NYU School of Medicine – Single IRB Standardization – 2018.09.10

GROUP 1 Informed Consent	Standard Approach	Hybrid Approach	Local Approach
Informed Consent Form	Standardized biomedical and non-biomedical informed consent form. No modifications can be made to these documents **(see document)**.	The standardized ICF that allows for modifications. Modifications can only be made to the sections indicated **(see document)**.	~~For non-biomedical and biomedical local approaches, please refer to documents.~~
Rankings	**Standard: 11 pts**	Hybrid: 10 pts	~~Local: 0 pts~~

GROUP 2	Standard Approach	Hybrid Approach	Local Approach	Significant Modification
Study Team Training & Qualification	The Reviewing IRB establishes standards which include: 1. **General training standards:** Key Personnel or involved study members as per NIH GCP policy must meet the following training requirements in order to perform study activities: a. Training in the protection of human subjects (e.g. CITI, NIH's Extramural Research Training, etc.) b. Good Clinical Practice (GCP) c. HIPAA 2. **Qualifications of the study team** should match the study focus and be assessed based on their expertise, education and qualifications. The Reviewing IRB is solely responsible for obtaining documentation and verifying that training and qualifications meet the established standards (e.g. reviewing CVs against educational requirements). The Reviewing IRB is not responsible for confirming if any additional local training requirements have been met.	**1. Training standards:** The Reviewing IRB sets minimum training standards. Relying Institutions may establish additional requirements but may not eliminate any requirements. Any additional institutional requirements should be met before the study is initiated at the Relying Institution. The Reviewing IRB's approval is issued once the Relying Institutions confirms that the minimum training requirements have been met. The minimum training requirements for key personnel or involved study members (as per NIH GCP policy) consist of: CITI training, NIH HSP Training or GCP (for clinical trials only). **2. Qualification of the study team:** The qualifications of the PI and study personnel are determined by the Relying Institution. The Relying Institution confirms to the Reviewing IRB that study personnel qualifications have been met prior to IRB approval.	The Relying Institution confirms to the Reviewing IRB that the study team has met all local requirements for training and are qualified to conduct research. The Reviewing IRB does not establish requirements beyond those of the Relying Institution.	**Pre- approval** – N/A **Post approval** PI initiated changes lead to modification submission to the Reviewing IRB. Other study team members' changes are reviewed and approved by the Relying Institution.
Target return time for review of other IRB documents	~~N/A (Grant calls for time frame only for hybrid or local approaches [reviewing IRB determines])~~	5-7 days	5-7 days	
Rankings	~~5 pts~~	**10 pts**	9 pts	
Data Safety Monitoring Plan/Charter	The Reviewing IRB reviews the proposed DSMP and determines whether or not it is sufficient. Relying Institutions are not allowed to modify or amend the DSMP. The plan should be tailored to the nature, size, and complexity of the research, the expected risks, and the type of subject population being studied. DSMP may include, but is not limited to, the following elements: 1. The monitoring entity and	The Reviewing IRB reviews select key elements of the DSMP and determines whether or not they are sufficient. Relying Institutions are not permitted to modify these sections, but are permitted to add additional information to meet institutional requirements prior to submission to the Reviewing IRB. Suggested key elements of the DSMP: 1. The monitoring entity and their responsibilities 2. The type of data or events	Relying Institutions can modify or amend any sections of a proposed DSMP or develop their own local DSMP. The Reviewing IRB then reviews each local DSMP and determines whether or not they are acceptable based on its policies and federal regulations.	**Pre-approval** Modifications to DSMP: input of all sites is sought by the main PI before the protocol if finalized. Any Relying Institution Modification to the DSMP are submitted to the Reviewing IRB **Post approval** Reviewing IRB reviews the changes to the

