How to submit new projects in NAGANO.

ABSTRACT
This simple guide will help you when submitting your research project in Nagano.

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Introduction

All research projects that include the CIUSSS West-Central Montreal will need to be submitting on our online submission platform, Nagano. Once the project has been submitted through Nagano, the project will undergo a review for Science, Ethics and Feasibility. If the CIUSSS West-Central Montreal is not the main evaluating REB, then the project will only undergo a feasibility review. After the project has been reviewed and received a positive result from Science, Ethics and Feasibility, the project will receive Institutional Authorization and recruitment can begin. **Projects cannot begin until the final authorization by the Formally Mandated Person has been granted.**
How to log into NAGANO

1. Use the following link to visit the website: ccomtl.nagano.ca
2. If you are not a new Nagano user:
   a. Type your username and password in the log in page
3. If this is your first time accessing Nagano
   a. Type your username and temporary password in the log in page
   b. You will be prompted to re-enter the temporary password and then to create/enter in a new one.
4. Then you will be brought to the main page of the platform.
How to access templates and reference documentation on Nagano

Once logged into Nagano, at the top of the page, there is a button that looks like a question mark (?). In this section, you can find important documentation relating to the submission of research projects.

For example, in this section you can find:

1. Special guidelines relating to COVID-19
2. The REB meeting dates and deadlines for the submission of projects
3. Consent form templates and guidelines
4. Protocol guidelines
5. Etc.

It is very important to refer to these documents/requirements when submitting new research as well as to submit quality documents, as they can facilitate the evaluation process. Please note that the Research Ethics Committee reserves the right to immediately refuse any research that does not meet these requirements.

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Your Dashboard

By logging into Nagano, you will be brought directly to your dashboard - the icon for this page is a house:

The dashboard is the main page of Nagano, where you can find information relating to all projects that you are a user on. There is information such as:

- Any announcements from the RRO- you should read any announcements written on the dashboard as they might have important information that could affect the research team
- Any messages that have been sent relating to your projects
- Any activities that have been done by the REB, the PM, etc. relating to your projects

You can also access the calendar, which has the REB meeting dates:
How to submit a new project in NAGANO

1. From the dashboard, click on the second icon (three pieces of paper overlapped) to bring you to the “New Project Creation Page”

2. To create a new project, click on the red button called 'new project'.
How to submit a Single Site project (CIUSSS COMTL = only site)

1. Once you have clicked “new project”, you will arrive at this page.
2. In the “Nagano Identifier” section- include a brief acronym of the project.
   a. N.B. please do not write the full title of the project in this section
3. The “project type” section allows for you to select which type of project is being submitted
   a. This section is important because it allows for the right submission form to be created.
   b. A more detailed explanation will be found later on in the guide.
4. The “projects language” section allows you to select the language that you want all your forms and official documents (approval letters) to be available and issued in.
5. The last question in this form allows for you to add “users” to the project.
   a. This can be anyone you believe or want to have access to the project
How to submit a Multisite project:

There are two ways in which a multisite project can be submitted.

**Important:** According to the “Cadre de référence des établissements publics du réseau de la santé et des services sociaux pour l’autorisation d’une recherche menée dans plus d’un établissement”, only one REB will act as the reviewing REB for projects with more than one site within Quebec.

Please be sure that to select the correct option when creating and submitting multisite projects. Selecting the incorrect option (MEO vs. MP) can create delays.

A) If the CIUSSS Centre-Ouest is the main (evaluating) REB [MP project]

If the CIUSSS COMTL will be the main/principle site of the project, then the CIUSSS COMTL REB will act as the reviewing REB. These multi-site projects will have the project number: MP-05-XXXX-XXXX.

1. **Nagano Identifier**: write a short acronym of the project.
2. If the project is a **multi-site project** (with other participating centers in Quebec), select the box
   a. Do not select this box if the participating sites are OUTSIDE Quebec.
3. “**Ethical assessment at this site**”: This section determines who will be the reviewing REB
   a. **Select **YES** if the CIUSSS Centre-Ouest will act as the main site and reviewing REB
   b. Selecting “**YES**” to this section will create an F0 form
      i. This form allows for the REB to accept (or refuse) to act as the reviewing REB
   c. Once the F0 form has been approved, an F11XX form will be generated.
4. “**Industry sponsored**”: Is the project is sponsored by a Pharmaceutical or private company
5. The “**project type**” section allows for you to select which type of project is being submitted
   a. This section is important because it allows for the right submission form to be created.
6. The “**projects language**” section allows you to select the language that you want all your forms and official documents (approval letters) to be available and issued in.

