

International Research and the IRB Process for Undergraduates in the Social Sciences and Humanities

for
Office for Undergraduate Research

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Overview

This workshop will provide information targeted specifically for undergraduate students planning to conduct “research with human subjects” abroad. The workshop will:

- Provide an overview of ethical issues and information about the IRB process that is similar for RESEARCH here and abroad
- Discuss when review and approval by the UNC IRB is necessary (that is, when your activity is “research with human subjects” according to the federal regulations) and when it is not (that is, when you are NOT doing “research” but are doing various activities abroad, including summer practica & internships, service, service-learning projects, and other projects that are NOT research)
- Provide an overview of the additional requirements and components that are relevant for RESEARCH ABROAD
- Provide information about Travel Abroad issues that are relevant whether you are doing research OR other activities

What IS the IRB?

- IRB stands for **I**nstitutional **R**eview **B**oard
- Three IRBs on UNC-Chapel Hill campus, including the Behavioral IRB, the Public Health-Nursing (PHN) IRB, and Biomedical IRBs A, B, C, & D (so there are 6 committees)
- The **Behavioral IRB** is most likely to review work in the social & behavioral sciences and the humanities, but it is also possible it could be reviewed by PHN IRB too
- Who's on the IRB? Faculty, community members, special advocates, non-scientists, & students
 - At least 5 members (at UNC, generally about 10-15) of diverse personal and academic backgrounds
 - At least one non-scientist must be part of the IRB roster, and a non-scientist, and quorum, must be present for a meeting of the convened IRB when it deals with studies requiring "full board review"

IRB Review and Approval

- The IRB's mandate & purpose is to review RESEARCH proposals that involve HUMAN SUBJECTS to HELP RESEARCHERS ensure ETHICAL TREATMENT of the people in their studies, and ETHICAL TREATMENT of the data in those studies
- "RESEARCH" includes undergraduate research, as defined by the federal regulations, AND as defined by UNC's Office of Human Research Ethics (OHRE)
- SEE "Student Research" side of 2-sided HANDOUT "IRB Guidance for Student Research and Class Projects"
- Other kinds of activities that are "NOT human subjects research" according to the federal regulations may also be submitted to the IRB for a "Determination" of that status
- Currently, the "Determination Form" is separate, but it may be integrated into the upcoming online application process, although that online application may not be available before you prepare your applications for summer 2010

IRB Review and Approval

- These other kinds of activities, which could include class projects, service-learning projects, internships or practica, and other activities, ARE NOT RESEARCH **because** their intent is NOT “research”
- In most cases, submission to the IRB for these other kinds of activities is NOT required because it is clear to everyone that these activities are NOT “research with human subjects” (or their data)
- However, for research that does NOT involve “human subjects” done by undergraduates for their honors theses, the Determination form DOES need to be submitted.
- In addition, if you are doing something abroad that is NOT research, then it may be very helpful to submit a description to the IRB using the Determination form, for documentation of IRB agreement that you do NOT need formal IRB approval

IRB Review and Approval

- IRB approval is required before formal contact is made with prospective RESEARCH participants, whether contact is for initial recruitment or actual data collection
- IRB approval is required before any change is made to an already-approved proposal, through submission of a Modification Form and any new or revised materials
- IRB approval is required before secondary analyses that are considered to be “human subjects research” are begun
- However, if the analyses are conducted BY STUDENTS as research, such as for undergraduate honors theses, these kinds of research activities WITHOUT human subjects still need IRB review via UNC’s Determination Form to document agreement of their “not human subjects research” status

IRB APPROVAL is only required if the activity meets the federal definition of “human subjects research” cont.

- PLEASE NOTE that at UNC, “Student Research” includes **undergraduate honors** and masters theses, masters papers and projects, dissertations, and comparable activities
- Student research can ALSO include research projects that are separate from those submitted for degree requirements; these could involve research projects that the student (perhaps with others) hope will be published or presented as generalizable knowledge in academic or professional journals or at academic or professional conferences
- The Student Guidance (see HANDOUT) differentiates between work that may “look like” research, but is done for practice or class projects, and “real” research—BUT it is only 2 pages, so the information is VERY condensed, and every word is important

IRB Review and Approval, cont.

