UNIVERSITY OF MIAMI

WORKSHEET: Communication of Review Results		
NUMBER	DATE	PAGE
HRP-303	05.20.2019	1 of 1

The purpose of this worksheet is to provide support for staff who send communications after an IRB review. This worksheet lists the letters that need to be prepared and sent after each review

IF THE CONVENED IRB, DESIGNATED REVIEWER, or other designee :	**COMPLETE THE FOLLOWING TEMPLATE LETTER AND TO ALL INDIVIDUALS LISTED IN CC LIST**
Approved protocol	Approval (HRP-510)
Acknowledged a protocol closure	Closure (HRP-511)
Required modifications to protocol to secure approval	Modifications Required to Secure Approval (HRP-512)
Determined that the activity is not Human Research	Non-Human Research (HRP-513)
Determined that the activity is Human Research in which the organization is not engaged	Non-Human Research (HRP-513)
With modifications the activity would not be Human Research	Modifications Required to Secure Determination (HRP-514)
THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB	
Deferred protocol	Deferral (HRP-516)
Disapproved protocol	Disapproval (HRP-517)
Tabled the protocol	Tabled (HRP-518) *Place on the agenda for the next IRB meeting*
Reviewed an information item	Information Item (HRP-519)
Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a Suspension or Termination that requires reporting to a federal agency	External Report (HRP-520)
Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA)	Significant Risk Device (HRP-521)
Approved research conducted or funded by DHHS involving prisoners as subjects	Certification of Prisoner Research (HRP-522)
Approved not otherwise approvable research involving children, pregnant women, or neonates	Not Otherwise Approvable Research (HRP-523)