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Legal, Regulatory and Ethics Compliance for International Researchers and Foreign Institutions Conducting Research in India

by
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This primer is our attempt to make international researchers aware of non-research aspects of doing research in India in a factual no-nonsense manner.

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Legal, Regulatory and Ethics Compliance for International Researchers and Foreign Institutions Conducting Research in India

Over last 12+ years of practice, NEERMAN has developed a new-found respect (and, dare we say, skillset?) for dealing with non-research aspects of research in India. This journey had been tough because there was never any guidance to make us aware and then help navigate myriad regulatory, financial and ethics pitfalls.

International researchers we work with are often as unaware of these non-research aspects of working in India as we were several years ago. There have been a few instances when such international organizations suffered in terms of financial fines and study delays, and the researchers lived under fear of dealing with regulatory and legal system in India. A few times international partners didn't even budget for tax burden they will face in India. A couple of US based researchers got in trouble due to Visa violations and we had to help them out. There are too many examples.

The 'new' India is moving towards more proactive and stricter enforcement of all laws which only means research community should take better care of non-research aspects of research in India.

Visas to India

You can find whether you need Visa and what type of visa you need, [here](#). Let us only highlight common mistakes and risks you may be inadvertently taking.

- **You are coming to India on visitor visa but actually conducting research.** Imagine someone complained to the local police station that a few people are doing surveys in our village and they look suspicious. And, you get called to the police station. If your visa stated 'visitor', but you were actually doing research in India, then, frankly, you are at mercy of that officer. Research Visa is the best visa category for you, but many international colleagues routinely complain of tedious application paperwork, inordinate delays, and suspicion by consular office in issuing such visas. Indeed, research visas have a very high rate of rejection.
- You are staying in India for longer than 6-months and don't bother to get an extension. Often foreign scholars intend to go home in a few months, but somehow get delayed beyond due to travels or work. This exposes you to risk of future denial of entry into the country or worse.
- You have an employment (salaries job) contract with an Indian firm but earning less than INR 100,000. The employment visa to foreigners mandates minimum monthly payment of Rs 100,000 and if you are earning less, you should have applied to a different visa category (business or research).

Our advice/suggestions

- If you are planning to be in India for 1-3 months to basically meet with your funders, visit study sites, review work by local vendors, make a few presentations, meet a few people, then obtain 'business' visa. If you are visiting India only for conferences and a few meetings, then visitor Visa is fine. It is best to have a local partner as a sponsor who can host your researchers as visiting scholars/peers and provide undertaking of your bona fides.
- If you are planning a much longer stay in India and do research yourself, then apply for research visa even if it is a painful and uncertain process. This visa's terms can be "potentially" used by government to deport you if they believe your research is not in best interest of India.



However, not having this visa can expose you to additional criminal charges if your research is found to be against India's best interest. Remember, there are no well-laid rules about what research is in India's best interest so its basically a decision by some govt officer and then only a court can adjudicate. Therefore, consider if you yourself must be present in India for 'long duration' as a researcher or assess cost-benefits of entering India with an incorrect visa category.

Foreign Contribution Regulation Act

FCRA has sharp teeth to bite any NGO (universities, institutes, trust or society and even not-for-profit companies) that receives any form of 'contribution' from a foreign country and ministry believes the funds are used against India's best interest. FCRA provisions can be used by authorities to halt our study, take penal action against your local partner, and even ban your organization from working in India if it is found that your research was not in best interest of India. For example, recently Amnesty International stopped their operation in response to action by government under FCRA provisions.¹

The act has defined 'contributions' so broadly that the Home Ministry can consider grants, donations, service income, goods income, and even goods or gifts in-kind from any foreign source (including grants by government or not-profits abroad) as contributions. Recent amendment in year 2020 has further tightened the requirements. While the full FCRA related information is available [here](#), in a nutshell, this is what it means to you as foreign university/institute:

- In case your local partner – for example, NEERMAN – is a private company (but not under Section 8 of the Companies Act), limited company, individuals, partnership, proprietor, etc.), then FCRA is not applicable.
- Ensure that the NGO/University/Foundation you will be sending money in any form, has valid FCRA registration. This NGO needs to have a separate bank account for foreign funds in designated Bank and Branch by the government (currently SBI new Delhi), get permission from Home Ministry prior to use of these funds, and file annual statement on fund utilization.
- You need to take a legally binding undertaking from the NG or do your own due diligence that the organization is in compliance with FCRA rules.
- 80% of your funding must be used for programme implementation activities and only 20% for admin expenses including any research.
- The NGO you contract cannot fund other NGOs (so mother and child NGO concept ceases to exist). Instead you need to contract each NGO separately irrespective of size of the contribution you make to them.
- Plan your work timelines with 3-6 months leeway in case the funds you transfer to the NGO get held up in permissions. Also plan getting bank guarantees from the NGO to refund your funds if their bank accounts get frozen due to non-compliance with FCRA.