- Examples of research with human subjects or their data that needs IRB approval:
 - Distributing paper & pencil surveys to collect anonymous responses to test hypotheses about differences between groups of participants, or relationships between responses, or simply to describe responses to questions no one has asked before, or no one has asked these questions of these particular kinds of participants before
 - Interviewing people to obtain answers to very specific questions, or to semi-structured, open-ended questions, or even “oral history” interviews with very broad questions about a person’s life
 - Conducting secondary data analyses on private, individually identifiable data, such as information that you pull out of individual medical, school, or employment records that are not generally accessible to the public
- The federal regulations define what is “research with human subjects” (more specific information is presented later)

Dual intents, or where intent changes

- On the “Class Projects” side of the Student Guidance, there are clear recommendations about what to do if something is intended BOTH as an “educational experience” (class project or practicum) AND as research => Submit an Application
- There are also clear recommendations about what to do if a student decides, AFTER the completion of a practicum or class project, to pursue additional activities with the same information that was collected or analyzed, but now with intentions to publish or submit as a master’s project or thesis
 - => Submit an Application form describing secondary use for research purposes of data collected originally for non-research purposes
 - => Determination form could be used if you never got or no longer have identifiers
- The guidance about how to handle a situation assumes that the original intent (class project, service-learning activity, and/or research) remains the same until the activity as originally intended is completed

CAUTION: Situations where intent appears to “evolve”

- It is important to note that you cannot decide part-way through what was intended as a NON-research activity to transform it into a RESEARCH activity WITHOUT obtaining IRB approval in advance of beginning what is now research
- See the sentence at the top of the Student Guidance that starts “Please note that IRBs do not have the option of granting “retroactive” approval after research is done...”
- That sentence was added following several cases, some of which dealt with work conducted abroad, that “evolved” into something that the student wanted to present as a thesis, but the student had collected the data before obtaining IRB approval
- For research abroad, approval for which is significantly more complicated to obtain than it is for research conducted locally, it is almost impossibly hard to get through all the steps necessary for IRB approval once you have left, there could be visa challenges if you change the purpose of your visit, and so forth

CAUTION: Situations where intent appears to “evolve” cont.

- This doesn't mean you can't learn from the challenge of writing up your experiences conducting a service-learning activity, or describing the insights you had in reflecting about the casual conversations you had, or the sights you saw, but it does mean you shouldn't attempt to call it “research” when you did not plan it systematically or carry it out systematically
- It may be best to treat your non-research activities and artifacts, whether your blogs, or notes, or photographs, as valid in and of themselves, and not try to convert them into something that they truly weren't—if you are interested in conducting “real” research on topics that now inspire you, then propose a study and do it
- The IRB cannot give “retroactive” approval, although they could approve a well-crafted, systematic exploration for a specific research purpose of artifacts or materials that were originally obtained for a different, non-research purpose
- PLEASE NOTE: You CAN modify an approved study from abroad if you have access to the web, if necessary, but it may be more complicated than just dealing with UNC's IRB if there is also a formal IRB approval process required by the host country—you might need to modify your proposal with that IRB too, depending on the scope of the change

Additional layers for research abroad

- IRBs have additional requirements that need to be met before the IRB can approve research conducted abroad, which can make the IRB process appear more “strict” and which take more time
- Conducting research abroad is definitely more complicated, with possible language and cultural differences that need to be addressed appropriately
- Conducting research abroad may involve layers of approval, including approval by IRBs or comparable organizations in the host country, and possibly approval by the government to let you enter the country to do research, all making the entire application process more complicated for you
- In addition, the University has requirements related to ANY kind of travel abroad that are separate from the IRB requirements

Additional layers for research abroad, cont.

- As students proposing research abroad, knowing in advance the requirements the UNC IRB has to meet to approve your study will help you give them the information they need, so there are fewer surprises after submission
- Right now, the only formal presentation of the IRB requirements (for the IRB) about INTERNATIONAL RESEARCH is in OHRE's Standard Operating Procedures on the OHRE website
- These requirements come from the federal regulations, and from the federal guidance from the Office of Human Research Protections (OHRP)

Additional layers for research abroad, cont.

- As researchers, you should look at all this information to help you understand in depth what the IRB needs to know, so you can provide as much as possible of the crucial information
- **Selected requirements are on the next slide**
- SEE ALSO the International Research Resources **HANDOUT** for information about how to find OHRE's SOP section on International Research

Additional layers for research abroad, cont.

SELECTED requirements (abbreviated) from the SOP:

■ **ETHICAL ISSUES:**

- IRB review of research to be conducted abroad must involve evaluation of the study which takes into account the local context and the specific study population
- IRB must determine that the proposed consent process is appropriate for the local context and culture (big section)
- IRB must determine if the study design adequately minimizes risks in that country and that culture
 - These requirements mean that the IRB must determine that all aspects of the research, including recruitment, consent, measures, protections of privacy of the individual and confidentiality of the data, are appropriate according to local norms.