	their responsibilities 2. The type of data or events that are to be captured under the monitoring plan 3. The time frames for reporting adverse events and unanticipated problems to the monitoring entity 4. The frequency of data assessments or events captured by the monitoring plan 5. A plan to keep all sites informed of new findings	that are to be captured under the monitoring plan 3. The time frames for reporting adverse events and unanticipated problems to the monitoring entity 4. The frequency of data assessments or events captured by the monitoring plan		DSMP via Amendment submission, the approved protocol is distributed to the Relying Institutions post approval. Sites can't alter DSMP based on Relying Institution preferences.
Target return time for review of other IRB documents	N/A (Grant calls for time frame only for hybrid or local approaches [reviewing IRB determines])	15-21 days	15-21 days	
Rankings	**14 pts**	9 pts	~~0 pts~~	
Recruitment Materials	The Reviewing IRB is solely responsible for reviewing and approving the recruitment plan and materials for the study. Recruitment plans and materials cannot be modified for each site with the exception of local contact information. The Reviewing IRB evaluates recruitment plan based on its effect on equitable subject selection and study inclusion/exclusion criteria, and should not include payment arrangements that target economically disadvantaged participants or can lead to unfair selection of participants. The Reviewing IRB reviews proposed recruitment plan and advertising materials to judge whether they fulfill the requirements for consent. Suggested Key Elements: • Purpose of the study • Risks of the study • Benefits of the study • Description of study procedures • Basic eligibility criteria	The Reviewing IRB approves core aspects of the recruitment plan and materials based on its effect on equitable subject selection, study inclusion/exclusion criteria, should not include payment arrangements that target economically disadvantaged participants or can lead to unfair selection of participants Relying Institutions may amend the recruitment plan and materials based on the Relying Institution's needs and requirements. Revisions to the plan and materials by the Relying Institution should be approved by the Reviewing IRB. Suggested Key Elements: • Purpose of the study • Risks of the study • Benefits of the study • Description of study procedures • Basic eligibility criteria	Each Relying Institution may develop recruitment plans and materials based on its institutional needs and policies. The Reviewing IRB assesses the acceptability of each institutions recruitment plan and materials based on: -effect on equitable subject selection, -study inclusion/exclusion criteria, -should not include payment arrangements that target economically disadvantaged participants or lead to unfair selection of participants -recruitment processes and advertising materials should fulfill the requirements for consent	**Pre-approval**- N/A **Post-approval** Any changes to the recruitment materials first vetted through Relying Institutions for any local institutional policies related to recruitment including local contact assessments. Once its verified, the recruitment is sent to the Reviewing IRB
Target return time for review of other IRB documents	N/A (Grant calls for time frame only for hybrid or local approaches [reviewing IRB determines])	5-7 days	5-7 days	
Rankings	**12 pts**	11 pts	~~0 pts~~	
Vulnerable Populations, description/ definitions	Vulnerable populations are based on federal regulations. In addition, decision impaired should be considered a vulnerable population. The Reviewing IRB will apply the criteria and measures of protections when reviewing vulnerable populations based on their policies. Additional populations may be considered vulnerable based on study specific procedures and the Relying	The Reviewing IRB identifies vulnerable populations and any additional protections. This is included in the approved protocol. Vulnerable populations are based on Federal regulations. In addition, decision impaired should be considered a vulnerable population. • When a Relying Institution has a specific local	The Reviewing IRB makes determinations for vulnerable populations based on Federal regulations. . Every Relying Institution provides a confirmation of their local assessment of vulnerable populations specific to the sites and sends the Reviewing IRB a protocol addendum describing additional measures of protection	Addition or removal of a vulnerable population can occur based on the changes to the protocol driven by the main PI request **Pre-approval** Relying Institutions assess and confirm that all site-specific

	Institution's requirements: • Physically Handicapped • Mentally Disabled • Economically Disadvantaged • Educationally Disadvantaged • Racial Minorities • Terminally Ill • Elderly/Aged • Institutionalized •Employees/Students/Normal Volunteers • International Research Subjects • Individuals of Domestic Violence/Sexual Assault The Reviewing IRB must receive any additional info regarding a Relying Institution's policies and local laws during the approval process.	requirement or circumstances related to the vulnerable population (e.g. child age of majority, decisional impairment policies, or lack of enrollment of any population) this information is provided to the Reviewing IRB as part of the site review. The Reviewing IRB can consider this information during the site's approval.	+ confirmation that the local policies and procedures are adhered to.	requirements and policies regarding vulnerable populations are met. Any site-specific measures related to protection of vulnerable population or additional vulnerable populations – the Relying Institution provides a Reviewing IRB with a site-specific protocol addendum to outline additional info to ensure state law and Institutional policy are complied with. **Post-approval** For addition or removal of a vulnerable population, a Relying Institution's impact assessment should be provided to the Reviewing IRB prior to approval.
Target return time for review of other IRB documents	N/A (Grant calls for time frame only for hybrid and local approaches [Reviewing IRB determines])	14-17 days	~~14-17 days~~	
Rankings	**12 pts**	6 pts	~~0 pts~~	
Review Financial Conflict of Interest	~~The Reviewing IRB makes determinations about conflict of interest and relatedness to the study.~~ ~~No IRB should review the management plan on the study that has Institutional conflict for this institution.~~ ~~All sites must be informed of a conflict of interest of the Lead PI conflict and the COIC determination and its effect on the enrolment.~~ ~~The Reviewing IRB comes up with the plan for Relying Institutions and seeks input and changes to the plan from Relying Institutional COIC~~ ~~If the lead PI of the entire study has a financial conflict that requires subject notification, all sites subjects are notified.~~	Relying Institutions make determinations on financial conflict for their site's study team members. Management plans set by the Relying Institution are submitted to the Reviewing IRB - the Reviewing IRB evaluates the plan prior to approval. Any additional changes have to be cleared by the Relying Institution's COIC. No IRB should review the management plan on a study that has institutional conflict with the Relying Institution. If the lead PI of the study has a financial conflict that requires subject notification, subjects at all sites are to be notified.	Relying Institutions are responsible for assessing financial conflict and proposing management plans based on their own institutional policy. Relying Institutions will forward their management plans to the Reviewing IRB. The Reviewing IRB has limited input.	**Pre-approval** – N/A **Post-approval** Any changes to the financial conflict of interest management plan are reviewed at the Relying Institution level. The change is then submitted to the Reviewing IRB for approval.
Target return time for review of other IRB documents	~~N/A (Grant calls for time frame only for hybrid or local approaches [reviewing IRB determines])~~	8-14 days	8-14 days	
Rankings	~~0 pts~~	**12 pts**	**12 pts**	