Our advice/suggestions

¹ <https://www.hindustantimes.com/india-news/amnesty-international-halts-work-in-india-after-govt-freezes-bank-accounts/story-caiIF3azmTqhNS9TloilGI.html>



- Do not ask for FCRA clearance from every vendor or company you work with in India; FCRA is only for NGOs. If you work with any private limited, limited, partnership, or proprietorship company, then there no need to worry anything about FCRA.
- Consult a good chartered accountant and lawyer to structure your funding mechanism for NGOs, do the due diligence and paper work prior to funds transfer.
- Prefer working with one or few large NGOs that will have resources to meet FCRA requirements as well as favourable dispensation with the government in power. Unfortunately, new amendments to FCRA will make survival of small NGOs difficult and investment in them is a financial risk.

Ethics in Research

In short, there is no dedicated Act or Rules governing ethics in research, but such authority is derived directly from the constitution, commitments of India under various UN resolutions, and government notifications and administrative notices. There are guidelines and procedures from ICMR and health ministry. Unfortunately, that these guidelines and procedures are often subjective, reactive, looked from the prism of bio-medical and health research, and lack any quick dispute resolution mechanism other than the mighty Indian justice system.

If you are conducting a clinical trial, bio-medical research, then guidelines by ICMR will be quite helpful and clearer ([here](#)). You can even register clinical trials [here](#). However, if you are doing socio-economic, demographic, economic, operations, or basically any research in engineering, humanities, and social sciences, then you are going to be stumped for four reasons.

1. First, you would not understand whether your study requires ethics committee (EC) approval/oversight in India. India has not defined 'research' legally in context of ethics so anything can be argued to be a research. Then, there is no clarity on what is meant by 'health' research. If you go by ICMR guidelines, then almost everything can be 'health research' because the guidelines use generalizable terms such as 'etc.' and 'any other' to cover all bases. So, if you are researching a programme for educating a child on handwashing washing to reduce diarrheal diseases, then that can be health research. If you are evaluating an income generation project of which one benefit is more investment in healthcare and nutrition for the family, then that can be health research. In short, any research in agriculture, environment, human rights, gender, and many other sectors can be argued to be 'health research' or not. Unfortunately, there is no clarity on how to decide or who decides.
2. Second, you cannot navigate 'not applicable and illogical' requirements which are relevant for bio-medical research with any EC. Because the guidelines are for biomedical and clinical research, there are requirements such as 'make provisions to compensate study participants if they suffer harm'. Now, what harm do you expect from asking them about their hand washing practices? Perhaps psychological? Shouldn't informed consent cover such 'minimal additional risk' when respondent agrees to participate in a survey? But the EC, will not know how to navigate such a situation because they don't want to deviate from ICMR guidelines. Some ECs may apply their mind and give you exemption, and many will just get frozen when you ask such questions.
3. If you decide that you are conducting 'health research' and having a local research institute/university/NGO as a partner, you need to worry whether you need approval from health Ministry's Screening Committee (HMSC). You will be confused as HMSC required prior



approval from EC and EC would require prior approval from HMSC so unless you push EDC to give a 'provisional or conditional' approval, your study is stuck. HMSC guidelines and procedures are written assuming that only government institutes, universities and NGOs do research in India and not private organizations, and for 'bilateral' and 'multilateral' agreements with different institutions. So, if you do not fit above clear definitions, there will not be any clarity whether you need HMSC clearance or not.

4. When you still go for EC approval/oversight, you will find that procedures, costs and timelines differ markedly from one EC to the other. Some will take a thousand dollars but process your application in three weeks and some will take months and look your PhD qualifying exam a breeze. Some will insist that you pay their members as consultants to visit your site and observe study themselves. Some will ask you legal indemnity even against a harm caused due to poor overnight by the EC (which, your legal department will never agree to sign).