Additional layers for research abroad, cont.

■ **ETHICAL ISSUES cont.**

■ **Notes about the consent process abroad**

- If you plan to do oral instead of written consent, you need to prepare a consent script in English—and even though you will be presenting that information orally
- The IRB may require you to provide that oral script translated into the language you will use, although that can happen as a “modification” after approval if necessary
- If you are presenting translations of recruitment, consent, interview and/or survey materials, etc. you should indicate the competency of the persons who made or helped with the translations
- Provide information about the cultural appropriateness of the consent process you have designed, and your sources of inspiration, if relevant; this is especially important if you need to obtain parental permission, permission of others, etc. , or if your participants may not be literate even in their own language

Additional layers for research abroad, cont.

SELECTED requirements (abbreviated) from the SOP:

■ **PROCEDURAL ISSUES:**

- UNC's IRB must determine whether a local IRB or other local analogous review body exists to provide local context and guidance
- IRB must determine whether an FWA (Federal Wide Assurance, negotiated with OHRP) is required for a local performance site, if such is involved
- Note that it is possible that even with all the information in your application, the UNC IRB may still need to provide only approval that is conditional upon approval from the IRB abroad — **IF SO, YOU WILL NEED TO SEND THAT TO THE UNC IRB ASAP**

Additional layers for research abroad: Helping the IRB process your application efficiently

- Determine, and SHARE with the UNC IRB in your application, your awareness of the rules and regulations regarding research in your host country
- YOU NEED TO KNOW THIS TOO, both for planning purposes (review by an IRB abroad can take many months, and sometimes up to a year, and can sometimes cost you money) and because it makes sense to complete the materials for UNC and for the host country in tandem, so the information is consistent across both applications, here and abroad
- Find experts who are familiar with your host country and culture—ask your advisor, other faculty, consult the Global Center listings
- Check if you need to get another layer of approval from the country itself in addition to the approval of a local research or ethics organization in the host country

Additional layers for research abroad: Helping the IRB process your application efficiently

- Contact relevant individuals in the host country where you intend to go, others who have been there before, etc. to get additional information and clarification about the proper procedures and organizations that need to provide approval
- Use the information you have been given by through your local UNC sources, others abroad, or the International Compilation
- Find out whether review or consultation with another comparable authority is sufficient, instead of an IRB in the host country—this may be more appropriate for much research in the social and behavioral sciences and humanities
- You may need direct assistance to get the information necessary and the forms because only some of the information is available directly through web-links

Additional layers for research abroad: Helping the IRB process your application efficiently

- In your IRB application, you need to indicate what steps you plan to take related to review abroad, i.e., whether you need IRB approval from the host country FIRST, or whether you can submit for IRB reviews in both places at the same time (in tandem), or whether there is another appropriate body for the host country's review process
- All these details vary with country, type of research, type of participants, and so forth, so a lot of prior information-gathering is absolutely critical.
- In your UNC IRB application, you may want to indicate (with their permission) the identity of and contact information for local UNC faculty with expertise in the host country or with your specific population, so the IRB can consult with them about the appropriateness of your plans—you could also ask relevant individuals here and abroad for a preliminary review before you submit to the IRB too, if your own advisor cannot function in that role

Additional layers for research abroad: Helping the IRB process your application efficiently

- ADD to your IRB application information to help the IRB understand more about YOU as a researcher (and to be able to trust you) and your advisor, if your advisor has relevant experience/expertise
 - Add information about yourself and your past experience(s) in the host country or other similar experiences (and advisor too if relevant)
 - Indicate your familiarity with the local language and culture, and what you know about age of majority (if relevant) and appropriate, respectful ways of obtaining consent and/or assent, as relevant
 - Indicate whether you will require an interpreter, and how that will be arranged, with special considerations if needed about confidentiality

Additional layers for research abroad: Helping the IRB process your application efficiently

- Other information that may help:
 - Provide some background about how you became interested in this area/topic, and whether you are joining an ongoing effort where there is lots of support, an established structure, etc.
 - If this is a new, independent effort, indicate whether you were invited into the community, or how your introduction was/will be arranged
 - Provide information about those you have consulted with as well as yourself, so the IRB can feel comfortable that you know, or can find out, what is appropriate in your host country

