversion Studies**
Captures information about study activities since the last renewal or initial approval and is relatively self-explanatory. Make sure to provide explanations for any unchecked boxes in the form.

**Zipline IRB Protocol** or **Zipline IRB Protocol, No Contact** and supplemental forms  
Designed to capture and reflect all of the current activities for a study. For conversions, the IRB Protocol will in essence replace most of the paper file and will be the basis for all future modifications to the study. This form will therefore need to completely and accurately reflect the currently approved and ongoing activities for a study. When completing the form:

- Do read and answer every question carefully
- Do refer directly to the appropriate sections of a separate protocol document or grant proposal if the study already has one (e.g. clinical trials).
- Do make sure to include all relevant information from all of the IRB’s previous reviews.
- Do provide any new information as needed to describe the current activities for the study
- Don’t simply copy and paste the same information into several different questions.
- Don’t refer to previous, paper-based submissions. (e.g. “see modification #2)
- Don’t describe study activities that have been completed.
- Don’t describe new activities or changes to the study

**Do you need new information?**

The new Zipline IRB Protocol asks different questions from HSD’s previous paper applications. You may need to provide new information about the study in order to answer these questions. For example, you may not have been asked previously to provide a copy of a Data and Safety Monitoring Plan, but you may now be asked to provide one. You will need to work with the study team to obtain this new information and make sure it is accurate.

**5 Submit in Zipline**

To submit your conversion, you will need to:
1) Understand Zipline basics  
2) Create the submission and complete the Zipline SmartForms  
3) Upload documents in the correct location  
4) Submit the application

**Learn how Zipline works**

Use the Zipline Online Help Library to orient yourself to the basics of working in Zipline and submitting studies.  

_TAKE NOTE!_ Key members of the study team, including the PI and whoever prepares and submits the submission, will need to be registered in Zipline before the study can be submitted.

**Create the submission and complete the SmartForms in Zipline**  

Conversion applications are submitted in Zipline as new studies. Follow the instructions for creating conversion studies or watch the ONLINE TUTORIAL: Converting an Existing Study into Zipline (You may need to login with your NetID). Anyone can create a study, but only the Principal Investigator can submit a study unless you have assigned a PI Proxy.  

_TAKE NOTE!_ It is important to answer all of the questions in the Zipline SmartForms carefully. Each section of the SmartForms collects different information about the study. In order to answer these questions, you may need to work with the study team to obtain new information. Missing information, such as not providing the eGC1 number for funding, will delay review of your conversion.
As you complete each section of the SmartForms, and upload documents it is important to remember to:

- **Upload documents in the appropriate section of Zipline.** Each section of the Zipline SmartForms collects specific kinds of documents.
- **Include only documents that support current activities.**
- **Upload the currently approved versions.**
- **Submit Word versions of consent forms.** Consent forms will be watermarked and converted into approved PDFs when the conversion status report is approved.
- **Name documents descriptively.** Give each electronic document a unique and descriptive name to help distinguish them in Zipline.
- **Do not include tracked changes versions of any documents.**
- **Do not upload copies of paper-based documents (e.g. the initial application)**

It is a good idea to re-review all of the sections of the SmartForms to make sure they are complete, contain the correct documents and the information matches that provided in the IRB Protocol.

Conversions **do not** require any approvals, or Ancillary Reviews, before submission. When ready, the PI or the PI Proxy can submit the application.

**Be prepared to respond to requests for additional information.** HSD staff carefully review conversion applications for completion. Almost all conversions will require some clarification and editing before they are ready to be approved.

For questions about conversions, contact HSD at hsdinfo@uw.edu, 206.543.0098, or contact your departmental Team Lead directly using the [Contact Finder](#).