

International Research
Biomedical Prep Work Checklist – Prior to Creating IRB Application

Things to think about...	Yes	No	N/A
<p>1. You may contact Cindy Brantmeier for consultation and advice while completing this checklist prior to IRB submission cbrantme@wustl.edu. Useful links include:</p> <ul style="list-style-type: none"> • HRPO website https://hrpo.wustl.edu/ • Research Guide http://online.fliphtml5.com/ikcz/ifub/#p=1 • myIRB research application program https://myirb.wusm.wustl.edu/ 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>2. Identify the international site's local regulatory requirements and reach out to your HRPO Partner to see whether or not they are already aware of your international site's regulatory requirements.</p> <ul style="list-style-type: none"> • For Country specific information go to: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html • Please note: There are differences across and within Countries. Each place the research is conducted should be treated as a separate entity and may be subject to regulatory requirements. <ul style="list-style-type: none"> ○ If you have funding associated with your project, you must adhere to the requirements of the funding agency. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>3.</p> <ul style="list-style-type: none"> • If local IRB or Ethical Committee review IS required Identify the processes needed to obtain the review. • Have you obtained the appropriate documentation (Letter of Approval)? • Please note: depending on the location, this review may take the form of a letter of approval from an IRB or research ethics committee, national regulatory office, local university department sponsoring the research, institutional oversight committee. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>4. If local IRB or ethical committee review is NOT required or is not available:</p> <ul style="list-style-type: none"> • You still need to have a cultural reviewer. Identify a Cultural Reviewer/Expert who can provide you with documentation of cultural appropriateness. This expert cannot be part of the study. • Identify the appropriate Regulatory Official or individual who can provide you with <u>documentation</u> that local IRB or ethics review is not required OR documentation of what the local requirements for conduct of human subjects research are. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5. Do your research documents need to be translated? Be sure to document the names and qualifications of translators for data collection instruments, informed consents, etc.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>6. Are specific international site permissions required? https://www.hhs.gov/ohrp/sites/default/files/2019-International-Compilation-of-Human-Research-Standards.pdf</p> <ul style="list-style-type: none"> • Do you know the processes for obtaining these permissions? Or when permission(s) cannot be obtained in advance, are you familiar with the process to acquire permission(s) prior to initiating research activities? <ul style="list-style-type: none"> ○ Note: some international sites may not allow you to obtain these permissions until you are in the country when the research commences. In these cases, it is good to know the process so you can communicate that to the WashU IRB. • Once received, do you have documentation of the permission(s)? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>7. Are there country-specific licenses, permits or other authorizations necessary for the procedures to be performed at the international site? For example, licensure for clinical procedures or permits for drugs, devices, or technology being brought into the foreign country.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>8. Do you want to compensate your research participants?</p> <ul style="list-style-type: none"> • If yes, are there any local laws or regulations that prevent you from doing this? • What is a culturally appropriate way to compensate them or offer extra credit? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>9. Are you going to ask local individuals (non-Washington University faculty, staff or students) to assist with study procedures, recruitment, and informed consent in the international setting?</p> <ul style="list-style-type: none"> • If yes, be sure to collect & document their names, qualifications, and protocol training. This is only required when the international sites do not have a local IRB or equivalent ethics 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

International Research
Biomedical Prep Work Checklist – Prior to Creating IRB Application