Ethics training issues for research abroad

- Student researcher and faculty advisor **MUST** have current human subjects research/ethics training (CITI online) to submit an [application for approval](#) (as for US research)
- Everyone else on the research team with access to **identifiable** information or in contact with participants needs to be ethics-trained too (as for US research)
- This can become quite complicated if you are planning to involve [people abroad as research staff](#) — this involves MORE paperwork and negotiation with the IRB—whether they would need to take the full CITI training, if so how, or whether a different training strategy could be used
- UNC uses the “CITI” online training, which is accessible via the OHRE website. You create your own username and password, and can take it in installments. Most likely you would need Group 2, Social-Behavioral, BASIC training.
- Note that ethics training is **NOT** required by the IRB prior to submission of the [“Determination”](#) form, but may be required by the faculty advisor

Ethics training issues for research abroad: Helping the IRB process your application efficiently

- After you have completed the standard Social Behavioral Research (SBR) (Group 2) BASIC CITI online module set that UNC requires, you should take the **OPTIONAL** module on **International Research-SBR—DETAILS BELOW**
- The information should help you with your IRB application
- Also, indicate that you have done the CITI International Research-SBR module in your application—that can help the IRB reviewers feel more comfortable with you as a researcher abroad
- Print out a copy for your own records of your grade report, or a completion report if possible, for this International module—it is NOT included in the official records at UNC
 - You may want to provide a copy of documentation related to the International module along with your application, but it is not required

Ethics training issues for research abroad: Helping the IRB process your application efficiently

- To access the BASIC training, go to <http://ohre.unc.edu>, link to **Required Education** on the left, and go to **CITI** online training; decide on your own username and password (write this down, along with whatever email address you are using); be sure to indicate that UNC is your affiliation and have your PID handy; you can do this training in installments
- After you have completed all the required modules, you can access the OPTIONAL modules from **your own CITI Main Menu** (accessed via your CITI username and password)
- Under My Courses will be listed "Group 2 Social and Behavioral Research: Basic Course, Passed, with a date
- Under "Add a course or update your learner groups," choose **International Research-SBR** and take that; you do not need to take the quiz unless you want to

“Back to Basics” IRB **APPROVAL** IS required, and is **ONLY** required, here and abroad, **IF** the activity meets the federal definition of “human subjects research”

- **“Research”** is defined by the federal guidelines as “as systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”
[45 CFR 46.102(d)]
- A **“human subject”** is defined by the federal regulations as a “living individual about whom an investigator **conducting research** obtains
 - (1) data through intervention or interaction with the individual, OR
 - (2) identifiable private information” [45 CFR 46.102(f)]

“Human Subjects Research” cont.

- These two features (“research” and “human subject”) **MUST** be considered in this order—is it “research” (according to the federal definition) and then only if the answer is “yes” is the question asked, does the research involve “human subjects” (according to the federal definition)
- The information obtained directly from participants can come from observations, interventions, interviews, surveys, experiments, and so forth

“Human Subjects Research” cont.

- The existing data (private AND identifiable) that could be used for secondary analysis could have been collected by other researchers, by administrators for their own purposes, be identifiable biological specimens, or be identifiable private records.
- If you are doing an “in-house” program evaluation, or a practicum project, what you collect or analyze might be private and identifiable, but if it is not research, then it is not “human subjects research”
- BUT if you have written a proposal for funding of your activity abroad and called it “research” even though it is really more of a practicum, or a way to provide assistance to an organization abroad by doing it for them, you would most likely need to apply for IRB approval
- And if you intend to write up your activities as part of an honors thesis, then it also becomes “research”

“Back to Basics” Applying for IRB Approval for Research Involving Direct Interaction or Identifiable Data

- Application for IRB Approval of Human Subjects Research on IRB website (www.ohre.unc.edu) under IRB Forms
- SEE OHRE Handout and BDG’s HANDOUT “Gloss” which explains in more detail the OPTIONS available for IRB APPROVAL of student research
 - The “Gloss” lists different scenarios for obtaining approval when the student work is NOT entirely separate from other already-approved research projects
- Informed consent/assent/fact sheet if interaction; justification for any consent waivers if secondary analyses ([consent forms on website too](#))
- All other documents that will be used with subjects (e.g., recruitment letter, advertising) if interaction
- Questionnaire, focus group guide, and other instruments, even if draft
- Copy of research proposal, if one exists

Hints for Completing the Application for IRB Approval

- Lay out a plan for your study FIRST, separate from the application, so you have a VERY clear picture of exactly what you want to do, when, with whom, and how you will recruit people and collect data
- IRB is concerned with specific details, and logistics, more than general plans
- See the Application form on the OHRE website under “IRB Forms”
- Add to your plan where information is needed after you have read the Application form, including the questions and checklists, carefully
- ASK your advisor or the IRB coordinators about specific questions so you can complete your plan before starting the Application
- Respond to the questions in the Application, following the directions carefully for the checklists and the prompts for answers

Hints for Completing the Application for IRB Approval, cont.

