Institutional Profile

Site Name: University of North Carolina at Chapel Hill

Last modified date: 04/17/2020

ABOUT THE INSTITUTIONAL PROFILE

The IREx IP contains basic information about your institution that another institution might use to determine if they feel comfortable relying on, or serving as the Reviewing IRB for, your institution. The IP can also be used by IRBs and study teams to better understand one's institutional processes and requirements when using reliance. This information will be visible to other users in IREx and publicly available as a downloadable PDF on the IREx Website here. This information is for general review purposes only. It may not be accurate and may be subject to change, withdrawn or revised at any time without notice. The Institutional Profile is not intended to serve as a complete record of an Institution's study-specific local considerations.

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Section 1: GENERAL HRPP INFORMATION

Institution	University of North Carolina at Chapel Hill
Federalwide Assurance (FWA) #	FWA00004801
FWA Expiration Date	2024-09-11
Does your institution have an internal IRB?	Yes
IRB Registry Number(s)	IRB00000538 IRB00000539 IRB00000540 IRB00001648 IRB00001649 IRB00009770
Is the IRB AAHRPP accredited?	Yes
Does your institution REQUIRE institutions to be AAHRPP accredited in order to serve as their IRB of Record (all the time)?	No
Describe any board specialties of your IRB.	There are six convened boards at UNC. Two boards have oncology expertise, and one has dental expertise. All other boards review any biomedical or social behavioral research arriving on their agendas.
Is your institution a covered entity?	Hybrid

Section 2: SITE-SPECIFIC LOCAL CONTEXT

This information may be helpful for a Reviewing IRB to understand when considering whether to serve as the Reviewing IRB for your organization. Additional, study-

specific information will be requested when a Reviewing IRB is reviewing a specific study for your site (e.g., COI, investigator training, study-specific consent requirements, state law or institutional requirements). However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).

To what state laws is your institutions subject?	• NC
Age of majority in your state?	18
What circumstances affect age of consent in your state? For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment	In North Carolina, under certain, limited circumstances, a minor can give effective consent to receive non-emergency medical care from a physician licensed to practice in North Carolina. More specifically, any minor can consent to receive a licensed physician's services for the "prevention, diagnosis and treatment of (i) venereal disease and other diseases reportable under N.C. Gen. Stat. § 130A-135, (ii) pregnancy, (iii) abuse of controlled substances or alcohol, and (iv) emotional pdisturbance." Please note that in NC, minors who have become parents may require their own parents permission to participate in research.
Do you have any state or local laws or institutional policies that require RECORD KEEPING for longer than federal law requires under the Privacy Rule or Common Rule?	Yes
Please describe how long you are required to keep your records.	Description of UNC's Record Retention policy may be reviewed here: http://library.unc.edu/wp-content/uploads/2016/06/unc_ret_sched.pdf
Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?	Yes, I will insert language in text box
Please insert the language required to be used around mandatory reporting to health authorities.	"Under North Carolina law, confidentiality does not extend to certain communicable diseases, such as TB, HIV, hepatitis,or other illnesses that put others at risk. If the researchers become aware that subjects have such an illness, they are required to report it to state authorities."
Does your site require a site-specific logo appear on consent forms and/or recruitment documents?	No
Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?	Yes
Does the site have a posted policy for the following? NOTE: Please only select those for which there is a	• Consent Process for those with Impaired

posted institution policy; generally accepted practice and guidance are not policy.	Decision-Making Capacity • Use of short forms for non-English speaking individuals • Translation of consent forms for non-English speaking individuals
Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?	Yes
Please enter any special formatting your IRB requires for HIPAA authorization forms?	UNC requires the use of our separate, standalone HIPAA authorization form.
Please enter your specific consent form language regarding payment for research-related injury.	What will happen if you are injured by this research? (This section may be omitted if the study involves no more than minimal risk and no chance of personal injury. The language below should be used if there is no commercial Sponsor; there is an alternative version for sponsored studies. To the extent they are known, describe any medical treatments for injury that might be available or where the subject can obtain further information.) All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries. If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do. By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.
Please enter your specific consent form language regarding costs to participants to participate.	Will it cost you anything to be in this study? If you enroll in this study, you will have costs which include: List the additional costs, such as parking, child care, travel, clinic or diagnostic fees. • List the additional tests/visits/procedures to be performed for research purposes only. Describe who will be responsible for paying the cost of research tests, procedures, visits, etc. that are not standard of care. • Clearly explain what the likely costs will be for participation in this research study and who will be responsible for those costs e.g. "... billed to you and/or your insurance." Or "... paid by the sponsor. • Describe specific items or procedures that may/may not be covered. Include

	clinic fees, transportation, and parking fees (if known). • Address clearly who will be responsible for the payment of the costs of standard treatment in the research study, e.g., "These costs will be billed to you or your insurance carrier."
Please upload your template HIPAA Authorization language.	
Do you have any additional HIPAA Authorization language template documents?	Yes

LOCAL CONTEXT: Component Sites As the FWA-holder of a component site, you are responsible for providing the relevant local considerations for component sites here, in the Institutional Profile, and for specific studies, as requested by the Reviewing IRB. If your component sites have information that differs from that provided in the previous section, specify the site and what differs below.

