

Research Decision Chart 5: What type of Research Agreement does this Activity Require?

(The Research Decision Charts are intended to assist researchers in understanding how various determinations are made regarding research projects. These charts are not to be used by researchers to make independent assessments for final decisions on classification of research projects or research requirements. All final classifications and requirement decisions are made through Trillium's Research Office)

This table is designed to assist Researchers in identifying what type(s) of Agreement(s) is/are required for their specific Research Activity. The legend below defines the different types of possible study details, and types of Research Agreements. Identify the combination of study details that pertain to your specific Research Activity, and reference the table entry that identifies the Research Agreement(s) required, and provides general comments regarding the required Agreement(s).

Study Detail Key:

1. involves participation of THC staff and/or patients
2. involves collection and disclosure of THC staff and/or patient information
3. involves sharing of proprietary information
4. involves transfer of material located at THC outside of THC
5. Financially supported by a research grant

Study Detail Key:

- CTA – Clinical Trial Agreement
- CA – Confidentiality Agreement
- NDA – Non-Disclosure Agreement
- MTA – Material Transfer Agreement
- G/FA – Grant/Funding Agreement

Study Details	Research Agreement Required					Comments
	CTA	CA	NDA	MTA	G/FA	
1	X					
2		X				
3			X			
4				X		
5					X	
1+2	X					The details contained in a Confidentiality Agreement are also included as a section (article) in the Clinical Trial Agreement
1+3	X		X			The Non-Disclosure Agreement should be executed prior to the Investigator receiving study specific information and agreeing to participate in the study. The Clinical Trial Agreement is executed once all parties agree to the terms of the Agreement (responsibilities)
1+4	X					The details in a Material Transfer Agreement should also be included as a section (article) in the Clinical Trial Agreement
1+5	X				X	If the funding received is a grant to fund the study, then a separate Grant/Funding Agreement should be executed between the Principal Investigator and the granting/funding agency. If the funding for the study are incorporated as

Research Decision Chart 5: What type of Research Agreement does this Activity Require?

(The Research Decision Charts are intended to assist researchers in understanding how various determinations are made regarding research projects. These charts are not to be used by researchers to make independent assessments for final decisions on classification of research projects or research requirements. All final classifications and requirement decisions are made through Trillium's Research Office)

Study Details	Research Agreement Required					Comments
	CTA	CA	NDA	MTA	G/FA	
						budgeted amounts provided by the Sponsor, and are incorporated in the Clinical Trial Agreement, then only the Clinical Trial Agreement is required.
2+3		X	X			Each of the Confidentiality Agreement and Non-Disclosure Agreement may be executed, or one amalgamated document that includes the pertinent details of each Agreement should be drafted and executed
2+4		X		X		Each of the Confidentiality Agreement and Material Transfer Agreement may be executed, or one amalgamated document that includes the pertinent details of each Agreement should be drafted and executed
2+5		X			X	Both the Confidentiality Agreement and Grant/Funding Agreement are required. The Confidentiality Agreement should be executed between THC and those parties requiring the data for research purposes. The Grant/Funding Agreement needs to be executed among the Investigator, Granting/Funding Agency and the Sponsor (if it is for studies being conducted at THC, THC should be the sponsor)
3+4			X	X		Each of the Material Transfer Agreement and Non-Disclosure Agreement may be executed, or one amalgamated document that includes the pertinent details of each Agreement should be drafted and executed
3+5			X		X	Both the Non-Disclosure Agreement and Grant/Funding Agreement are required. The Non-Disclosure Agreement should be executed between the Investigator, and those parties they will be sharing/disclosing and/or receiving proprietary information with/from. The Grant/Funding Agreement needs to be executed among the Investigator, Granting/Funding Agency and the Sponsor (if it is for studies being conducted at THC, THC should be the sponsor)
4+5				X	X	Both the Material Transfer Agreement and Grant/Funding Agreement are required. The Material Transfer Agreement should be executed between Trillium Health Centre, the external party that requires Material from Trillium Health Centre for research purposes. The Grant/Funding Agreement needs to be executed among the Investigator, Granting/Funding Agency and the Sponsor (if it is for studies being conducted at THC, THC should be the sponsor)
1+2+3	X		X			The Non-Disclosure Agreement should be executed prior to the Investigator receiving study specific information and agreeing to participate in the study. The Clinical Trial Agreement is executed once all parties agree to the terms of the Agreement (responsibilities). The details contained in a Confidentiality Agreement are also included as a section (article) in the Clinical Trial Agreement
1+2+4	X					The details in both the Confidentiality Agreement and Material Transfer Agreement should also be included as separate sections (articles) in the Clinical Trial Agreement
1+2+5	X				X	Both the Clinical Trial Agreement and the Grant/Funding Agreement are required. The details contained in a

Research Decision Chart 5: What type of Research Agreement does this Activity Require?