- ADD information early on about recruitment or consent, etc. that you cover later on **IF** that will help the reviewer understand your responses better to the earlier questions
- Watch for different areas that “cover the same territory” to make sure that the information is consistent, even if there are more details in some places than others; use your “plan” to cross-check for consistency between areas
- Use your plan and careful reading of your application to make sure that information is consistent between the application and the study materials (consents, recruitment, measures)
- Proof read carefully, and get someone else to do it too, before you ask your advisor to read it VERY carefully—it might be best to provide an electronic AND paper copy so it is easy for your advisor to edit
- Careful, thoughtful preparation will speed up review and approval

Hints for Completing the Application for IRB Approval, cont.

- The IRB application must be presented with enough information for the reviewers to evaluate risks and benefits, adequacy of consent procedures, and protection of confidentiality
- Studies with no more than minimal risk generally receive EXPEDITED review, by 2 or more reviewers as they are submitted (instead of review by full board that meets monthly)
- IRB approval is usually for one year and must be renewed for continued research activity, including analysis of identifiable data, as long as you are a student at the university, and perhaps after graduation
- Any changes, anticipated or unanticipated, to your procedures, sample, or measures must be approved as “modifications” **prior** to implementation—don’t hesitate to submit modifications
- Keep track of how many people you recruit each “approval year,” withdrawals, and any modifications to your protocol or sample, for your renewal report

Hints for Completing the Application for IRB Approval, cont.

- You CAN submit **MODIFICATIONS** (using another form on the OHRE website) via email if you are abroad, but you need to be careful in sending—discuss with the chair who approves your study to whom a modification should be emailed prior to departure
- Modifications involve the **MODIFICATION FORM**, whatever materials you are changing (recruitment script, consent, measures), and may require updating your approved application by incorporating the modifications in it
- **MODIFICATIONS** also allow the researcher to apply for approval as the research develops—you don't have to know absolutely everything in advance, but say so if something you mention in the application will be submitted later, so the IRB doesn't think it's "missing"

“Back to Ethics” Belmont Report

- The **Belmont Report** provides the philosophical & conceptual foundation and **guidance** about ETHICS (not IRB procedures) to:
 - the IRB members who review research studies,
 - the researchers (and the STUDENT RESEARCHERS) who propose them, and
 - the students interacting with persons in a research-like manner doing class projects or practica, or other activities that involve individuals but which do not require IRB review—ethical treatment is ALWAYS the foundation
- For research, and for class projects or practica, the faculty advisor and/or other responsible adult should provide specific ethical and practical guidance for the student’s activity in the specific cultural context
- There are 3 ethical principles in the Belmont Report:
 - Respect for persons
 - Beneficence
 - Justice

Belmont Report Principle #1 Respect for Persons

- Recognition of the personal dignity and autonomy of individuals, with special protections for those with diminished autonomy
- Research applications of “Respect for Persons”
 - Protecting personal privacy and confidentiality of data (almost always, unless agreed otherwise); especially important if the questions OR the responses are “sensitive” which can depend on the cultural context, but which generally include information about illegal behavior, sexual behavior, specific diagnoses, and could include membership in specific organizations, income, etc.
 - Informed consent—researcher tells or gives prospective participants the information they need to know before they decide to participate; gives chance to ask questions and get answers; consent may or may not involve signing a form; researcher may need to get permission of others first, such as village elders or husbands, even if participants are adults
 - Voluntariness—no coercion or subtle pressure or “undue influence” to participate

Belmont Report Principle #2 Beneficence

- Protect participants in research or other activities from any harm (risks)—obligation to minimize as much as feasible
- Activity should involve sufficient benefits to individual participants AND/OR to society in the form of knowledge to balance whatever risks there are to participants
- For research, IRB has to decide there is a favorable risk-to-benefit ratio (more benefit than risk)
- Studies with considerable risk can be approved if there is sufficient likelihood of important generalizable knowledge
- Faculty advisor and the student need to decide about the ratio for non-research projects
- Direct benefit to participants is NOT required for minimal risk projects
- Class projects, practica, and service-learning activities should not have more than minimal risk

