



RESEARCH PROTECTIONS OFFICE

UVMClick – IRB Forms Library

You will need to initiate a new protocol through the [UVMClick – IRB](#) module. This will require that you complete a General SMARTForm and attach completed consent forms/documents as applicable.

Application Materials for Initial Submission

EXPEDITED & FULL BOARD APPLICATIONS

Protocol Forms	Use	Updated
<u>Human Research Protocol (DOCX)</u>	For any human subjects study that does not have a specific “protocol” from the sponsor.	02/27/19
<u>Biological Specimens/Data Repository Protocol (DOCX)</u>	When the only activity is the collection, storage, and distribution of data or specimens for research.	11/29/18
<u>Blood Collection Protocol for Non-Clinical Laboratory Research (DOCX)</u>	When the only activity is blood collection for bench science.	11/29/18
<u>Qualitative Research Protocol (DOCX)</u>	To be used if the research is purely qualitative. If there are any medical procedures use the Human Research Protocol.	11/29/18
<u>Initial Review of an Administrative Tool or Projects to be Developed (DOCX)</u>	Only used when human subject activities are delayed but an IRB certificate is required from the sponsor.	11/19/18

EXEMPT APPLICATIONS, NOT HUMAN SUBJECTS & NOT RESEARCH

Determination Forms	Use	Updated
<u>Exemption 1 (Educational Research) (DOCX)</u> <u>Exemption 2 (Surveys and Interviews) (DOCX)</u> <u>Exemption 3 (Behavioral Intervention) (DOCX)</u> <u>Exemption 4 (Secondary Data Uses) (DOCX)</u> <u>Exemption 5 (Demo Projects) (DOCX)</u> <u>Exemption 6 (Food and Taste) (DOCX)</u>	When studies are minimal risk and meet certain criteria for exemption from IRB review. <u>Common Rule 2018 Exemption Changes (PPTX)</u>	05/03/19
<u>Not Human Subject Determination (DOCX)</u>	When studies involve the review of data or specimens when there are	02/26/19

	no identifiers.	
<u>Not Research Determination (self-determination tool)</u>	When projects are quality improvement or assessment and do not meet the criteria as research.	11/19/18

DATA MANAGEMENT & SECURITY PLAN

The Research Data Management and Security Plan form is required to be submitted along with all new expedited and full level protocols as well as any protocols where the IRB requires a clearer plan for the protection of data.

[Research Data Management and Security Plan \(DOCX\)](#)

[Research Data Management and Security Plan Guidance \(DOCX\)](#)

Consent Information

2018 COMMON RULE GUIDANCE

A concise summary of study activities, risks, and benefits presented to research participant in advance of the body of the consent form is now required as part of the 2018 Common Rule change for any new protocol or active protocol where subjects are still being enrolled. The IRB will not require re-consent for subjects already enrolled.

Additionally, there are new elements of informed consent that are required as applicable. These can be found in the UVM sample consent template document in BLUE text.

[Examples of the new concise key information section \(DOCX\)](#)

View the **[HIPAA and Research FAQ \(opens in a new window\)](#)**

Search for a term in the **[Medical Dictionary \(opens in a new window\)](#)**

INFORMED CONSENT TEMPLATES

Consent Forms	Updated
<u>Adult Behavioral/Social Study Consent (DOCX)</u>	04/25/19
<u>Adult Medical Study Consent (DOCX)</u>	04/25/19
<u>Child Assent (DOCX)</u>	04/25/19
<u>Blood Collection Consent (DOCX)</u>	04/25/19
<u>Debriefing Consent (DOC)</u>	10/12/16
<u>Information Sheet (DOCX)</u>	03/09/18
<u>Media Consent (DOC)</u>	10/06/03
<u>Pregnant Partner Consent (DOCX)</u>	06/22/18
<u>Repository Consent (DOCX)</u>	04/25/19
<u>Short Form for Non-English Speaking (DOCX)</u>	01/01/16
<u>Expanded Access Consent (DOCX)</u>	11/20/18

CONSENT PROCESS DOCUMENTATION EXAMPLES

Documentation Forms	Updated
<u>Example 1 (DOCX)</u>	07/26/18
<u>Example 2 (DOCX)</u>	03/18/19
<u>Legally Authorized Example (DOCX)</u>	04/11/18

ONGOING CONSENT TEMPLATES

Consent Addendum

To be used anytime you have some additional information for subjects that may affect their willingness to continue participation. Prior IRB review and approval is required.

[Consent Addendum \(DOC\)](#)

Continued Participation After Child Reaches 18 years of age

To be completed with the child who has now turned of age. You must review the originally signed consent with the now adult child and obtain consent to continue their participation. This form does not require prior IRB review and approval unless you need to modify the template.

[Continued Participation after Reaching Age of Majority \(DOCX\)](#)

Application Materials to Rely on Single-External IRB

REQUEST TO RELY

[Request to Rely on External IRB \(DOCX\)](#)

UVMClick Data Entry Instructions

- [How to Request Reliance on Another IRB \(DOCX\)](#)
- [How to Respond to a Clarification Request \(DOCX\)](#)
- [How to Create a Modification to Change Study Team Members \(DOCX\)](#)
- [How to Create an RNI \(DOCX\)](#)

Related Documents & Resources

DATA USE AGREEMENT

Where faculty are receiving or sharing human subject data as part of a research collaboration, they will need to ensure that an appropriate Data Use Agreement or other form of research collaboration or confidentiality agreement is in place.

Contact spa@uvm.edu for more information.

LIMITED DATA SETS

If the research includes use of a limited data set from the UVM Medical Center, [you must enter into a Data Use Agreement with the hospital \(opens in a new window\)](#).

UVMCMC REVIEWS PREPARATORY TO RESEARCH

If you wish to review records (not taking any protected health information) to design a research study or assess the feasibility of conducting a study, you must complete this form and forward it to the UVM Medical Center Privacy Officer for approval.

[UVM Medical Center Reviews Preparatory to Research \(DOCX\)](#)

ATTESTATION FOR DECEDENT RESEARCH

If your research uses decedent UVMCMC PHI, fill this form out and send to Lianne.Cleary@uvmhealth.org.

[Attestation Form for Decedent Research \(DOCX\)](#)

[Follow-on Submissions \(SMARTForm Only\)](#)

MODIFICATIONS

This category applies to all protocol changes including safety updates that do not affect risk to subjects, and key personnel changes.

Instructions for Initiating a Modification can be found under "User Guides" on the [UVMClick – IRB \(opens in a new window\)](#) module web page.

CONTINUING REVIEWS

You will need to Initiate a Continuing Review through the UVMClick – IRB module. This will require that you complete a Continuing Review SMARTForm.

Instructions for Initiating a Continuing Review can be found under "User Guides" on the [UVMClick – IRB \(opens in a new window\)](#) module web page.

SAFETY - REPORTABLE NEW INFORMATION (RNI)

This category applies to adverse events, unanticipated problems or noncompliance that may affect risk to subjects. Please do not submit Investigator Drug Brochure (IDB) updates or safety updates from the sponsor that do not affect risk, these are modifications.

Instructions for Initiating a Reportable New Information (RNI) can be found under "User Guides" on the [UVMClick – IRB \(opens in a new window\)](#) module web page.

STUDY CLOSURES

Instructions for Initiating a Study Closure can be found under "User Guides" on the [UVMClick – IRB \(opens in a new window\)](#) module web page.

ETHICS AND COMPLIANCE REPORTING 877-310-0413