N.B. If the project has already received an REB evaluation from an external REB (i.e. not the CIUSSS Centre-Ouest), please go to the next section.
B) If the CIUSSS Centre-Ouest is a participating site (not main REB)

If the CIUSSS COMTL will be a participating site for the project, then the reviewing REB will be whichever site is the principle/main site for the project. These multi-site projects will have the project number: MEO-XX-XXXX-XXXX.

1. **Nagano Identifier**: write a short acronym of the project.
2. If the project is a **multisite project** (with one or more participating centers in Quebec), select the box
3. **Ethical assessment at this site**: This section determines who will be the reviewing REB
   a. Select “NO” if the project has already been reviewed by an external REB (i.e. the ethical assessment is done at another site)
   b. Select the **reviewing REB** from the drop down list
4. **Industry sponsored**: Is the project is sponsored by a Pharmaceutical or private company
5. The “**project type**” section allows for you to select which type of project is being submitted
   a. This section is important because it allows for the right submission form to be created.
6. The “**projects language**” section allows you to select the language that you want all your forms and official documents (approval letters) to be available and issued in.

N.B. After selecting “create”, an F11MEO form will be generated
How to complete the F0 form

When you are creating a multi-site project in Nagano and you would like the CIUSSS COMTL to act as the reviewing REB, you will first need to create an F0 form (this process is described in the section above). This form is the “declaration to act as the reviewing REB for the project”. The REB can then review the form and either accept (or refuse) to act as the reviewing REB for a specific project.

Once the F0 has been created, it will need to be completed as accurately as possible. Not completing the F0 form accurately can cause issues with the synchronization of participating sites.

Please include the title in English and/or in French (section 1-2)

Please include the primary investigator at the CIUSSS COMTL and any LOCAL co-investigators (section 3-4)

You can indicate whether the project will require a scientific review or whether it has already undergone a science review by a scientific evaluation committee or a recognized peer committee, as defined by the MSSS (section 5).

Please provide a summary of the project in lay terms (section 6).

Identify in the participant profile section what participants are being recruited/solicited for this project (section 7).

In the section external investigators please include ONLY the local investigators of the participating sites within Quebec (section 8).

In the section competencies of the external researcher please attach either the Research privileges of the external investigators and/or the license of practice and CV (section 9).

Please upload the protocol in section 10.

In the participating sites section, please include all the sites WITHIN Quebec that are participating in the project. N.B. Please be sure to provide the contact information of either the Local investigator or the research team of the participating site that will create the project in their own respective Nagano (section 11).

Please provide any site characteristics, if applicable (section 12).
Navigating the “My Projects” dashboard:

Once you have completed the previous steps, and the project has been successfully created, you will be brought to the page “My Projects”. This page is sub-divided in sections for easy follow-up of projects.

The different sections are: My projects to follow, my activated projects and my inactive project. We will go through each subsection further in the guide.

My projects to follow

Clicking on the “My Projects” page will automatically bring you to the “my projects to follow” page. This page contains a list of all projects and their various statuses. For example, in this section you can find projects that are created but not yet submitted, as well as projects that are submitted but not yet authorized for research. You can also find in this section projects that have been re-opened and projects that are waiting to be renewed for ethics.

You will also be able to see whether there are any ongoing discussions for a particular project and other various information.
My activated projects:
In the section “My activated projects” you will find a list of all projects that have been authorized for research (i.e. have received institutional authorization). You will also notice any discussions or forms that are currently open for a specific project.

My inactive projects:
In this section, you will find a list of all terminated or inactive projects.
How to Search for a Specific Project

There are two ways in which you can search for a specific project; the first is by searching directly through the “my projects page” and the second is by searching through the “home” page.

Searching through the “my projects” page

- When you are on the “my projects” page, you can click directly on the project number or Nagano Identifier to go to the main page of the project.
- If you want to directly go to the form that was created, you can click on “shortcut” and you will be brought to the form.

Searching through the “home” page

If you are on the main page (i.e. dashboard, little house), you can search the project by typing either the Nagano Number or the Nagano Acronym in the “Projects” search bar at the top right hand corner of the page.
Navigating the main dashboard

The main dashboard will provide you with different information, from discussions relating to your project, to forms pending submission, to projects waiting to be renewed. Moreover, you will be able to see a list of all activities that have been done to your projects. For example, if the REB has added a discussion or has opened or approved a form, this action will appear on this page. You will also see any forms that need to be submitted on your part, as well as any messages relating to your projects and any important announcements that the RRO would like you to be aware of.
Navigating your projects

Main page of the project

After searching for a project using the “dashboard”, you will be brought to the main overview page of the project.