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GROUP 3 *Reporting*	**Standard Approach**	**Hybrid Approach**	**Local Approach**
Definitions	**Reportable Event:** New information that meets one or more of the following criteria: 1. Unanticipated problem 2. Non-Compliance 3. Information that indications one of the following: a. Changes to the protocol taken to eliminate an immediate hazard b. Incarceration of a participant (where prisoners were not an approved population to be enrolled) c. Breach of confidentiality d. Disqualification or suspension of investigator by FDA, NIH, or any other agency; or suspension or restriction of an investigator's clinical professional license e. Protocol exception request 4.Unresolved Subject Complaint **Non-compliance:** Failure to follow the federal regulations, Institutional policies, or state or local laws pertaining to human subject protections, or failure to follow the requirements or determinations of the IRB, which compromises the rights and/or welfare of subjects or others. **Serious Non-compliance:** Non-compliance which significantly affects or has the potential to affect the rights and/or welfare of subjects or others. *Significantly in the above definition is defined as having:* *A) an impact on subjects or others that is life-threatening or results in serious physical, psychological, or legal harm or risk of harm, such that the risks of the study outweigh the potential benefits to participants or generalizable knowledge; or* *B) an impact on research data, resulting in data that is compromised to the point of which the data is unusable.* **Continuing Non-compliance:** A pattern of non-compliance that suggests that non-compliance will continue without intervention. **Unanticipated Problem:** Any incident, experience, or outcome that meets all of the following criteria: 1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; 2. Related or possibly related to participation in the research (in this	**Reportable event:** New information that meets one or more of the following criteria: 1. Unanticipated problem 2. Non-Compliance 3. Information that indications one of the following: a. Changes to the protocol taken to eliminate an immediate hazard b. Incarceration of a participant (where prisoners were not an approved population to be enrolled) c. Breach of confidentiality d. Disqualification or suspension of investigator by FDA, NIH, or any other agency; or suspension or restriction of an investigator's clinical professional license e. Protocol exception request f. Subject complaint (as defined by the institution) **Non-compliance:** Failure to follow the federal regulations, Institutional policies, or state or local laws pertaining to human subject protections, or failure to follow the requirements or determinations of the IRB, which compromises the rights and/or welfare of subjects or others. **Serious Non-compliance:** Non-compliance which significantly affects or has the potential to affect the rights and/or welfare of subjects or others. *Significantly in the above definition is defined as having:* *A) an impact on subjects or others that is life-threatening or results in serious physical, psychological, or legal harm or risk of harm, such that the risks of the study outweigh the potential benefits to participants or generalizable knowledge; or* *B) an impact on research data, resulting in data that is compromised to the point of which the data is unusable.* **Continuing Non-compliance:** A pattern of non-compliance that suggests that non-compliance will continue without intervention. **Unanticipated Problem:** Any incident, experience, or outcome that meets all of the following criteria: 1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; 2. Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the	**Reportable event:** Reportable events criteria are determined by the Reviewing Institution. Relying Institutions must follow Reviewing Institutional definitions. **Non-compliance:** Non-compliance, including serious or continuing non-compliance, is determined by the Reviewing Institution. Relying Institutions must follow Reviewing Institutional definitions. **Unanticipated Problem:** Any incident, experience, or outcome that meets all of the following criteria: 1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; 2. Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and 3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. *Note that the definition of unanticipated problem cannot be revised as it is defined by OHRP guidance on Unanticipated Problems Involving Risks & Adverse Events dated January 15, 2007.* **Complaint:** Reviewing Institutions are responsible for defining reportable subject complaints.

	guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and 3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. *Note that the definition of unanticipated problem cannot be revised as it is defined by OHRP guidance on Unanticipated Problems Involving Risks & Adverse Events dated January 15, 2007.* **Unresolved Complaint:** a complaint made by a subject or other individual related to research procedures or participation that is a result of either noncompliance with the protocol or has a negative impact on rights and welfare of subjects or others, and cannot be resolved by the research team.	procedures involved in the research); and 3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. *Note that the definition of unanticipated problem cannot be revised as it is defined by OHRP guidance on Unanticipated Problems Involving Risks & Adverse Events dated January 15, 2007.* **Complaint:** Reviewing Institutions are responsible for defining reportable subject complaints.	
Ranking	**7 pts**	4 pts	~~0 pts~~
Process of Reporting	*Responsible Party* Option 1: The Principal Investigator (PI) at the Institution where the reportable event is identified is responsible for reporting events to the Reviewing Institution. In cases where an event affects the overall conduct of the study at all institutions, the lead Institution PI is responsible for reporting the event to the Reviewing Institution. ~~Option 2: The Reviewing Institution Principal Investigator (PI) is responsible for reporting events to the Reviewing Institution.~~ ~~The PI may delegate an individual on the study team to report on behalf of the PI.~~ *Timelines for Reporting* All events must be reported to the Reviewing Institution at most 21 calendar days from the date the study team becoming aware of the event. An initial report for serious or life-threatening events, or apparent continuing or serious non-compliance, must be provided to the IRB within 7 calendar days. *IRB Responsibilities* The Reviewing Institution is responsible for ensuring proper reporting to federal agencies for all federally-funded research. The letter to federal agencies will be drafted by the Reviewing Institution and sent to the Reliance Coordinator or Relying Institution's contact for feedback and additional edits. Relying Institution will have 5 business days to review with the understanding that there may be more or less flexibility depending ~~on the urgency of~~	*Responsible Party* The Reviewing Institution determines whether or not the relying PI or the overall PI is responsible for reporting all events to the Reviewing Institution. The Reviewing Institution determines who may report on behalf of the PI. *Timelines for Reporting* The Reviewing Institution policies and procedures determines the time frame for reporting of events. *IRB Responsibilities* The Reviewing Institution determines who is responsible for proper reporting to federal agencies for all federally-funded research. The letter will be drafted by both the Reviewing Institution and Relying Institution. Reviewing Institution and Reliance Coordinator will establish timelines for review to ensure timely reporting to federal agencies.	*Responsible Party* The Reviewing Institution determines whether or not the Institution PI or the overall PI is responsible for reporting events to the Reviewing Institution. The Reviewing Institution determines who may report events to the IRB on behalf of the PI. *Timelines for Reporting* The Reviewing Institution policies and procedures determines the time frame for reporting of events. *IRB Responsibilities* The Reviewing Institution and Relying Institution are responsible for determining who do proper reporting to federal agencies for all federally-funded research. The letter will be drafted by the reviewing IRB and sent to the Reliance Coordinator or Relying Institution contact for feedback and additional edits. Reviewing IRB and Reliance Coordinator will establish timelines for review to ensure timely reporting to federal agencies.

