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| [applicable logo] | [Type of standard if applicable] |
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| **Subject: Nurses Conducting Home Visits in Clinical Trials** | |
| **From:** ⚫ [if applicable] | |
| **To:** ⚫ | |

**Purpose**

In conjunction with a clinical trial sponsored by a private company (each, a “**sponsor**”), various medical visits may be required under the protocol. These visits may take place within the facilities of a health and social services network institution (an “**institution**”) or remotely. In the latter case, a nurse may be called upon to travel to the home of participants. The nurse may then be: (1) employed by the institution; (2) employed by a contract staffing agency (an “**agency**”) and dispatched on behalf of the institution under the terms of an agreement between the agency and the institution; or (3) dispatched by the sponsor on behalf of the institution.

Because the insurance coverages administered by the Direction des assurances du réseau de la santé et des services sociaux [health and social services network insurance branch] (“**DARSSS”**) in a research context cover institutions (and some individuals working within them, such as their employees) and not third parties (including subcontractors), institutions must, where cases (2) and (3) apply (i.e. when the nurse is not employed by the institution[[1]](#footnote-1)) ensure that they:

* + do not accept responsibility in connection with a nurse’s acts and omissions; and
  + do not intimate that they assume any such responsibility.

This is all the more important because, under the applicable legislation, persons are responsible for the acts of their employees and agents. Consequently, in the absence of contractual provisions and the implementation of any other measures, the institution could expose itself to additional legal risks.

An overview of the considerations applicable to each of these scenarios can be found in the **appendix**.

**Appendix 1**

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| Scenario | Contextual Situation | Recommendations |
| **(1)** Nurse employed by the institution | The institution may have in its employ a nurse who is able to perform tasks | The institution may agree to assume responsibility for the nurse’s acts and omissions when the nurse performs certain procedures required by the protocol. |
| **(2)** Nurse provided to the institution by an agency (retained by the institution) | The institution may already have an agreement in place with an agency  or  The institution may enter into a contract staffing agreement with an agency | The institution must ensure that:  1- the agreement with the agency is worded accordingly and, in particular, that the institution does not accept any responsibility in connection with the acts of the nurse, that no sharing of responsibility permits the inference that any responsibility is assumed beyond the foregoing, and that the agency will indemnify the researcher and the institution for the acts of the nurse;  2- no documentation from the clinical trial and no transmitted information insinuate that the institution or researcher is responsible for the acts of the nurse, consent forms and information communicated verbally by nurses to patients should be reviewed accordingly; and  3- proof documenting the nurse’s qualifications is obtained to ensure that the institution and the researcher meet their legal and contractual obligations.  *For indicative purposes only*, the agreement with the agency may include the following clause, with any necessary adaptations:  The agency acknowledges and agrees that the nurse is not an employee of the institution or the researcher and was selected by the agency to perform the tasks described in this agreement. In this regard, the agency agrees to: (i)  assume any responsibility that may arise from the acts and omissions of the nurse and defend, indemnify and hold harmless the institution and the researcher from any such responsibility; (ii) assume all management and supervisory tasks in respect of the nurse (other than the professional supervision of tasks performed by the nurse when dispatched if supervision is carried out by the institution or the researcher); (iii) maintain the required insurance coverages in force; and (iv)  ensure that the nurse is required to comply with applicable institutional policies (including confidentiality of medical records).  (This clause could also take any other form as deemed advisable by the institution.) |
| **(3)** Nurse provided to an institution by a sponsor | A sponsor may dispatch a nurse in its employ on behalf of an institution  or  A sponsor may enter into an agreement with an agency in order for the agency to dispatch one of its nurses on behalf of an institution  or  A sponsor may enter into an agreement with a self-employed nurse in order for her to be dispatched on behalf of an institution | The institution must ensure that:  1- the research agreement is worded accordinglyand, in particular, that the institution does not accept any responsibility in connection with the acts of the nurse, that no sharing of responsibility permits the inference that any responsibility is assumed beyond the foregoing, and that the sponsor will indemnify the researcher and the institution for the acts of its subcontractors (e.g. nurse and agency);  2- no documentation from the clinical trial and no transmitted information insinuate that the institution or researcher is responsible for the acts of the nurse, consent forms and information communicated verbally by nurses to patients should be reviewed accordingly; and  3- proof documenting the nurse’s qualifications is obtained to ensure that the institution and the researcher meet their legal and contractual obligations.  *For indicative purposes only*, the research agreement may include the following clause, with any necessary adaptations:  The sponsor acknowledges and agrees that x (the **nurse**) is not an employee of the institution or the researcher, carries out certain procedures under the protocol at the sponsor’s request, and was selected by the sponsor to perform such procedures. In this regard, the sponsor agrees to: (i)  assume any responsibility arising from the acts and omissions of the nurse and defend, indemnify and hold harmless the institution and the researcher from any such responsibility; (ii) assume all management and supervisory tasks in respect of the nurse (other than the professional supervision of tasks performed by the nurse in conjunction with the clinical trial if supervision is carried out by the institution or the researcher); (iii) maintain the required insurance coverages in force; and (iv)  ensure that the nurse is required to comply with applicable institutional policies (including confidentiality of medical records).  (This clause could also take any other form as deemed advisable by the institution.) |

1. *The existence of an employment relationship is a question of fact. It can be created between an individual (even if initially employed by an entity) and another organization on the basis of: (1)  the relationship of subordination between the organization and the individual, (2) the individual’s onboarding within the organization, (3) the day-to-day management of the organization, (4) the duration of the relationship, (5) the applicable remuneration method, and (6) the identity of the person who assesses, manages absences or manages disciplining of the individual, and so on. It is therefore important that management by the institution and its researcher (contractually and in practice) be limited to the professional supervision of tasks performed under the protocol (versus performance review, absence management, layoff or hiring, etc.).* [↑](#footnote-ref-1)