On this page you will find information about the project such as:

- Project title
- Project type
- The reviewing REB
- The status of the project
- The status of the Ethics, Science and feasibility Approval
  - You will also see any pending departmental feasibility reviews listed here
- The name of the PI and Co-PI’s
- Important dates (i.e. submission date, REB approval date, Institutional feasibility date, renewal date, etc.)
- % of funding that is privately funded

Different tabs within your project

Forms tab

In the “FORMS” tab at the top of the page, you will find information about all forms related to the project. For example, any new forms that have been created, or approved by the REB, as well as any forms that have been re-opened by the REB etc.

If you want to select a form, click on the blue text (FXX-XXXX). Selecting this form will open the form where you will need to perform certain actions (i.e. fill out sections or respond to REB comments).

N.B. If you do not see all the forms you have filled it, it could be because it was modified more than two months ago, and will be in the section “Forms modified more than 2 months ago”
This section is also where you would create new forms, for example, deviation forms, amendment forms, termination forms etc. In order to create a new form, click the green **new** button on the top right hand corner of the forms tab. This will bring you to a new page where you can select the type of form you need to create.

**Status tab**

The **status tab** has information about the status of the different evaluations for the specific project. You can select each section to obtain a more detailed view:
The first section gives a general overview, for example, the status of the REB review, the science (SEC) review, the different departmental feasibility reviews.

The next section is the **project status section**, that outlines the current status of the project overall.

You will also find information about the REB and SEC meetings, as well as the status of those reviews under the **offices tab**:

The last remaining sections outline the different institutional departmental feasibility reviews and the status of those reviews. If the study is a multi-site study, you will also see a list of all **participating sites**.
Uploaded files tab
In the **uploaded files section** you will find all files that have been uploaded and/or added (by the research team or the REB) relating to the project. You will also find official documents such as final ethics approval and institutional authorization letters.

If you select **all files** you will see all the project files uncategorized. However, if you prefer to have a uniform view, you can select the category to which the file you are looking for belongs.

Discussion tab
If you want to write a discussion to a member of the Research Review Office (RRO), be it the REB specialist or a question relating to feasibility or any other project related questions, you can create a **discussion**. In this section, you will also see any questions or discussions created from the RRO.
Comms or Comms-Multi tab

The **Comms or Comms-Multi** tab represents the communications tab. For single site studies, you will see it as the **COMMS** tab, which will have information about when official documents have been transmitted to the research teams.

For multi-site studies, you will see it as the **COMMS-Multi** tab, which will have information about the participating sites and their synchronization status as well as when official documents and other documents have been transmitted to the local research team as well as the participating sites.
Different types of Projects and their corresponding Form:

When you submit a project to Nagano, it is very important that you keep in mind the type of project it will be. Each project type in Nagano corresponds to a specific “Initial Submission Form” with questions that are specific to that type of research. If a project is incorrectly submitted, the Research Review Office may ask you to resubmit the project using the correct form.

The different project types that can be selected are:

- Medical-Biomedical Clinical Research (Clinical Trials)
- Medical Research (Other than Clinical Trials)
- Banking/Registry (Creation of a New Bank / Registry)
- Banking/Registry (Secondary Research using Existing Bank/Registry)
- Psychosocial research: (e.g.: social, behavioral, education, social work, cultural, etc.)
- Retrospective Research (Chart Review)
- Mise-en-oeuvre (MEO) projects – CIUSSS COMTL NOT the reviewing REB

The next pages will outline the different forms that correspond to each type of project as well as which questions to pay more attention to.
**Medical/Biomedical: Clinical Trials and non-Clinical Trials**

In order to be able to submit the complete form, all sections with a **RED !** need to be completed. **Even though a section is not mandatory, if you have the information being asked, please complete it in the form.**

Please include the project title, as well as the name of the primary investigator and ALL co-investigators involved with the study.

In the case of **clinical trials**, the project should to be registered in a **public registry** (i.e. clinicaltrials.gov etc.)

For clinical trials, please select which **field of research** summarizes the project.

If a project **has not** been reviewed by a funding agency, then the project must undergo a **Science review**.