	~~reporting.~~		
Rankings	**Option 1 – 5 pts** ~~Option 2 – 1 pts~~	**5 pts**	~~0 pts~~
IRB Review Process	*Determinations* All reportable events, including unanticipated problems, unresolved subject complaints, and non-compliance must be reviewed by the convened IRB. Subject complaints are generally managed by the Relying Institution, unless they indicate non-compliance or an unanticipated problem, at which point they will require reporting to the Reviewing Institution. *Corrective Action Measures* The study team will propose a corrective and preventative plan at the time of reportable event submission. A standard corrective and preventative action plan template should be implemented for all institutions relying on a single IRB. The Reviewing Institution is responsible for IRB review and recommendations of the plan, however may request additional input and review from the Relying Institution. Standard elements will be provided in the	*Determinations* The process for review of the event is determined by the Reviewing Institution and should be done in conjunction with review by the Relying Institution, when appropriate. Reviewing Institutions are encouraged to use Institutional processes, committees, or review bodies other than IRBs in place to review reportable events. Unresolved subject complaints are reviewed as per the Reviewing Institution's existing procedures. Institutions are required to report complaints to the Reviewing Institution as determined by the Reviewing Institution, and the Reviewing Institution can determine on an individual basis when Relying Institutional review is warranted. *Corrective Action Measures* The study team will propose a corrective and preventative plan at the time of reportable event submission. The plan is reviewed by the Relying Institution before submission to Reviewing Institution. The Reviewing Institution	*Determinations* The process for review of the event is determined by the Reviewing Institution and should be done in conjunction with review by the Relying Institution, when appropriate. Reviewing Institutions are encouraged to use Institutional processes, committees, or review bodies other than IRBs in place to review reportable events. Unresolved subject complaints are reviewed as per the Reviewing Institution's existing procedures. Institutions are required to report complaints to the Reviewing Institution as determined by the Reviewing Institution, and the Reviewing Institution can determine on an individual basis when Relying Institutional review is warranted. *Corrective Action Measures* The study team will propose a corrective and preventative plan at the time of reportable event submission. The plan is reviewed by the Relying Institution before submission to Reviewing Institution. The Reviewing Institution will make the final determination, taking into account Relying Institutional

	template, which will guide study teams in developing a corrective and preventative plan.	will make the final determination, taking into account Relying Institutional resources and input.	~~resources and input.~~
Rankings	3 pts	**6 pts**	~~2 pts~~
Communication	The Relying Institution, at the time of site activation, is responsible for reporting any site PI's serious non-compliance that is either relevant to the new study or has not been resolved. This information is captured during the Relying Institution context review. Final determinations of unanticipated problems are sent to the Relying Institution PI as well as PI's of affected institutions. All unresolved subject complaints and findings of serious or continuing non-compliance require Relying Institution review with final weigh in before final Reviewing Institution determination. The final determination is sent to the Relying Institution PI, Reviewing Institution PI, and Reliance Coordinator or Institutional Contact.	The Relying Institution, at the time of site activation, is responsible for reporting any site PI's serious non-compliance that is either relevant to the new study or has not been resolved. This information is captured during the Relying Institution context review. Final determinations of unanticipated problems are sent to the Relying Institution PI as well as PI's of affected institutions. All reportable subject complaints and findings of serious or continuing non-compliance require Relying Institution review with final weigh in before final Reviewing Institution determination. The final determination is sent to the Relying Institution PI, Reviewing Institution PI, and Reliance Coordinator or Institutional Contact. Reviewing Institutions must have a system in place to communicate relevant policies and procedures to Relying Institutions to ensure compliance with requirements for reportable events.	~~The Reviewing Institution determines what information must be provided from the Relying Institution at the time of site-activation, which may include past PI's serious non-compliance. This information is captured during the Relying Institution context review.~~ ~~Final determinations of unanticipated problems are sent to the Relying Institution PI as well as the Reviewing Institution PI.~~ ~~All reportable subject complaints and findings of serious or continuing non-compliance require Relying Institution review with final weigh in before final Reviewing Institution determination. The final determination is sent to the Relying Institution PI, Reviewing Institution PI, and Reliance Coordinator or Institutional Contact.~~ ~~Reviewing Institutions must have a system in place to communicate relevant policies and procedures to Relying Institutions to ensure compliance with requirements for reportable events.~~
Rankings	5 pts	**6 pts**	~~3 pts~~
GROUP 4 *for first 3 items, these are identical across approaches	~~Standard Approach~~	Hybrid Approach	Local Approach
Definition of ancillary review	Ancillary review is conducted in coordination with IRB review to review human subjects research, ensuring research risks are minimized and compliance requirements are met.		
Types of ancillary review	a. Radiation Safety b. Institutional Biosafety (recombinant DNA/gene transfer studies) c. Embryonic Stem Cell Oversight d. Scientific Review Committees e. Conflict of Interest f. IT security g. Clinical trials office h. Genomic data sharing institutional certification i. Environmental Health & Safety j. Nursing k. Research Pharmacy/Controlled Substances		
When ancillary review occurs in relation to IRB Review	a. The following must occur before reviewing IRB approval is issued: i. Radiation Safety ii. Institutional Biosafety (recombinant DNA/gene transfer studies) iii. Embryonic Stem Cell Oversight iv. Scientific Review Committees v. Conflict of Interest b. Other committees, those on which risks to subjects or institutional requirements do not depend, may be reviewed during or after reviewing IRB approval.		
Maximum duration of ancillary review	~~30 days~~	30-45 days	45 days

