



SOP: Establishing Authorization Agreements					
NUMBER	DATE	VERSION	AUTHOR	APPROVED BY	PAGE
HRP-801	01/19/2019	1	C. Gates	C. Gates	1 of 1

1 PURPOSE

- 1.1 The purpose of this process is to execute Authorization Agreements with other institutions.
- 1.2 This process begins when an institution/organization has been identified for a potential Authorization Agreement.
- 1.3 This process ends when an Institutional Profile has been established.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 The Human Research Protection Program Plan (HRP-101) details the criteria for reviewing for or relying on other institutions/organizations.

4 RESPONSIBILITIES

- 4.1 The Associate Director for reliance review generally carries out these procedures.

5 PROCEDURE

- 5.1 Determine whether an Authorization Agreement should be executed with an institution/organization.
- 5.2 Refer to WORKSHEET: Reliance Agreement (HRP-334) to determine if UM requirements are met.
- 5.3 If the criteria have been met, execute an Authorization Agreement with that institution/organization.
- 5.4 If the criteria have not been met, do not execute an Authorization Agreement. Communicate this to the other institution/organization.
- 5.5 Master Reliance Agreements can be utilized when multiple studies are ceding review to a specific external IRB. Master Agreements may be reciprocal in that signatory institutions can act as the site providing IRB review and oversight or the site relying. Master Reliance Agreements may be for a single protocol or a number of protocols and are negotiated on a case by case basis. The University of Miami IRB currently has master agreements in place with several external IRB's including the Smart IRB model that enable single IRB review

6 MATERIALS

- 6.1 Human Research Protection Program Plan (HRP-101)
- 6.2 FORM: Institutional Profile (HRP-815)
- 6.3 WORKSHEET: Communication and Responsibilities (HRP-830)
- 6.4 WORKBOOK: Institutional Profiles (HRP-861)

7 REFERENCES

None.