All projects submitted will require a **protocol**, and a **consent form** (either English or French). Final approval will only be granted when both EN and FR versions have been submitted. It is important to provide the WORD version of the consent forms.

Specifically for clinical trials, if a **pharmacy manual** is available it is important to submit it, as well as the **NOL** if available.

If a **project is funded**, regardless of whether it is private or non-private funding, you need to upload a **budget and the funding letter**.

If you have already obtained support letters from the department(s) implicated in your project, you can upload them in the department/program head support letter section.

The **Finance and Feasibility** section is an important section with regards to Institutional Authorization. In this section, you will be asked to select all departments, programs or services that are implicated with the project.

Implicated how?
- Participants are being recruited from the department, service or program
- Staff from the department, service or program are helping with recruitment
- Services from the department, service or program are being used (i.e. imaging, pharmacy etc.)

In the case of clinical trials, it is important to complete the separate sections (i.e. Pharmacy section, Nursing section, etc.) as accurately as possible, missing information can cause delays in the feasibility review of the project.

If you would like the RRO office to know something specific about the department selected, please add that information in the **other** section or in the **additional comments/information section**.

**N.B.** Please note that it is important that this section is completed as accurately as possible. Not completing this section accurately can cause delays when obtaining letters of support. Moreover, the **convenience module** is partially active, therefore, requests will automatically be sent to certain implicated departments, if applicable.
After all the previous sections are completed, please be sure to answer the Agreement and signature of the investigator section.

Before submitting the form you must have the Primary Investigator sign the commitment and signature link. This confirms that they have agreed to the submission and that you will be submitting on their behalf (by selecting the option as submitting the initial review request as the research study coordinator or collaborator).

If the Primary Investigator wishes to sign the form themselves, they can log into their own Nagano account and they will have access to the study since the study will be under their name.
Banking/Registry (Creation of New Bank)

In order to be able to submit the complete form, all sections with a **RED !** need to be completed. Even though a section is not mandatory, if you have the information being asked, please complete it in the form.

Please include the **project title**, as well as the name of the **primary investigator** and **ALL co-investigators** involved with the study.

If the study involves McGill university faculty and/or staff, please be sure to complete the **McGill university faculty section**. If the study involves any university students, please complete the **university students section**.

If a project is **privately funded**, it is important to provide the sponsor address/contact information.

If a project has not been reviewed by a funding agency, then the project must undergo a **Scientific review**.

For the creation of a new bank, it is important to fill out the **Specific Characteristics** section. This section contains information of the bank (i.e. location of bank, name of bank, etc.).

It is important to complete the **Recruitment, enrollment and consent** section accurately, as this provides information about the participants being recruited for the creation of the new bank.

The **protection of data and personal information** is important as it specifies where the data is being stored, who is collecting the data as well as how the collected data will be protected to ensure that no nominative information will be shared.
The **Site Specific Assessment/Feasibility** section should be filled to describe where the participants will be recruited from. In this section, you will be asked to select all departments and sites that are implicated. Not filling this section accurately can cause delays in obtaining support letters needed for the project.

A **Biobank Framework** is required for the creation of a new bank.

English and French **Consent Forms** are also required, because the data for the creation of the bank are coming from participant data and not already collected data. N.B. Data here can mean both biological and non-biological data.

If you have already obtained support letters from the department(s) implicated in your project, you can upload them in the **department/program head support letter** section.

The **Contractual Feasibility** section is important for projects where an agreement may be necessary. This can be a clinical trial agreement, a data sharing agreement, material transfer agreement etc. Please be sure to fill that section as accurately as possible, not filling the section accurately can cause delays in granting institutional authorization.

Any time a contract or agreement will be drafted, please attach a draft of the agreement to the **Agreements drafts section**.

**Budget and Funding letter** section is important for projects that are funded. If a project is funded, regardless of whether it is private or non-private funding, you need to upload a budget and/ or the funding letter.

The **Commitment and Signature** section needs to be filled out with the signature of the Primary Investigator.
In order to be able to submit the complete form, all sections with a **RED !** need to be completed. Even though a section is not mandatory, if you have the information being asked, please complete it in the form.

Please include the **project title**, as well as the name of the **primary investigator** and **ALL co-investigators** involved with the study.

If the study involves McGill university faculty and/or staff, please be sure to complete the **McGill university faculty section**. If the study involves any university students, please complete the **university students** section.

If a project is **privately funded**, it is important to provide the sponsor address/contact information.

If a project has not been reviewed by a funding agency, then the project must undergo a **Scientific review**.