Risk in Research

- Remember your responsibility to protect participants in research (or other activities) from harm (risks) by avoiding or minimizing them as much as feasible
- Types of risk (some not likely in social-behavioral research)
 - Physical (e.g., pain, side effects, injury)
 - Psychological (e.g., emotional distress from sensitive or intrusive questions—and only include if absolutely necessary)
 - Social (e.g., stigmatization from others knowing someone was or is in the study); can be truly dangerous in special situations
 - Economic (e.g., loss of a job)
 - Legal (e.g., from requirement to report some illegal activities)

Risk in Research

- Most (but not all) risks in social/behavioral/humanities studies stem from problems that could ensue if there were accidental disclosures, or breaches of confidentiality, about IDENTIFIABLE illegal or IDENTIFIABLE “sensitive” behaviors (and sometimes, that could mean being known as a participant in the study, if the topic is highly sensitive in that particular cultural context)
- As defined in 45 CFR 46.102(i), minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

Belmont Report Principle #3 Justice

- Selection of participants needs to be FAIR if there is a possibility of important direct benefits to participants from the research (not relevant for many studies)
- Selection of participants needs to NOT burden participants unfairly if there is risk but no real chance of benefit to them
- Researchers must provide additional protections for “vulnerable populations” which in the federal regulations known as 45 CFR 46 include:
 - Children (minors under the age of majority)
 - Pregnant women (if recruited intentionally for a study that impacts them or their fetuses)
 - Prisoners
 - Individuals who are “decisionally impaired” or have diminished cognitive capacity
- Research studies which include “vulnerable populations” need to be designed very carefully, with full attention to the local context

(No more than) Minimal Risk

- Examples of minimal risk:
 - Collection of hair or nail clippings, urine, small blood samples
 - Recordings of physiological data using non-invasive procedures (blood pressure, EEG, EKG)
 - Interviews, questionnaires, focus groups on NON-sensitive subject matter **likely in social/behavioral & humanities studies and analyses
 - "Sensitive" information collected anonymously, or with identifiers destroyed almost immediately, and without risk of "deductive disclosure" of identity; sensitive information maintained in "coded" datasets without identifiers **likely in social/behavioral & humanities studies and analyses
- Studies with no more than minimal risk receive expedited review, rather than being reviewed at monthly meetings by the convened IRB

Before & After Submission

- When in doubt, ask the IRB—there are IRB coordinators, IRB chairs, and IRB consultant(s), who can help you minimize RISK and improve your risk to benefit “ratio” IF you are applying for approval, and help walk you through the Determination Form if that’s all you need
- You can talk to them about the responses you get back from the IRB too, if needed, and if things are really complicated, a “conference call” or a meeting with you and your advisor and the IRB reviewer or chair may be helpful
- Once you have submitted an Application or a Determination form, you will get an email within a few days saying it has been received, and giving you the study number.
- You will then get an email after that which tells you if you have been approved, or, more likely, that you need to do a few things before the IRB can approve your study—the time lag varies a LOT, some of the variability relates to things outside your control, but a lot depends on whether the application is in really great shape when you submit
- Generally the IRB wants things submitted as PAPER copies when you respond to the IRB’s questions (these are not really “modifications” but are instead responses to “stipulated changes”) but you might find that the Chair who sent you the email is willing to accept emailed responses—if so, you can do that.

Before & After Submission

- Follow the directions in the IRB's response to you VERY carefully
 - It is best in your response to repeat the question or request, in another font, and then answer it as thoroughly as needed
 - You can point the reviewer to the additional forms, the changes (exactly where), etc., to make it easy to see all that you have done
 - You may be asked to "update" the application and show the changes with underlining—I recommend using Word's track changes to do that, and also highlight in yellow electronically.
 - Then you can "accept" the changes later, if you need to do a modification, or at renewal, since they would have already been approved
 - The "response to stipulated changes" process is a lot like that for journal and grant submission, so your advisor should be familiar with this kind of back & forth, and it may take more than 1 round
- When in doubt, ask the IRB
 - **IRB phone 6-3113** This is the general number, but you can ask to speak to the Behavioral coordinators or others familiar with student research abroad
 - **IRB website** <http://ohre.unc.edu>
 - barbara_goldman@unc.edu (IRB consultant for tricky problems)