Last updated: 2018.09.10

NYU School of Medicine – Single IRB Standardization – 2018.09.10

Ancillary reviews that can be deferred to the reviewing institution	All of the following are deferred to the reviewing institution: a. Radiation Safety (if institutions do not have their own RAD license) b. Institutional Biosafety (recombinant DNA/gene transfer studies) c. Embryonic Stem Cell Oversight (CA, NY and some other states have specific state regulations; cede may not be possible) d. Scientific Review Committees e. Conflict of Interest f. IT security g. Environmental Health & Safety	Some ancillary review can be deferred to the Reviewing IRB, such as the following: a. Radiation Safety (if institutions do not have their own RAD license) b. Institutional Biosafety (recombinant DNA/gene transfer studies) c. Embryonic Stem Cell Oversight (CA, NY and some other states have specific state regulations; cede may not be possible) d. Scientific Review Committees e. Conflict of Interest f. IT security g. Environmental Health & Safety	All types of review <u>are</u> deferred to the Relying Institution, depending on resources, local laws, and institutional policies.
Process to facilitate the outcome of ancillary review	The reviewing IRB should as part of their own review have the outcomes of the determined ancillary reviews for the lead institution before IRB approval is granted. These determinations should be communicated to all Relying Institutions. Relying Institutions would continue to have responsibility for their own ancillary reviews as required by the institution and have the opportunity to make requests to the reviewing IRB if site-specific information is need before the Relying Institution is approved by the reviewing IRB. These reviews at both the lead and Relying Institution must be completed within the time frame identified below.	The Reviewing IRB should complete ancillary reviews for the lead institution and any relying institutions that have allowed for such before IRB approval is granted. These determinations should be communicated to all Relying Institutions. Relying Institutions would have responsibility for the ancillary reviews they have opted to perform as required by local law and institutional policy and have the opportunity to make requests to the reviewing IRB if site-specific information is need before the Relying Institution is approved by the reviewing IRB. These reviews at both the lead and Relying Institution must be completed within the time frame identified.	Ancillary review is not deferred to the Reviewing Institution, and can occur at the Relying Institution. The reviewing IRB should receive the determination of these ancillary review committees before IRB approval is granted. These determinations should be communicated to all Relying Institutions. Relying Institutions would have responsibility for their own ancillary reviews as required by the local law and institutional policy and should have the opportunity to make requests to the Reviewing IRB if site-specific information is need before the Relying Institution is approved by the reviewing IRB. These reviews at both the lead and Relying Institution must be completed within the time frame identified.
Rankings	~~Standard: 1 pt~~	**Totals: 9 pts**	Totals: 4 pts

GROUP 5 *Reliance Agreements*	**<u>Standard Approach</u>**	**<u>Hybrid Approach</u>**	**<u>Local Approach</u>**
Process for Reliance Agreement	Institutions would agree to use SMART IRB's reliance agreement with addition of "WG5 Addendum" **(see document)**.	Institutions would agree to use SMART IRB's reliance agreement with addition of a modifiable addendum.	~~Individual IAAs based on OHRP template~~
Rankings	**8 pts**	4 pts	~~0 pts~~
Addendum Document	Modifications to the "WG5 Addendum" would NOT be permitted.	Modifications to the "WG5 Addendum" would be permitted.	~~Custom addendum~~
Rankings	**8 pts**	7 pts	~~0 pts~~

Completion period for reliance agreements	• Reliance efforts begin upon receipt of fundable score
	  ○ Advisable to ensure Relying Institutions join SMART IRB closer to grant submission
	• Relying Institution turnaround time of Addendum: 2 weeks
	• Reviewing IRB turnaround time
	  ○ If Relying Institution
		• Reliance efforts begin when institutions decide
		  ○ Advisable to ensure Relying Institutions join SMART IRB closer to grant submission
		• Relying Institution turnaround time of Addendum: 2 weeks
		• Reviewing IRB turnaround time
		  ○ If Relying Institution
			Custom

Last updated: 2018.09.10

	○ requested changes: 2 weeks If Relying Institution signed: 1 week	○ requested changes: 2 weeks If Relying Institution signed: 1 week	~~~~
Rankings	**8 pts**	No votes*	~~0 pts~~