When using previously collected data from a bank or registry, it is important to fill out the **Specific Characteristics** section. This section contains information about which bank is being used for the project. It is important to also provide a letter of support from the Fiduciary of the bank.

It is important to complete the **access to files already created** section. It provides additional information on the type of data being used for the project.

The **Protection Personal Information** as well as the **Data Retention** section is important and should be filled with as much detail as possible. This section outlines who will have access to the data collected as well as where the data will be stored.

The **Site Specific Assessment/Feasibility** section should be filled out only if the data is from a **bank within the institution**, Therefore, please list the department where the bank is located. If the bank is an external bank, then this section does not need to be filled.
The Contractual feasibility section is important for all projects. This section has specific questions to help determine whether an agreement is necessary or not for a specific project. This can be a clinical trial agreement, a data sharing agreement, material transfer agreement etc. Please be sure to fill that section as accurately as possible, not filling the section accurately can cause delays in granting institutional authorization.

Please be sure to attach a protocol as well as any biobanking framework for the bank related to the project.

In the Department/program head letter section please attach the letter granting access to the specific bank that is being used for the project (whether it is a bank located within the intuition or outside of the institution).

Any time a contract or agreement will be drafted, please attach a draft of the agreement to the Agreement drafts section.

The Budget and Funding letter section is important for projects that are funded. If a project is funded, regardless of whether it is private or non-private funding, you need to upload a budget and either a draft contract or the funding letter.

The Commitment and Signature section needs to be filled out with the signature of the Primary Investigator.
Retrospective Chart Review

In order to be able to submit the complete form, all sections with a **RED !** must be completed. Even though a section is not mandatory, if you have the information being asked, please complete it in the form.

Please include the **project title**, as well as the name of the **primary investigator** and **ALL co-investigators** involved with the study.

If the study involves McGill university faculty and/or staff, please be sure to complete the **McGill university faculty section**. If the study involves any university students, please complete the **university students** section.

Please complete the **funding** section. If there is no funding, please select the “no funding” option.

If a project has not been reviewed by a funding agency, then the project must undergo a **Scientific review**.

The **Director of Professional Services/DPS** section needs to be filled if there will be access to charts **WITHOUT consent**. Please be sure to clearly define what the objective and purpose of the chart review is. N.B. it is important to fill ALL the subsequent questions in this section. Not completing a question can cause delays.

The **Protection Personal Information** as well as the **Data Retention** section is important and should be filled with as much detail as possible. This section outlines who will have access to the data collected as well as where the data will be stored.

The **Contractual feasibility** section is important for projects where an agreement may be necessary. This can be a data sharing agreement, a collaboration agreement, an inter-institutional agreement etc. Please be sure to fill that section as accurately as possible, not filling the section accurately can cause delays in granting institutional authorization.

Any time a contract or agreement will be drafted, please attach a draft of the agreement to the **Agreement draft section**.

The **Budget** section is important for projects that are funded. If a **project is funded**, regardless of whether it is private or non-private funding, you need to upload a budget and the funding letter.

The **Commitment and Signature** section needs to be filled out with the signature of the Primary Investigator.
Psychosocial Research Projects (i.e. social, behavioral, social work, cultural etc)

In order to be able to submit the complete form, all sections with a **RED !** must be completed. Even though a section is not mandatory, if you have the information being asked, please complete it in the form.

Please include the **project title**, as well as the name of the **primary investigator** and **ALL co-investigators** involved with the study.

If the study involves McGill university faculty and/or staff, please be sure to complete the **McGill university faculty section**. If the study involves any university students, please complete the **university students section**.

If a project has not undergone a science review by a scientific evaluation committee or a recognized peer committee, as defined by the MSSS, then the project must undergo a **Scientific review**.

Please provide a summary of the research project in the **summary section**.

In the **MSSS research categories section** please select the option that best classifies the research project.

In the **participant profile section**, please identify the participants implicated in the project.

Please provide a clear description of the **recruitment process** and how **consent** will be obtained. It is important to complete this section as accurately as possible. There are consent form templates available for Psychosocial research in the Documentation section in Nagano.

The **Protection of Personal Information** and the **Protection and storage of data sections** are important and should be filled with as much detail as possible. Specifically, it is important to consider data management and data security as well as who will have access to this data.

The **Site Specific assessment/Feasibility** section is an important requirement for feasibility. In order to ensure that feasibility requests are sent quickly, please be sure to select all the departments, services and programs implicated in the study.