Our advice/suggestions

- **Always get permission/cooperation from some government department:** In case your study runs into any ethics problem (say, a complaint by any bystander to the police; need not be even a survey participant), then the local administration, police, community leaders will not give 2-cents importance to the IRB/EC approval you have. They will only ask one thing – on whose authority are you conducting this survey/study? You must get a letter stating at least awareness of the survey and requesting cooperation with researchers from some ministry, department, government owned company, district administration; whoever is most suitable for your study.
- **Get IRB from your own country/Institution as well as Indian IRB:** Don't only rely on EC/IRB approvals from India alone. Finding a good-fast IRB in India will be challenging but your local research partners such as NEERMAN should help you with those. Plan for at least three months' time for IRB approvals. Don't wait for your protocol to be almost final and perfect; get the approval first based on whatever is closest to final design and later worry about amendments.
- **Do not seek HMSC clearance unless absolutely clear that you need it:** Clear law and rules making is duty of the legislature and bureaucracy; people and organizations are not expected to interpret it (which is a job of courts). So, we recommend not going for HMSC clearance unless your research is covered under some inter-governmental or inter-institutional agreements, it is clearly a grant for some 'pure' bio-medical and health research and not some consultancy type of research (say impact evaluation), if you are dealing with a private company (except pharma or bio-medical companies), etc. HHMC meets once every three-months, the members are attuned to bio-medical issues and not general health research in social sciences so that you will risk delays, rounds of inquiry, illogical and costly requirements to comply with if you chose to apply. Not applying also has a risk because anything can be perceived and argued to be health research and thus requiring HMSC clearance. You can better weigh the risks with help of your local research partner or [here](#).
- **Get assent/consents from community, household head and the respondent:** Although the IRB may approve consent from an adult respondent, we suggest you take 'written assent' from community leaders (formal is better), and assent from the household head (unless she/he is



also the respondent). One way to ensure assent from head of the household or another adult having authority for decision making is to make them witness to the consent you administer to the respondent.

You should strive to get signature on written consent form, but sometimes this will back fire if the signatory is illiterate or afraid of legal ramifications. Even if IRBs approve verbal consent, we now recommend something written. If written consent is not possible, then get some witness to sign the consent. We also recommend audio-recording consent if App-based survey tools are being used. Remember, written consent makes the study safe because otherwise respondents can flatly refuse ever giving a consent and getting the study in deep trouble.

- **Do not export identifiable data, bio-samples etc outside India:** Unless you are some WHO body or have explicit permission / research agreements with institutions such as ICMR, don't transfer bio-samples (tissues, hair, blood, etc) outside India. If you need to, then there is a very complex process to follow where you have to prove why such testing is necessary for research and why such testing cannot be done in India. Many foreign students/researchers smuggle when there are few items that fit in a small attaché, but 'PLEASE DONT'.

Also ensure your survey agency stores all data on servers in India, and you have access to only de-identified information. Even if IRB may have given you consent to get identifiable data, Indian Government's data privacy and security rules don't.

Goods and services tax

This is a type of value-added-tax applicable across India which will be levied by any India-based organization providing any service or goods to anyone (surveys, car hiring, hotel, food etc). Comprehensive documentation on GST is available [here](#).

- If you intend to hire an India-based firm, consultant, travel agency, or buy a phone here, you will be paying GST. The rate is currently 18% for most goods and services but varies from 5% to 43% in a few cases.
- If your university/institute has established any direct or indirect centre or office in India, chances are that you can get 'offset' for some of the GST you pay. Therefore, the effective GST the organization pay can be lower than 18%.
- If you make a contract with an India-based entity (person, institute, firm, etc) such as NEERMAN in a foreign currency and do not have a local tax-residence in India, and the contract clearly specifies services by the Indian entity as export, you should not be charged GST. Please ensure that your India-based vendor is not charging you 18% GST unjustly (and making unethical profits on these grounds). If he is, insist on proof of GST filing.
- Even if you end up paying GST, you will get refund of the GST your organization paid from the government if your organization was exempt from paying GST. Most prominent of these exemptions is GST charged to UN-established organizations such as WHO, World Bank, UNICEF and others.

Income Tax and Tax Deducted at Source

This relates to tax on income earned by any tax-resident of India. When an Indian entity gives a payment to any organization, they are required by law to 'assume' that the entity receiving payment has a tax liability in India, and (generally) deduct 10% of this payment as tax owed to India and



immediately deposit it with the taxman – this is called Tax Deducted at Source (TDS). You can learn more about income tax for foreign organizations [here](#).

- If international organizations receive any payment (grant, donation, contract, fees etc) from an Indian entity, TDS 'may' be deducted at 10%-20% if it cannot be proven that you are not a tax-resident in India (double negative is by intention – basically, Indian entities are supposed to err on side of assuming that you owe taxes to India). Indian entity will deduct (generally) at @20% if the international organization is not registered with income-tax department and has a PAN card; read about PAN card [here](#). If you have a PAN card, Indian entity 'may' withhold TDS at 10%.
- It is highly likely that your country of tax-residence has a double-tax avoidance tax treaty with India. Under this treaty, you may be able to get full or partial credit for the tax withheld in India. For example, if a US firm has \$6000 TDS withheld in India, they would simply subtract \$6000 from their tax-liability in the US. Of course, it is not that easy because no country likes to lose tax income but let your CPA/CA slug it out.
- If your service can be considered 'export' of service to an Indian entity or import of service by an Indian entity, then legally, Indian firm should not withhold your TDS or income in anyway. Unfortunately, Indian tax laws are highly confusing, and it can always be argued that you earned your income by activities in India. Therefore, wording of your contract (grant or otherwise) and determination of tax-residence in India is very important.
- Finally, if you have any direct/indirect centre or office in India with a PAN card, you may be required to withhold TDS from payment you make in INR (Indian rupees) to any India-based consultant or contractor. And, then file TDS returns within one month of such deduction at maximum.