Do you have a component site on your FWA?	Yes
What is the name of this component site?	UNC HealthCare
Do you have another component site on your FWA?	No

Section 3: LOCAL INSTITUTIONAL REQUIREMENTS FOR INVESTIGATORS WHEN RELYING ON ANOTHER IRB.

These steps occur BEFORE the study is approved by the Reviewing IRB:	
How should an investigator request to cede review to an external IRB? For example, should they email the IRB? Is there a specific person at the IRB? Should they just submit the request via your local IRB system (as outlined in the questions below)?	Submit a local application in IRBIS, selecting submission type Rely on External IRB, and then specify further the reviewing IRB type (commercial, institutional, NCI CIRB, or collaborative)
Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely?	No
These steps occur AFTER the study is approved by the Reviewing IRB: Indicate below what documentation and events are submitted to your local IRB when relying on an external IRB.	
After your HRPP has provided local reviews to the SIRB, does your IRB or HRPP require a submission of your site's sIRB approved documents before your site is activated/enrollment can begin?	No
Should your investigator submit any of the following to your HRPP when ceding review to another institution? If checked, you will be asked to detail what should be submitted.	• Local amendments (personnel modifications) • Continuing review • Serious or continuing non-compliance

- Unanticipated problems
- Final report

What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?	personnel changes, title change, sponsor change, any amendment to the protocol which would trigger a local ancillary review at UNC (radiation safety, biosafety, etc)
What should be submitted at continuing review?	For studies that require a continuing review, a renewal submission in IRBIS, along with the Reviewing IRBs renewal approval letter (when applicable) should be submitted to UNC IRB. UNC will still require an administrative review annually to manage institutional requirements such as COI, even when the reviewing IRB may have determined that continuing reviews will not be required of the project.
What should be submitted for serious or continuing non-compliance?	After the reviewing IRB has determined that an event at UNC meets the criteria for serious or continuing non-compliance, the UNC team should submit an NSI report in IRBIS and include the reviewing IRBs determination letter
What should be submitted for unanticipated problems?	After the reviewing IRB has determined that an event at UNC meets the criteria for an unanticipated problem, the UNC team should submit an NSI report in IRBIS and include the reviewing IRBs determination letter
What should be submitted for final reports?	a closure submission in IRBIS
Who at your institution should be contacted if a Lead IRB wishes to report an unanticipated problem, a determination of serious or continuing non-compliance, or a suspension or termination?	
Name	Jeanne Lovmo, Compliance Manager (Safety)
Email	lovmo@unc.edu
Phone Number	(919) 633-3113

Section 4: The Study-Specific Reliance Plan The questions below have been harmonized with the SMART IRB Agreement Implementation Checklist and serve as your reliance preferences when serving as the IRB of record for other sites.

If you decide to serve as the Reviewing IRB in IREx, when you create the study, these preferences will appear as the basis for your SSRP. You may edit your responses for the study or for one (or more) sites, if requested, at your discretion.

Is your institution willing to serve as the IRB of Record for other institutions? If yes, more information on your	Yes

reliance preferences/requirements will be collected below.

STANDARD OPERATING PROCEDURES ("SOPs")	Using SMART IRB SOPs (recommended)
HIPAA DETERMINATIONS AND ACTIONS	If one or more Relying Institution(s) are HIPAA Covered Entities, Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution(s) to use/disclose PHI (as specified below, if applicable).
HIPAA DETERMINATIONS AND ACTIONS: REVIEWING IRB ACTIONS	When applicable, the reviewing IRB will make determinations regarding partial and full waivers of HIPAA, as well as alterations. When UNC is the reviewing IRB and the relying site typically uses a separate HIPAA authorization, the relying site retains oversight of the HIPAA authorization language.
HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS	Reviewing IRB requires HIPAA authorization language to be incorporated into an authorization form separate from a consent form.: The Relying Institution shall be responsible for ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule.
CONFLICTS OF INTEREST	Relying Institution(s) will perform conflict of interest analyses under their policies
IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)	Reviewing IRB will provide notifications through another party
NAME OF NOTIFYING PARTY	Study liaisons provide notifications to relying sites
IRB-INITIATED AUDITS/INVESTIGATIONS	Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis
IRB-INITIATED EXTERNAL REPORTING	Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis
CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS	Another party will review congruence
NAME OF PARTY THAT WILL BE RESPONSIBLE FOR REVIEW	UNCs Office of Clinical Trials provides grant congruency check
FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]	Reviewing IRB/Institution will not charge Relying Institution(s) for costs of review: The Relying Institution(s) will not be responsible for financial support of the costs of review of the identified study(ies). The Reviewing IRB may charge the sponsor or other third parties for those costs.
QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM("QA/QI")	QA/QI program access required Each Participating Institution engaged in or conducting the identified

	study(ies) must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements.
INSURANCE	Insurance required: Each Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified study(ies), including coverage of its IRB/IRB members when acting as a Reviewing IRB. (State/federal agencies or instrumentalities of state/federal government may provide documentation of self-funded liability coverage or of reliance on applicable law providing immunity from or limiting liability.) Note: Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).
INDEMNIFICATION	One or more Participating Institutions require an indemnification agreement: The Reviewing IRB and Relying Institution will enter a separate indemnification agreement or agreements or other contractual arrangements for allocation of liability among them with respect to the identified study(ies): The executed separate indemnification agreement(s) will be maintained on file with the Reviewing IRB.