Things to think about...		Yes	No	N/A
	<p>committee approval (i.e. there is no local IRB or ethics committee and you wish for WashU IRB to serve as the IRB for the local research staff).</p> <ul style="list-style-type: none"> Be sure to clearly describe their role and identify them as non-WashU research staff in your IRB application 			
10.	<p>Are there country-specific laws or regulations about data collection and/or data transportation?</p> <ul style="list-style-type: none"> Are there any country-specific laws or regulations about storing consent forms, research data/documentation and/or any identifiable data? Have you reviewed WashU’s guidance on electronic storage of research documents? https://research.wustl.edu/electronic-storage-research-study-documents/ For studies in the European Union, the General Data Protection Regulation (GDPR) applies: https://ec.europa.eu/info/law/law-topic/data-protection_en You must adhere to all local requirements related data collection, storage, and transport of all research data and/or biospecimens regardless if they are “identifiable” or not. <ul style="list-style-type: none"> Please note, the local definition for what is considered “identifiable” may differ from one place to another. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	If the research is federally funded, have you provided the FWA number assigned to the foreign site?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	<p>Is your consent process culturally appropriate?</p> <ul style="list-style-type: none"> Consider discussing the consent process with your cultural expert. Contact your WashU HRPO/IRB Partner for advice and guidance on different consent processes that may be used. Build in flexibility 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	<p>Have you built in flexibility into your research protocol?</p> <ul style="list-style-type: none"> For example, if you plan to interview participants in several places and not just a single location, be sure to describe all options. Use the term “may” if one or more study procedure could be used. Be sure to ask your IRB Partner for suggestions if the “normal” process makes implementing the research too difficult or culturally inappropriate. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	<p>If you are student, have you identified your WashU Faculty Sponsor?</p> <ul style="list-style-type: none"> Please review the following with your Faculty Sponsor: <ul style="list-style-type: none"> All research team members, including your Faculty Sponsor, must have CITI human subjects training in order to be added to the research team in myIRB. This can cause delays if you or your Faculty Sponsor has not completed this training. IF non-WashU individuals will be participating in the research, be sure to work with you HRPO partner to develop appropriate training for the participating non-WashU staff. The Faculty Sponsor is ultimately responsible for overseeing the research you are conducting. It is highly important that you make arrangements (and document them) to review your research records with your Faculty Sponsor. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	<p>Have you thought about your research documentation?</p> <ul style="list-style-type: none"> It is very important that you document what you do, when you do it, and with whom it is done with. It is also equally as important to document when something cannot be done and why. Good research documentation includes maintaining records of all data and observations pertinent to the research and the research subjects. These records should be verifiable and record the original source the information was recorded from. Research documentation should be ALCOAC: <ul style="list-style-type: none"> Attributable – can you tell who wrote or performed the study procedure or observation? Legible – can you read it, are all pages present etc.? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

International Research
Biomedical Prep Work Checklist – Prior to Creating IRB Application

Things to think about...	Yes	No	N/A
<ul style="list-style-type: none"> ○ Contemporaneous – Is the data current and collected within the correct time frame? For example, a notation recorded in the research record should be signed and dated by the person making that notation at the same time. ○ Original – and if not an original, an exact certified copy of the original. A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy, having all of the same attributes and information as the original. ○ Accurate – real representation of fact. The consent should precisely reflect the event ○ Complete – Research documentation should be completed to the fullest extent and should explain any discrepancies, missing, and/or incomplete data. <ul style="list-style-type: none"> ▪ Always remember...If it's not documented, then it did not happen. ● The Human Subjects Research Website provides forms and templates that you can use to document your research: https://research.wustl.edu/topics/human-subjects-research/ ● Contact the Human Research Quality Assurance Program for additional resources or research documentation support. HRQA@wustl.edu or +1 314-747-5525 			
16. Have you consulted the WashU policies about taking data or research materials with you if/when you may permanently leave WashU for a job at another university?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Additional Considerations to think about: <ul style="list-style-type: none"> ● Does the trial need to be registered at clinicaltrials.gov? <ul style="list-style-type: none"> ○ https://research.wustl.edu/clinical-trials-registration-guideline/ ● Are there regulations regarding the import of pharmaceuticals and/or medical devices? ● Are there regulations regarding the export of biomedical samples (especially potentially infectious material)? ● Are there any specific regulations regarding the use of local laboratories to perform clinical lab testing? ● Are there any specific regulations regarding use of diagnostic imaging? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>