It is especially important to complete the **Contractual Feasibility** section—this section has specific questions that will determine whether an agreement is necessary for the study. These can be collaboration agreements, inter-institutional agreements, data transfer agreements, etc. Please be sure to fill this section as accurately as possible, not filling the section accurately can cause delays in granting institutional authorization.
Please be sure to attach a **protocol** that follows the guidelines from the Psychosocial committee. These guidelines can be found at the bottom of the Nagano Platform or in the Documentation section.

**N.B.** Please note that the REB has the right to refuse any research that does not meet the requirements set by that committee.

Include in the next sections all **consent forms** and **questionnaires/recruitment documents** that will be given to the participants and all documents that the research team will use.

If a letter of support from a specific department/service/program has been obtained, attach it in the **department/program head section**. Please note that having this letter is not a requirement to submit the project for review.

Any time a contract or agreement will be drafted, please attach a draft of the agreement to the **Agreement Draft section**.

The **Budget and Funding letter** section is important for projects that are funded. If a project is funded, regardless of whether it is private or non-private funding, you need to upload a budget and the funding letter.

The **Commitment and Signature** section needs to be filled out with the signature of the Primary Investigator.
Mise-en-oeuvre (MEO) projects – CIUSSS COMTL NOT the reviewing REB

When the CIUSSS COMTL is NOT the reviewing REB for a research project, the project will still need to be created and submitted in Nagano to undergo a Feasibility review. These projects will have the project number MEO-XX in Nagano.

In order to ensure that the project is submitted correctly, the following are the important documents and sections that MUST be completed. Not completing the form accurately will mean that the form could be re-opened and can cause delays in the revision of the project.

In order to be able to submit the complete form, all sections with a RED ! must be completed. Even though a section is not mandatory, if you have the information being asked, please complete it in the form.

Please include the project title, as well as the name of the primary investigator and ALL co-investigators involved with the study.

Please list ALL the participating sites in Quebec that are participating in the project.

Please specify the funding type if there is no funding, please select “no funding”.

Please clarify whether a science review has been completed.

Please provide a summary of the project, in lay terms.

Complete both the MSSS research categories and Specific Characteristics sections, which will help identify which research category the project falls within.

For clinical trials only, please complete the experimental design, standard treatment, use of placebo, risks and benefits sections.

Please complete the privilege to conduct research section.

Please provide information on the participant profile, compensation and visits. This information may be important for clinical and non-clinical departments when reviewing for feasibility.

It is very important to complete the Methods of recruitment, Methods of Consent and Recruitment and consent process sections. This will provide a clear idea of how participants will be recruited as well as how consent will be obtained. This section should be completed as accurately as possible.

The access to files already created section should be completed when the research team will be accessing existing records (i.e. medical records, government databases, data collected in another research project, etc).
The Protection of Personal Information and the Protection and storage of data sections are important and should be filled with as much detail as possible. Specifically, it is important to consider data management and data security as well as who will have access to this data as well as where the data will be stored.

The Site Specific assessment/Feasibility section is an important requirement for feasibility. In order to ensure that feasibility requests are sent quickly, please be sure to select all the departments, services and programs implicated in the study.

Implicated how?
- Participants are being recruited from the department, service or program
- Staff from the department, service or program are helping with recruitment
- Services from the department, service or program are being used (i.e. imaging, pharmacy etc.)

N.B. It is important that this section is completed as accurately as possible. Not completing this section accurately can cause delays when obtaining letters of support (delays in the feasibility review of the project). Moreover, the convenience module is partially active, therefore, requests will automatically be sent to certain implicated departments, if applicable.

It is especially important to complete the Contractual Feasibility section - this section has specific questions that will determine whether an agreement or contract is necessary for the study. These can be collaboration agreements, inter-institutional agreements, data transfer agreements, etc. Please be sure to fill this section as accurately as possible, not filling the section accurately can cause delays in granting institutional authorization.

Please provide either the Final Ethics approval letter or the Declaration letter that mentions our site as a participating site.

Provide the latest approved protocol as well as consent forms and recruitment documents (that have the site specific modifications).

For clinical trials it is important to provide the NOL and the Pharmacy Manual.

If a draft contract or agreement was received, please attach it to the Agreement Draft section.

The Budget and Funding letter section is important for projects that are funded. If a project is funded, regardless of whether it is private or non-private funding, you need to upload a budget and the funding letter.

The Commitment and Signature section needs to be filled out with the signature of the Primary Investigator.