(The Research Decision Charts are intended to assist researchers in understanding how various determinations are made regarding research projects. These charts are not to be used by researchers to make independent assessments for final decisions on classification of research projects or research requirements. All final classifications and requirement decisions are made through Trillium's Research Office)

Study Details	Research Agreement Required					Comments
	CTA	CA	NDA	MTA	G/FA	
						Confidentiality Agreement are also included as a section (article) in the Clinical Trial Agreement. The Grant/Funding Agreement needs to be executed among the Investigator, Granting/Funding Agency and the Sponsor (if it is for studies being conducted at THC, THC should be the sponsor)
1+3+4	X		X			The details in a Material Transfer Agreement should also be included as a section (article) in the Clinical Trial Agreement. Both the Clinical Trial Agreement and Non-Disclosure Agreement are required.
1+3+5	X		X		X	Each of the Clinical Trial Agreement, Non-Disclosure Agreement and the Grant/Funding Agreement are required.
1+4+5	X				X	Both the Clinical Trial Agreement and Grant/Funding Agreement are required. The details of the Material Transfer Agreement should be included in the Clinical Trial Agreement as separate section (article)
2+3+4		X	X			Both a Confidentiality Agreement and Non-Disclosure Agreement are required. The details of the Material Transfer Agreement and Confidentiality Agreement should be amalgamated into one Agreement that contains all pertinent elements of each of the individual Agreements in separate sections (articles).
2+4+5		X			X	Both the Confidentiality Agreement and Grant/Funding Agreement are required. The details of the Material Transfer Agreement and Confidentiality Agreement should be amalgamated into one Agreement that contains all pertinent elements of each of the individual Agreements in separate sections (articles).
2+3+5		X	X		X	Each of the Confidentiality Agreement, Non-Disclosure Agreement and the Grant/Funding Agreement are required.
3+4+5			X	X	X	Each of the Material Transfer Agreement, Non-Disclosure Agreement and the Grant/Funding Agreement are required.
1+2+3+4	X		X			Both the Clinical Trial Agreement and the Non-Disclosure Agreement are required. The Non-Disclosure Agreement should be executed prior to the Investigator receiving study specific information and agreeing to participate in the study. The Clinical Trial Agreement is executed once all parties agree to the terms of the Agreement (responsibilities). The details contained in the Confidentiality Agreement and Material Transfer Agreement should be included as separate sections (articles) in the Clinical Trial Agreement
1+2+4+5	X				X	Both the Clinical Trial Agreement and Grant/Funding Agreement are required. The details contained in the Confidentiality Agreement and Material Transfer Agreement should be included as separate sections (articles) in the Clinical Trial Agreement.
1+3+4+5	X		X		X	Each of the Clinical Trial Agreement, Non-Disclosure Agreement and Grant/Funding Agreement are required. The details of the Material Transfer Agreement should be included as a separate section (article) in the Clinical Trial Agreement. The Non-Disclosure Agreement should be executed prior to the Investigator receiving study specific information and agreeing

Research Decision Chart 5: What type of Research Agreement does this Activity Require?

(The Research Decision Charts are intended to assist researchers in understanding how various determinations are made regarding research projects. These charts are not to be used by researchers to make independent assessments for final decisions on classification of research projects or research requirements. All final classifications and requirement decisions are made through Trillium's Research Office)

Study Details	Research Agreement Required					Comments
	CTA	CA	NDA	MTA	G/FA	
						to participate in the study.
1+2+3+5	X		X		X	Each of the Clinical Trial Agreement, Non-Disclosure Agreement and Grant/Funding Agreement are required. The details of the Confidentiality Agreement should be included as a separate section (article) in the Clinical Trial Agreement. The Non-Disclosure Agreement should be executed prior to the Investigator receiving study specific information and agreeing to participate.
2+3+4+5		X	X		X	Each of the Confidentiality Agreement, Non-Disclosure Agreement and Grant/Funding Agreement are required. The details of the Material Transfer Agreement and Confidentiality Agreement should be amalgamated into one Agreement that contains all pertinent elements of each of the individual Agreements in separate sections (articles). The Non-Disclosure Agreement should be executed prior to the Investigator receiving study specific information and agreeing to participate.
1+2+3+4+5	X		X		X	Each of the Clinical Trial Agreement, Non-Disclosure Agreement and Grant/Funding Agreement are required. The details contained in the Confidentiality Agreement and Material Transfer Agreement should be included as separate sections (articles) in the Clinical Trial Agreement. The Non-Disclosure Agreement should be executed prior to the Investigator receiving study specific information and agreeing to participate.