Our advice/suggestions

- Always check if your university/institute has any direct or indirect centre/office in India. The contract wording matters a lot in Indian regulatory and legal contexts, but often ignored by institutes from countries which have much simpler and trust-based regulatory framework (e.g. US or UK). As a result, the mothership (main institute) can become liable for variety of regulations and taxation in India. If you have a local centre/lab/office in India, then definitely get advice from tax consultants from India and your own country both.
- Understand if your TDS will be withheld at the time of contract/grant negotiation and make provisions in the budget accordingly. If your TDS will be deducted, then have a PAN card in India so that at worst you lose out 10% of your payment from any Indian entity. However, don't bother filing tax returns in India (too complicated and some tax consultants can take you for a ride). Instead, get credit / relief in your own country of tax-residence (I am assuming your country will have easier compliance).
- Try hard to not get charged 18% GST through proper partnerships and contract wording. Avoid working with individual consultants who do not have any GST registration, and thus, do not charge you GST. You need undertaking from consultants/companies you pay that they have exemptions from registering for GST and thus collecting GST from you.
- If you are getting GST charged, then ensure that GST you pay is actually paid by your vendors to the taxman. The GST Act requires you to assume responsibility that your vendor pays GST.



If your vendor defaults, you will also face consequences (please don't ask why!). So, always get some evidence that your vendor has paid GST before approving/paying their next invoice.

- There are many state and local-body taxes which your consultants and contractors from India need to comply with. Therefore, get an indemnity in the contract that the consultant/contractor is in full compliance with any such local/state taxes, laws etc.

Insurance

Most developed countries have insurance requirements for professional liability, public liability, and workers' compensation. India does too, but the requirements are frankly quite mild. All you have to ensure is that your vendors and consultant comply or indemnify you from any claims.

Workers compensation: This requires permanent and temporary workers to get some minimum compensation for loss of limb, life or livelihood. Often your local partners will not get any insurance for their staff or for freelancers they hire to cover this liability. If they don't, this liability can be passed on to you. You can read about workers compensation law [here](#) and insurance [here](#).

Vehicle insurance: The law requires vehicle owners to maintain a public or third-party liability insurance only. There is no legal provision to insure life of vehicle passengers. You can read about motor vehicle insurance requirements [here](#).

Our advice/suggestions

- Your contract office may insist different types of insurances and for much higher amount of coverage as per the laws in your country. For example, NEERMAN is sometimes asked for \$5 million liability insurance. Indian firms are not legally obliged to follow such high coverage suitable only for high-income-countries such as the US or UK. If you insist on such large coverage or types of insurance then your vendor will charge you extra for any non-essential or extra insurance type or amount you insist on, in addition to the quoted budget. You are legally and financially better off taking a full indemnity from your vendors about any liability they may face during your research.
- In case of bio-medical and health research, you may have to make provisions for or take insurance for study participants. Such provision is best done through your Indian partner, but also list your research under your institution-wide professional liability insurance coverage (which we are sure you have).
- Avoid hiring freelancers (survey staff, local consultants, etc) directly because they you become their employer. As such you become liable for their well-being, compliance with labour laws, taxation etc. Your contract with them has to be very carefully worded so that you don't inadvertently get exposed to such risks and the contract clearly rules out any employee-employer relationship.



How we can help?

NEERMAN is a research organization that specializes in impact evaluations, program evaluations, monitoring & evaluation systems development, and allied evaluation and policy research. NEERMAN partners with UN agencies, international foundations, NGOs, and CSRs to conduct impact evaluations, develop monitoring and evaluation systems, and policy research to aid programming. To know more about us, please visit www.neerman.org.

As your local research partner, we can provide the following non-research support.

- **Freedom from FCRA:** NEERMAN was established as a not-for-profit company, but over time we realized that our vision and mission is best served as a for-profit company which doesn't accept grants but provides contractual service related to research. One of the advantages is that we are exempt from FCRA as a commercial company.
- **Legal and regulatory compliance assurance:** NEERMAN will undertake the liability to meet India laws and regulations.
- **Help you manage reputational and financial risks:** Our contracts team can help you create instruments which creates an arm's length distance for you to face reputational risks. We also help you structure your payments to us in a way it can save tax burden
- **Secretariate Support:** We will provide support in terms of advice and documentation for matters related to Visa, travel logistics, medical emergencies, legal, and tax compliance.

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